
The European public health response to the COVID-19 pandemic: Lessons for future cross-border health threats

STUDY



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The European public health response to the COVID-19 pandemic: Lessons for future cross-border health threats

Study

This study was drawn up to support the work of the European Parliament's Special Committee on the COVID-19 pandemic. It examines the European Union's public health response to the COVID-19 pandemic across the following five pillars: (1) the EU vaccines strategy and national vaccination strategies; (2) independent scientific evidence on vaccine effectiveness; (3) the EU public health response to COVID-19, addressing the EU framework for crisis response; (4) the EU's prevention and preparedness efforts for future health threats; and (5) considerations regarding EU competences in public health.

By assessing the lessons of the COVID-19 pandemic, the current state of play, challenges, and opportunities for improvement in EU public health governance, a series of recommendations are proposed to strengthen the EU's resilience and preparedness for future cross-border health threats.

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Executive summary

Introduction

The COVID-19 pandemic cast unprecedented strain on European health systems and European solidarity and demonstrated the need for common European action. The pandemic also revealed deep-seated socio-economic inequalities and institutional weaknesses, with the most vulnerable populations and communities bearing the brunt of the crisis.

The early lessons from the pandemic underlined that challenges to health systems and economies, including supply chain problems and vaccine hesitancy, could no longer be overcome by European Union Member States acting alone. Public health measures needed to be consistent, coherent, and coordinated, to ensure maximal effectiveness. Health was increasingly reinforced as a global public good.

The COVID-19 pandemic intensified discussions on the EU's competences in public health and prompted a reshuffling of EU health policy through the establishment of the European Health Union. On the external front, the COVID-19 pandemic provided a political opportunity for the EU to take a strategic leadership role in global health.

Scope and methodology

This research study analyses the EU's public health response to the COVID-19 pandemic. It examines five pillars: (1) the EU vaccines strategy and national vaccination strategies; (2) independent scientific evidence on vaccine effectiveness; (3) the EU public health response to COVID-19, addressing the EU framework for crisis response; (4) the EU's prevention and preparedness efforts for future health threats; and (5) considerations regarding EU competences in public health. This study assesses the lessons from the COVID-19 pandemic, the current state of play, challenges, and opportunities for improvement to public health governance in the EU, including a series of actionable, evidence-informed recommendations to strengthen the EU's resilience and preparedness for future cross-border health threats. The findings are based on a literature review and interviews with representatives from EU Member State authorities, EU institutions, international organisations, civil society, and private sector actors. The research was conducted from August to November 2022, in the rapidly shifting policy context of EU health policy and pandemic response.

Main findings

Pillar 1 documents EU national vaccination strategies and studies vaccine uptake using Vaccine Tracker data collected by the European Centre for Disease Prevention and Control (ECDC). A substantial variation is found among EU Member States in terms of vaccine uptake, with a higher vaccine coverage rate in the older age groups. The study gives an overview of some factors behind the differences in vaccination progress and coverage, such as national vaccination programmes, vaccine hesitancy, an infodemic, and trust in public authorities. In some Member States, initial reluctance has turned into vaccination acceptance, while it remains relatively high in others.

Pillar 2 discusses the impact of the EU vaccines strategy and, in particular, examines the transparency controversy over stages ranging from vaccine development to vaccine procurement. The study looks into the role played by the European Medicines Agency (EMA) in activating the fast-track procedure to issue conditional marketing authorisation for COVID-19 vaccines that allowed timely access to vaccines. Next, the study provides an overview of existing evidence of vaccine effectiveness collected by clinical trials and epidemiological studies. Finally, the study presents a correlation analysis that shows a general negative relationship between COVID-19 mortality rates/excess mortality rates and national vaccination progress. However, excess mortality rates were still high in 2022, suggesting that vaccines need to be supplemented by other policies and tools to restore EU public health.

Pillar 3 presents an ex-post assessment of the EU's public health response to the COVID-19 pandemic, covering effectiveness, coherence, and the EU added value. The study finds that after a slow start, the EU was very effective in mobilising a variety of resources in public health, financial instruments and civil protection, to provide emergency support and long-term structural support within the EU. The EU added value of the COVID-19 response is exemplified in the European Health Union, EU vaccines strategy, the joint procurement and deployment of vaccines and medical countermeasures, and the provision of the 'Green Lane' approach and the EU Digital COVID certificate to maintain the integrity of the single market. In contrast, despite the EU's major contributions to global health, the COVID-19 pandemic triggered a significant reversal in progress towards the United Nation's Sustainable Development Goals (SDGs) and widened global inequities, including access to COVID-19 vaccines worldwide.

Pillar 4 discusses the EU's prevention and preparedness for future health threats. COVID-19 was likely transmitted from animals to humans, and is linked to the human relationship with nature. Moreover, the COVID-19 pandemic had an uneven impact on communities and continents, with especially vulnerable populations worst affected by the adverse effects of the crisis. The COVID-19 pandemic masked a 'shadow pandemic' of domestic violence, mental illness, educational deprivation, and social isolation exacerbated by lockdowns and continuous disruptions to chronic care. Persistent global vulnerabilities and major unmet medical needs, both drawn to the fore by the COVID-19 pandemic, will mandate an enhanced level of preparedness at the EU level. Against this background, the study discusses the extended mandates of the EU agencies (the ECDC and EMA), the state of health preparedness under the newly created Health Emergency Preparedness and Response Authority (HERA), the EU global health strategy, the World Health Organization (WHO) pandemic treaty, and the rising challenges of antimicrobial resistance (AMR). The study reiterates that prevention and preparedness will need to be anchored in robust forms of international cooperation and a deep preventive approach. This will require a 'one health' approach (emphasising the interdependence of human, animal and planetary health), together with a focus on the social and environmental determinants of ill health, and greater global collaboration.

Pillar 5 reviews the state of play of the EU's competences in public health, followed by key discussions on the future of Europe on public health. It reviews Europe's transitions – from a period of immediate response, to the COVID-19 pandemic, to managing prevention and recovery. It concludes with reflections on the EU's upgraded framework for serious cross-border health threats.

Recommendations

On the basis of this study, key recommendations are to:

- Improve the transparency of the development, production and procurement of vaccines;
- Provide guidelines on joint procurement of vaccines and medical equipment;
- Bargain for more favourable conditions in future contracts with companies;
- Study the efficiency of the EMA's expedited authorisation;
- Invest in new technologies for drug and vaccine development;
- Improve communication with Member States;
- Improve communication and engagement with citizens;
- Invest in a more comprehensive approach to public health emergency prevention, preparedness, and response;
- Study the roots of vaccine hesitancy and enhance public trust;
- Adopt balanced disease prevention strategies that account for health system inequalities and community-based approaches;
- Secure medical supply chains and ensure strategic autonomy at the EU-level for medicines and medical devices;
- Invest in resilient healthcare systems that are responsive to the needs citizens and communities.

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List of abbreviations

ACT	Access to COVID-19 Tools Accelerator
AMR	Antimicrobial resistance
APA	Advance Purchase Agreement
API	Active pharmaceutical ingredients
CEPI	Coalition for Epidemic Preparedness Innovations
CGD	Center for Global Development
CHMP	Committee for Medicinal Products for Human Use (EMA)
CMA	Conditional Market Authorisation
CoFoE	Conference on the Future of Europe
COVI	European Parliament Special Committee on the COVID-19 pandemic: lessons learned and recommendations for the future
CRII/CRII+	Coronavirus Response Investment Initiative
CSO	Civil society organisation
DARWIN EU	Data Analysis and Real-World Interrogation Network
DG ECHO	European Commission Directorate-General for European Civil Protection and Humanitarian Aid Operations
DG SANTE	European Commission Directorate-General for Health and Food Safety
ECA	European Court of Auditors
ECDC	European Centre for Disease Prevention and Control
EEA	European Economic Area
EHDS	European Health Data Space
EHU	European Health Union
EIB	European Investment Bank
EMA	European Medicines Agency
EMRN	European medicines regulatory network
EP	European Parliament
EPRS	European Parliamentary Research Service
ERCC	Emergency Response Coordination Centre
ESI	Emergency Support Instrument
ETF	Emergency Task Force (EMA)
EU	European Union

EUA	Emergency use authorisation
EUL	Emergency use listing
EWRS	Early Warning and Response System
FDA	US Food and Drug Administration
GAVI	Global Alliance for Vaccines and Immunisation
GDPR	General Data Protection Regulation
GMO	Genetically modified organism
HERA	Health Emergency Preparedness and Response Authority (European Commission)
HiAP	Health in all policies
HSC	Health Security Committee
HTA	Health technology assessment
ICU	Intensive care unit
IHR	International health regulations
IP	Intellectual property
IPR	Intellectual Property Rights
JPA	Joint Procurement Agreement
LMIC	Low- and middle-income countries
MEP	Member of the European Parliament
MoU	Memorandum of Understanding
MS	Member State
NATO	North Atlantic Treaty Organization
NGO	Non-governmental organisation
NPI	Non-pharmaceutical intervention
OECD	Organisation for Economic Co-operation and Development
PHEIC	Public Health Emergency of International Concern
PPE	Personal protective equipment
R&D	Research and development
REACT-EU	Recovery Assistance for Cohesion and the Territories of Europe
RRA	Rapid risk assessments
SAGE	Strategic Advisory Group of Experts on Immunization

SME	Small and medium-sized enterprise
SmPC	Summary of product characteristics
TESSy	the European Surveillance System
TEU	Treaty on European Union
TFEU	Treaty on the Functioning of the European Union
TRIPS	Trade-related aspects of Intellectual Property Rights
UCPM	Union Civil Protection Mechanism
UNICEF	United Nations International Children's Emergency Fund
UNODC	United Nations Office on Drugs and Crimes
WHO	World Health Organization
WTO	World Trade Organization

Country codes

AT	Austria
BE	Belgium
BG	Bulgaria
CY	Cyprus
CZ	Czechia
DE	Germany
DK	Denmark
EE	Estonia
EL	Greece
ES	Spain
FI	Finland
FR	France
HR	Croatia
HU	Hungary
IE	Ireland
IS	Iceland
IT	Italy
LI	Liechtenstein
LT	Lithuania
LU	Luxembourg
LV	Latvia
MT	Malta
NL	Netherlands
NO	Norway
PL	Poland
PT	Portugal
RO	Romania
SE	Sweden
SI	Slovenia
SK	Slovakia
UK	United Kingdom
US	United States of America

1. Introduction

The report starts with a general background of the study (section 1.1), followed by the purpose and scope of the study (section 1.2), the methodological approach (section 1.3), and a reading guide (section 1.4).

1.1. General background of the study

1.1.1. Lessons of COVID-19

The COVID-19 pandemic cast unprecedented strain on European health systems and European cohesion and spurred the need for common European action and solidarity. It also prompted intensive discussion on the European Union's (EU) competences in the health domain. In the initial stages of the pandemic, government responses were fragmented and uncoordinated and marked by piecemeal controls intended to inhibit coronavirus transmission. EU Member States experienced severe disruption to their medical supply chains for essential countermeasures (e.g. face masks and ventilators) and reported significant capacity strain to their hospitals and intensive care units (ICUs).¹ National governments initially resorted to their own responses, including national lockdowns, temporary border restrictions and export restrictions on facemasks.^{2 3} Such measures could not impede the spread of the SARS-CoV-2 virus but resulted in immense disruption to the socio-economic life of European societies and threatened the functioning of the single market and free movement across the EU area.^{4 5}

The pandemic shed light on underlying long-term societal challenges beyond the immediate implications of the pandemic. These included broader issues such as the resilience of health systems, sustainable socio-economic recovery, the prioritisation of global health security through a 'one health'⁶ focus on public health and the environment (see section 4.5 on one health) and restoring failing public trust in government and scientific evidence.

The early lessons from the pandemic underlined that the challenges to health systems and economies, including vaccine hesitancy and supply chain problems, could no longer be overcome by nation-states acting alone. Public health measures needed to be consistent, coherent, and coordinated to ensure maximal effectiveness. Health was increasingly reinforced as a public good. The health situation and health security in one Member State were contingent on that of its neighbours.⁷

¹ Mauer N. et al., '[Towards a European Health Union: new instruments for stronger and more resilient health systems](#)', *Eurohealth*, Vol. 28(1), 2022, pp. 57-61.

² OECD, '[The face mask global value chain in the COVID-19 outbreak: Evidence and policy lessons](#)', *OECD Policy Responses to Coronavirus (COVID-19)*, 2020.

³ For example, France, Germany, and Czechia imposed export bans on personal protective equipment (PPE), e.g. face masks, despite severe shortages in other Member States. Source: Anderson M. and Mossialos E., '[Editorial: Covid-19 exposes weaknesses in European responses to outbreaks](#)', *British Medical Journal*, 368, 2020.

⁴ Beaussier A. and Cabane L., '[Improving the EU response to pandemics: key lessons from other crisis management domains](#)', *E-international relations*, 2021.

⁵ Beaussier A. and Cabane L., '[Strengthening the EU's response capacity to health emergencies: insights for EU crisis management mechanism](#)', *European Journal of Risk Regulation*, Vol. 11(4), 2020, pp. 808-820.

⁶ [One health](#) is an integrated, unified approach that aims to sustainably balance and optimise human, animal, and planetary health, which are recognised to be interlinked.

⁷ Beaussier A. and Cabane L., '[Strengthening the EU's response capacity to health emergencies: insights for EU crisis management mechanism](#)', *European Journal of Risk Regulation*, Vol. 11(4), 2020, pp. 808-820; Beaussier A. and Cabane

COVID-19 is amongst the most recent in a worryingly regular spate of epidemics and designated Public Health Emergencies of International Concern (PHEIC) registered since 2009.⁸ Although experts had warned that it was only a matter of time before a new pandemic would appear,⁹ the sheer scale, the suddenness, and serious social and economic consequences of COVID-19 took the world by surprise. COVID-19 showed that there is no predictable certainty of future health emergencies.¹⁰ Its outbreak provides a timely reminder of the need to prioritise epidemic preparedness and long-term prevention – premised on global health security and health system resilience – which will, in turn, strengthen the epidemic response.

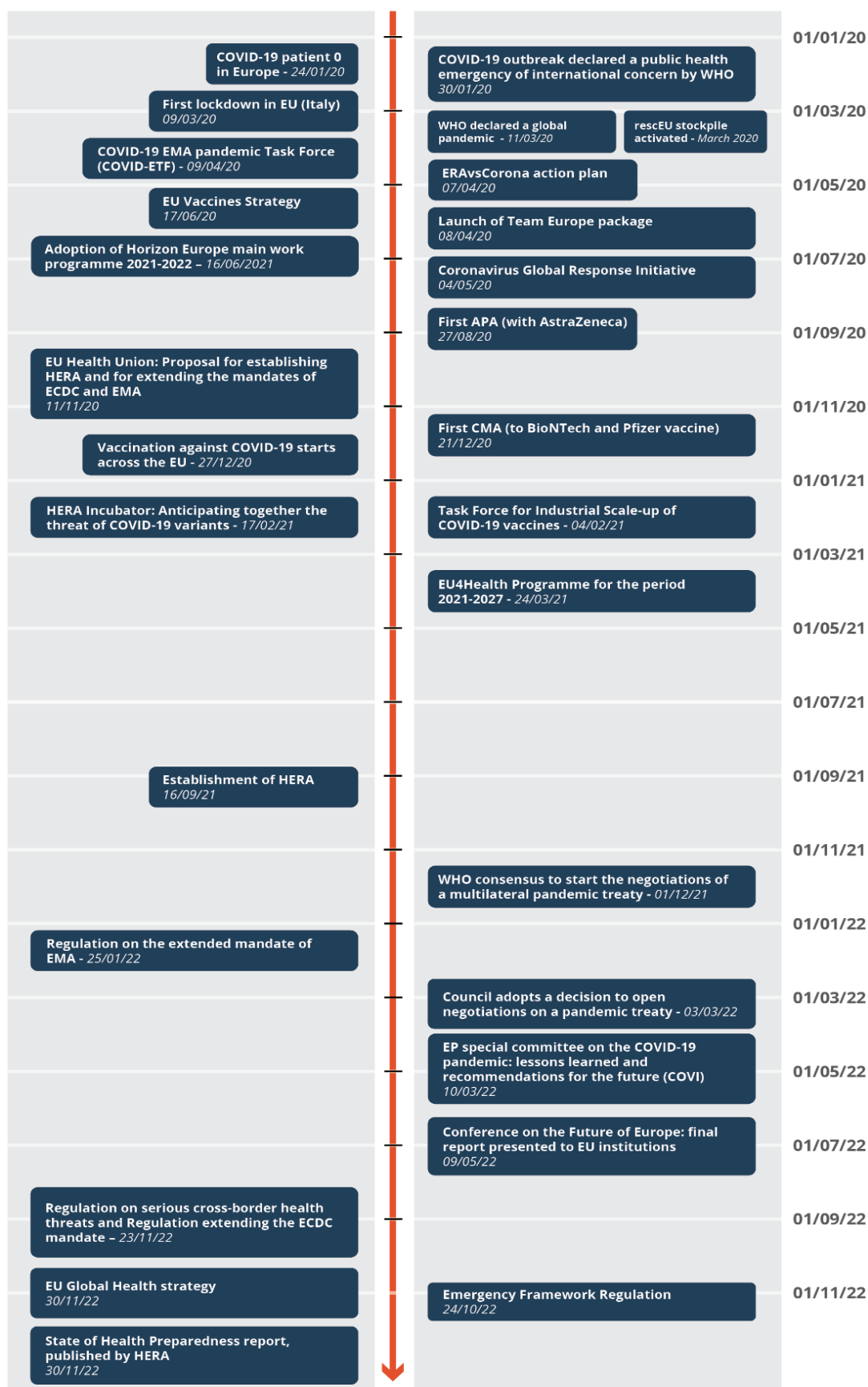
L. (2021); Beaussier A. and Cabane L., '[Improving the EU response to pandemics: key lessons from other crisis management domains](#)', *E-international relations*, 2021.

⁸ Prior to the COVID-19 outbreak, these included: influenza H1N1 pandemic (2009), polio (2014), Ebola epidemic in West Africa (2014), Zika virus (2016), Ebola epidemic in DR Congo (2020). Medialdea Carrera R., '[The importance of cross-border pandemic preparedness](#)', *Eurohealth*, 26, 34, 2020. In 2022, monkey pox was added to that list.

⁹ Mackenzie D., '[The covid-19 pandemic was predicted – here's how to stop the next one](#)', *The Scientist*, 16 September 2020.

¹⁰ The Lancet, Editorial: '[COVID-19: the worst may be yet to come](#)', *The Lancet*, Vol. 396, 2020, p. 71.

Figure 1: Timeline of EU the public health response



Source: authors' compilation

1.1.2. Parliamentary oversight during the COVID-19 pandemic: mechanisms, patterns, successes and shortcomings

As the pandemic unfolded, the EU developed and coordinated a wide range of policy actions in public health, crisis management, and economic relief and recovery. This is exemplified in the EU vaccines strategy, the joint procurement and deployment of vaccines and medical countermeasures, the provision of the 'Green Lane' approach,¹¹ and more recently, the EU Digital COVID certificate¹² to maintain the integrity of open borders and the single market.

In addition, the EU mobilised fiscal and financial instruments and emergency tools to counter the crisis and manage long-term recovery. These included the Emergency Support Instrument (ESI), the Joint Procurement Agreement (JPA) for vaccines and other countermeasures, the activation of the Union Civil Protection Mechanism (UCPM) for emergency support and repatriation of EU citizens stranded abroad, as well as the release of significant funds through the Coronavirus Response Investment Initiative (CRII) to assist Member States financially in their immediate response to the COVID-19 crisis and mitigate its long-term impact.

The EU's COVID-19 response was mediated by a structural division between EU responsibilities in public health and national competences in healthcare.¹³ Whereas public health includes health information systems, health promotion and disease prevention, health emergencies and health protection, healthcare falls under national health systems – and is thus a prerogative that lies within the remit of the EU Member States. At the same time, the EU, under the public health provisions of Article 168 TFEU, complements national health policies, inter alia, by facilitating access to better and safer healthcare, dealing with cross-border threats, and harmonising health strategies.

Beyond the divergences in the national health system capacities and health outcomes¹⁴ of Member States, the EU's coordinated COVID-19 response must also account for priorities for pandemic preparedness and prevention at the global level, while at the same time meeting the expectations of its own citizens, as was most recently articulated in the proposals of the Conference on the Future of Europe (CoFoE¹⁵ – see chapter 5.2). This includes the containment of the grave threat of antimicrobial resistance (AMR) through the 'one health' approach, alongside the sustained prioritisation of global health security.

COVID-19 also showed the need for a systematic and common approach to health emergencies and serious cross-border health threats and the relative effectiveness of the EU's various strategies and instruments that complemented national measures. Additionally, the COVID-19 experience yielded an accumulated body of knowledge of, insights in, and organisational expertise to manage crises and coordinate intersectoral action. A key lesson from the COVID-19 pandemic is how well these insights can translate into a coherent policy initiative.

¹¹ On 16 March 2020, the European Commission issued practical guidance on the implementation of '[green lane](#)' border crossings to keep movement of freight transport open during the COVID-19 pandemic.

¹² The [EU Digital COVID certificate](#) is a digital proof that a person has been vaccinated, received a negative test or recovered from COVID.

¹³ Bucher A., [Does Europe need a Health Union?](#), Bruegel, 2022.

¹⁴ Meaning changes in health as a result of interventions and health care investments.

¹⁵ Conference on the Future of Europe, [Final report](#), May 2022.

1.2. Purpose and scope of the study

Upon a request from the European Parliament's Special Committee on the COVID-19 pandemic (COVI),¹⁶ this study was commissioned by the European Parliamentary Research Service (EPRS) within the context of the Multiple Framework Contract EPRS/DIRC/SER/19/002. The Centre for European Policy Studies (CEPS) and Ecorys were contracted to provide the requested expertise.

The study examines the effectiveness, coherence, and the EU added value of the EU's COVID-19 response and preparedness for future health threats. By assessing the lessons from the COVID-19 pandemic, the current state of play, challenges, and opportunities for improvement in public health governance, it develops actionable, evidence-informed recommendations to strengthen the EU's preparedness for future cross-border health threats. In so doing, the study builds on the European Commission's communication on the early lessons from the pandemic.¹⁷

Specifically, this study examines the EU strategy across the following pillars:

- Vaccination strategies: this section includes the development and roll-out of COVID-19 vaccines; Member States' national vaccination strategies; the added value of the EU vaccines strategy; and the EU guidance for national vaccination strategies;
- Vaccine evidence, the independent scientific evidence on vaccine effectiveness;
- EU public health response to COVID-19, addressing the EU framework for crisis response, including management and coordination of serious cross-border health threats;
- EU prevention and preparedness for future health threats, including a response capacity, and the development towards a European Health Union (taking into account the upgraded mandates of the two EU agencies: the European Centre for Disease Prevention and Control (ECDC) and European Medicines Agency (EMA); the World Health Organization (WHO) pandemic treaty; and the one health approach);
- Considerations regarding EU competences in public health, to strengthen the EU's resilience and preparedness for cross-border health threats.

Research questions

This study offers an overview of the state of play and current knowledge base, drawing on qualitative and quantitative data. In doing so, it provides a context for further studies (e.g. into the effectiveness of vaccines) and policy analysis (e.g. the EU global health strategy). It is driven by the following research questions:

- To what extent did the EU effectively use its resources to provide Union-level protection, prevention, preparedness, and response during the COVID-19 pandemic?
- To what extent are the activities of the EU COVID-19 response consistent with those of other Union policies, Member States, and global priorities?
- What was the added value of the EU's COVID-19 response?

Box 1: Definition of EU added value

EU added value 'looks for changes that are due to the EU intervention, over and above what could reasonably have been expected from national actions by Member States'. 'Under the principle of subsidiarity (Article 5 TEU), and in areas of non-exclusive competence, the EU should only act when the objectives can be better achieved by Union action rather than action by the Member States. It requires consideration of the added value of EU action compared to that of other actors.'

Source: European Commission, 2021 Better Regulation Toolbox, [chapter 6](#).

¹⁶ European Parliament [decision](#) of 10 March 2022 on setting up a special committee on 'COVID-19 pandemic: lessons learned and recommendations for the future, its responsibilities, numerical strength and term of office.

¹⁷ European Commission, Drawing the early lessons from the COVID-19 pandemic, Communication [COM\(2021\) 380](#), 15 June 2021.

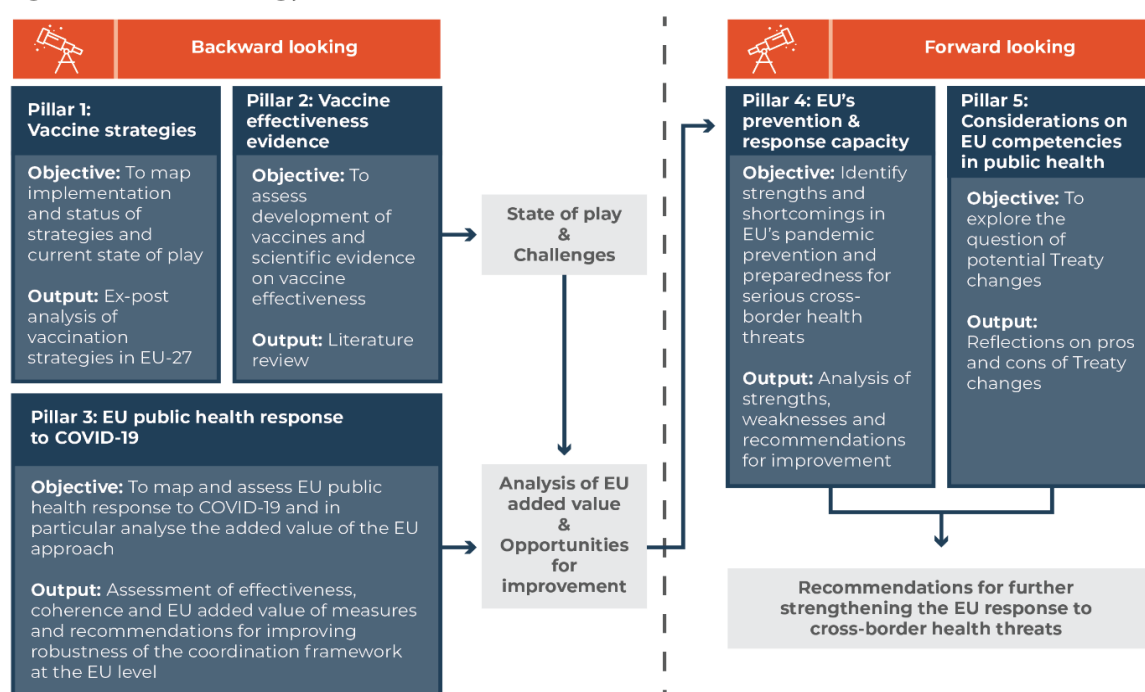
1.3. Methodological approach to the study

The five pillars described above can be divided into two groups (see Figure 2). Pillars 1, 2 and 3 are backward-looking, as they analyse events that have already occurred (or are still ongoing at the time of writing): e.g. national vaccination strategies and EU pandemic response policies. In adherence to the EU's Better Regulation guidelines, EU policy instruments and action are evaluated for their effectiveness, coherence, and overall EU-added value.¹⁸

Pillars 4 and 5 are forward-looking and address, respectively, the EU's pandemic preparedness and prevention plans, and the action required to further strengthen Europe's prevention and preparedness for future health threats. In each case, the analytical emphasis is to determine the extent to which EU policies and competences are fit to address a future threat.

In conclusion, the study offers recommendations for further strengthening the EU's preparedness for future cross-border health threats.

Figure 2: Methodology



Source: Compiled by the authors.

This study draws on various complementary methods for data collection:

- Desk research of relevant themes and topics to provide the structure and context for Pillars 1, 2, 3, 4, and 5. A bibliography is provided in Annex I;
- Literature review of peer-reviewed scientific publications on vaccine effectiveness. The literature review comprises two parts: (1) lab-based clinical trials and (2) epidemiological studies in the field. A comprehensive analysis of these studies was conducted, comparing relevant information, e.g. the vaccines being tested, author affiliations, objectives and scope, publication date, sample size, estimated magnitude, significance level, choice of estimator, etc.;

¹⁸ Relevance and efficiency are outside of the scope of this assessment due to the evolving nature of the pandemic and its response.

- Quantitative data collection of COVID-19 vaccine roll-out in the EU27 Member States, including the timing of roll-out of vaccines/boosters, overall vaccination rate, early access of vaccines to vulnerable groups, and the timing of the roll-out of boosters;
- Stakeholder consultations, including interviews and questionnaires with key stakeholders. These include interviews with representatives of Member States, EU institutions and agencies (including DG SANTE, HERA, EMA, ECDC), international organisations (e.g. OECD), and civil society organisations (CSOs). A wide cross-section of opinions was included to represent the diverse stakeholders **involved in**, or **affected by**, the EU COVID-19 response and crisis management. Insights from stakeholder interviews were anonymised and reported in group summaries throughout the study (Pillars 1-5: Chapters 2 to 5). In total, 23 interviews took place with 30 people. Most responses come from EU institutions (n=12), followed by representatives of Member States (n=9), and other types of stakeholders such as international organisations and from the private sector (n=2). Authorities in all EU Member States were approached and given the possibility to participate in a telephone interview or provide written feedback on the basis of a questionnaire. In total, nine Member States provided feedback, out of which six were written responses. A list of interviewees (i.e. organisation name and date) is provided in Annex II.

1.4. Reading guide

The chapters of the study follow the structure of the pillars as presented in Figure 2 (above).

- Chapter 1 provides an introduction to the study, together with the methodological approach and reading guide;
- Chapter 2 integrates Pillar 1 and Pillar 2 together and presents the findings in a chronological order. The chapter first discusses the EU vaccines strategy and in particular the transparency in the stages of research, development and manufacturing, procurement, and authorisation. The chapter moves on to present national COVID-19 vaccination strategies, and the state of play of COVID-19 vaccination across the EU27 by 30 September 2022, before discussing some factors determining vaccine uptakes. This chapter ends with a short analysis of vaccine effectiveness before summarising EU added value;
- Chapter 3 presents the findings of desk research and key stakeholder interviews on the EU public health response to COVID-19 (Pillar 3). Important EU-level initiatives, i.e. the European Health Union, Joint Procurement Mechanism, Civil Protection Mechanism, Emergency Support Instrument, Coronavirus Response Investment Initiative, and Team Europe's contributions to global health security, are evaluated through a discussion of their effectiveness, coherence, and EU added value;
- Chapter 4 presents insights into EU prevention and preparedness for future health threats (Pillar 4). This involves a discussion of the relative strengths and weaknesses of core EU agencies (the ECDC and EMA) and their recently extended mandates, the creation and mandate of HERA, proposed investments in the 'one health' approach, and a future WHO pandemic treaty;
- Chapter 5 presents preliminary reflections on the legislative package required for strengthening EU-level competence in managing and coordinating cross-border health events. This includes a discussion of the citizen-driven CoFoE proposals and emerging insights on the discussion regarding a potential Treaty change. Wherever possible, the text incorporates insights and concerns raised by key stakeholders in interviews;
- These also inform Chapters 6 and 7, presenting respectively the conclusions and recommendations of the study.

The study is supported by five annexes:

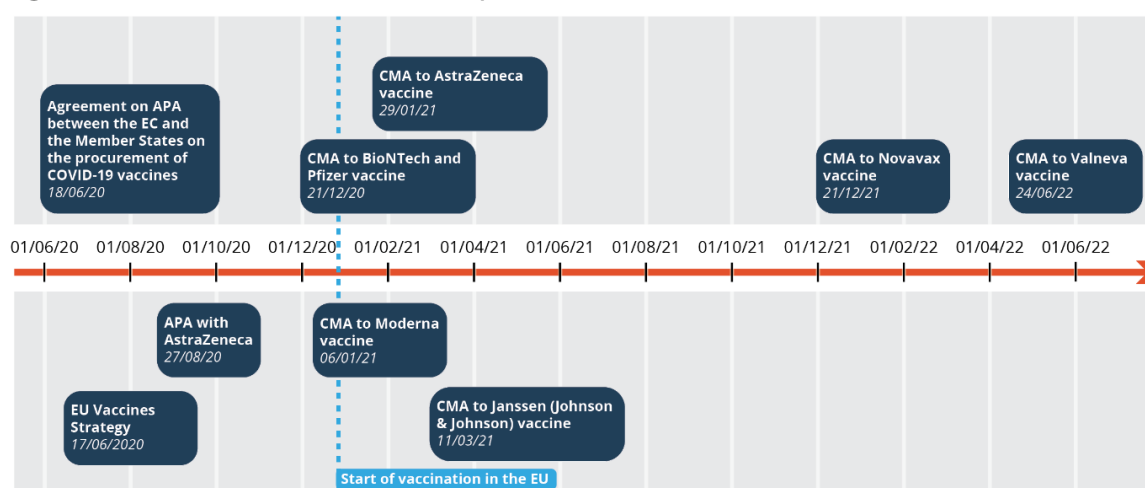
- Annex I includes the bibliography;
- Annex II includes the list of interviewed stakeholders;
- Annex III discusses intellectual property sharing;
- Annex IV includes information on vaccine development, funding, procurement, and delivery;
- Annex V includes a list of clinical trials and epidemiological studies.

2. EU vaccines strategy, vaccination, effectiveness, and evidence (Pillars 1 & 2)

Vaccines have proven to be a very effective means of containing the spread of certain infectious diseases. Therefore, vaccine development, together with other countermeasures, has been at the core of pandemic control since the outbreak of COVID-19 all over the world. From pessimistic expectations that an effective vaccine would not be ready in a year to the unprecedented speed of COVID-19 vaccine development and the ensuing vaccination programmes, the EU and its Member States have gone through successes and controversies. This chapter, taking a chronological approach, aims to provide an objective overview of the development and procurement process of COVID-19 vaccines in the EU through the EU vaccines strategy, and to present opinions from different perspectives concerning some more controversial issues, namely, the transparency of some steps in the process.

Since the WHO declared the COVID-19 outbreak a global pandemic on 11 March 2020, the world has gone through several COVID-19 waves. At the same time, pharmaceutical companies and academic institutions have accelerated vaccine development.

Figure 3: Timeline of vaccine development



Source: Compiled by the authors.

Figure 3 presents a timeline of events concerning the vaccine development, procurement, and authorisation in the EU. On 17 June 2020, the European Commission released the EU vaccines strategy to accelerate the development, authorisation, manufacturing, and deployment of vaccines against COVID-19.¹⁹ The main driver of progress was the use of Advance Purchase Agreements (APA) to secure the production and delivery of COVID-19 vaccines in the EU. From the first APA that was concluded on 27 August 2020, the first Conditional Market Authorisation (CMA) – granted to Pfizer-BioNTech's vaccine on 21 December 2020 –, to the beginning of the vaccination roll-out in the EU on 27 December 2020, it took a mere four months. Such speed is unprecedented considering how much longer such processes took before the pandemic.

This chapter will first discuss the impact of the EU vaccines strategy in three different stages; namely, research, development, and manufacturing (section 2.1.1), procurement (section 2.1.2) and authorisation (section 2.1.3). The chapter then moves on to discuss national vaccination strategies

¹⁹ European Commission, EU Strategy for COVID-19 vaccines, Communication [COM\(2020\) 245](#), 17 June 2020.

and vaccination progress in the EU Member States (section 2.2) before a brief study of vaccine effectiveness (section 2.3). The chapter ends with a discussion of the value added through the EU vaccines strategy and the EU guidance for national vaccination strategies (section 2.4).

2.1. The impact of the EU vaccines strategy

The EU vaccines strategy,²⁰ presented on 17 June 2020, laid down the objectives of the EU in using vaccines for pandemic control. The objectives of the EU vaccines strategy are:²¹

- to ensure the quality, safety, and efficacy of vaccines;
- to secure timely access to vaccines for Member States and their population while leading the global solidarity effort;
- to ensure equitable access for all in the EU to an affordable vaccine as early as possible.

This study analyses the impact of the EU vaccines strategy in three stages, namely, i) research, development, and manufacturing, ii) procurement and iii) authorisation. Apart from documenting and studying the actions taken, the related transparency controversy in each stage will be discussed.

2.1.1. Research, development, and manufacturing

The COVID-19 pandemic had put pressure on global supply chains, including the pharmaceutical sector. The EU's open strategic autonomy stresses the importance of domestically managing the supply chains in strategic sectors as much as possible while at the same time keeping the EU market open in alignment with EU values of maintaining free international trade. The pandemic hinted at a business model for the pharmaceutical industry in which the public sector is involved in innovating and providing global public goods. Indeed, COVID-19 vaccine R&D investments come from sources such as national governments, the EU or the Coalition for Epidemic Preparedness Innovations (CEPI).²² An early survey in April 2020 found that, while private companies were the majority, 28% of COVID-19 vaccine developers worldwide were led by groups from academia, the public sector and other non-profit organisations (Le et al., 2020). The same survey documented that five out of fourteen confirmed development projects were publicly funded.

Apart from providing public funding for research, the EU helped quickly ramp up the production of COVID-19 vaccines in Europe, even while localised in specific countries. Despite a sluggish start, the EU has successfully expanded its capacity to produce vaccines, becoming the production centre of both Pfizer-BioNTech and Moderna and surpassing the US in the first half of 2021 (Bown, 2022). The establishment of the Task Force for Industrial Scale-up of COVID-19 vaccines²³ in February 2021 was a key step towards facilitating the ramp-up of production capacity for COVID-19 vaccines and therapeutics in the EU in a short timeframe. Following the Task Force's identification of supply chain bottlenecks, new mechanisms managed by the recently established Commission Directorate-General HERA were set up, such as the key initiative 'EU FAB'.²⁴ EU FAB aims to create a network of 'ever-warm' production capacities for vaccines and therapeutics, which can be quickly activated in case of a health emergency.²⁵ Another significant factor is that the EU has not imposed an export

²⁰ European Commission, EU Strategy for COVID-19 vaccines, Communication [COM\(2020\) 245](#), 17 June 2020.

²¹ European Commission, [webpage](#) EU Vaccines Strategy: documents.

²² European Commission, DG Research and Innovation newsroom, [COVID-19 Vaccine R&D Investments](#), 2021.

²³ The Task Force was set up by the European Commission's Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW). See European Commission, [Webpage](#) of Task Force (Accessed 9 January 2023).

²⁴ For details on the EU FAB network, see European Commission, [Factsheet EU FAB](#), 2022.

²⁵ The Commission published its call for a framework contract for 'the reservation of capacities and a priority right for manufacturing of vaccines under EU FAB' on 27/04/2022, which aims to reserve a manufacturing capacity of minimum

ban on COVID-19 vaccines, motivating companies to keep and expand production capacity within the EU (Bown, 2022). Other key actions introduced during the implementation of the EU vaccines strategy and meant to speed up vaccine development are:

- Establishing selection criteria for vaccine candidates - contextually to the EU vaccines strategy, the European Commission provided specific selection criteria for vaccine candidates that account for the following factors: soundness of scientific approach and technology used, speed of delivery at scale, cost, risk sharing, liability, coverage of different technologies, capacity to supply through development of production capacity within the EU, global solidarity, and engagement at an early stage with EU regulators.²⁶ The European Commission established a portfolio of several vaccine candidates;
- Introducing a derogation on the legislation on genetically modified organisms (GMOs): Regulation (EU) 2020/1043²⁷ provides a temporary derogation from EU GMO Directives for COVID-19 vaccines. These directives (2001/18/EC and 2001/20/EC) require a complex procedure for products containing or consisting of GMOs prior to being authorised in the EU market. The development of some COVID-19 vaccines contained attenuated viruses or live vectors (e.g. nucleic acid vaccines containing DNA and mRNA and non-multiplicative viral vector vaccines), thereby possibly falling under the definition of a GMO and hence being subject to regulation by GMO Directives.²⁸ If the GMO Directives had been applied to these COVID-19 vaccines, the competent authority could have required an environmental risk assessment before giving written consent to the developers. The derogation thus avoided delaying clinical trials by sidestepping this complex procedure for medicinal products containing or consisting of GMOs if these products intended to treat or prevent COVID-19. Indeed, according to EU legislation (in particular Directive 2001/18/EC), the derogation bypasses this requirement and allows a quicker entrance into the market of COVID-19 vaccines;
- Introducing flexibility regarding labelling and packaging requirements: the European Commission signed a Memorandum of Understanding (MoU) with Member States concerning simplified labelling and packaging flexibilities for COVID-19 vaccines in order to speed up their deployment, in September 2020.²⁹ In particular, the MoU concludes that, considering the emergency circumstances and the need to speed up the procedures, some of the language requirements for vaccines' labels are alleviated and COVID-19 vaccines packaging should consist of multi-dose vials.

Transparency: use of public funds

'Vaccine transparency' in the context of this study refers to public authorities' disclosure of information about the research, development, procurement, authorisation, and distribution of COVID-19 vaccines. During the COVID-19 crisis, concerns about transparency related to vaccines became prominent due to the virus' infectiousness and lethality, and also due to the magnitude of

450 million doses for mRNA-based, vector-based and protein-based vaccines. The [tender specification](#) is updated on 14/10/2022.

²⁶ European Commission, EU Strategy for COVID-19 vaccines, Communication [COM\(2020\) 245](#), 17 June 2020.

²⁷ [Regulation \(EU\) 2020/1043](#) of 15 July 2020 on the conduct of clinical trials with and supply of medicinal products for human use containing or consisting of genetically modified organisms intended to treat or prevent coronavirus disease (COVID-19).

²⁸ European Commission, EU Strategy for COVID-19 vaccines, Communication [COM\(2020\) 245](#), 17 June 2020.

²⁹ European Commission, [Memorandum of Understanding](#) (MoU) with Member States on regulatory flexibility for COVID-19 vaccines, 2020.

public investment necessary for vaccine development and distribution. EU primary law enshrines the right to accountability.³⁰

The case for transparency in public Research and Development (R&D) investment also applies to COVID-19 vaccines. The unprecedented urgency for developing vaccines against COVID-19 has led to substantial financial support to speed up R&D in the field (UNODC, 2020) and the majority of COVID-19 vaccines have received some form of public support.³¹ In the EU, the European Commission, via the European Investment Bank (EIB), funded COVID-19 vaccine capacity development through the Horizon 2020 InnovFin Infectious Disease Finance Facility (H2020 InnovFin IDFF).³² The EU objective was to ensure an extensive portfolio of potential vaccines for COVID-19 for the benefit of citizens. For example, BioNTech concluded a debt financing agreement with the European Investment Bank of €100 million in June 2020³³, and CureVac received a loan of €75 million in July 2020.³⁴ In 2020, the European Commission mobilised a budget of €400 million from the InnovFin mechanism.³⁵

Additionally, Advance Purchase Agreements (APAs) between the Commission and pharmaceutical companies allocated part of these amounts to support companies' development of COVID-19 vaccines. For instance, according to the Commission's answer to a parliamentary question, the upfront payments which CureVac received from the Commission in December 2020 covered the development and production of the vaccines.³⁶ Similarly, GSK and Novavax attested during public hearings with the COVI committee on 10 October 2022³⁷ that APA payments were used to develop the vaccine and begin manufacturing at risk. This can be considered an upfront de-risking investment that the Commission provided for companies.

In September 2020, six healthcare civil society organisations (CSOs) asked the Commission to break down the disbursement of the EU's funding support for pharmaceutical firms carrying out R&D of vaccines.³⁸ Other CSOs calling for transparency in the use of public funding for pharmaceutical companies and vaccine contracts include Médecins Sans Frontières, Human Rights Watch, and Health Action International. In its 21 October 2021 Resolution on 'EU transparency in the development, purchase, and distribution of COVID-19 vaccines', the European Parliament called for the Commission's disclosure of detailed information on the public spending on vaccine development and the cost-sharing between the Commission and pharmaceutical companies for the development of vaccines.³⁹ The European Court of Auditors published a special report on COVID-19

³⁰ [Article 42](#) of the EU Charter of Fundamental Rights (Right of access to documents) states that 'any citizen of the Union, and any natural or legal person residing or having its registered office in a Member State, has a right of access to documents of the institutions, bodies, offices and agencies of the Union, whatever their medium'.

³¹ Tanveer S. et al., '[Transparency of COVID-19 vaccine trials: decisions without data](#)', *BMJ Evidence-Based Medicine*, Vol. 27(4), 2021, pp. 199-205.

³² European Investment Bank, [InnovFin Infectious Diseases](#), 2021.

³³ European Commission, Investment Plan for Europe: European Investment Bank to provide BioNTech with up to EUR100 million in debt financing for COVID-19 vaccine development and manufacturing, [press release](#), 11 June 2020.

³⁴ European Commission, Commission and EIB provide CureVac with a €75 million financing for vaccine development and expansion of manufacturing, [press release](#), 6 July 2020.

³⁵ European Commission, DG Research and Innovation, [Annual Activity Report 2020](#).

³⁶ [Answer](#) to written question E-001822/2022 given by Commissioner Kyriakides on behalf of the European Commission.

³⁷ See [recordings](#) of the COVI meetings of 10 October 2022.

³⁸ See [joint statement](#) on transparency (Accessed 31 October 2022). The six CSOs include the International Association of Mutual Benefit Societies, the Standing Committee of European Doctors, Access to Medicines Task Force, Association of European Cancer Leagues, the European Public Health Alliance, the European Social Insurance Platform, and European Alliance for Responsible R&D and Affordable Medicines.

³⁹ European Parliament, [Resolution](#) of 21 October 2021 on EU transparency in the development, purchase and distribution of COVID-19 vaccines (2021/2678(RSP)).

vaccine procurement in the EU in September 2022. The report discloses that by the end of 2021, the Commission paid more than €2.55 billion in down payments to vaccine manufacturers (out of the total budget of €2.9 billion to fund vaccine APAs).⁴⁰ However, pharmaceutical companies are reluctant to disclose information about the actual overall costs for the development of COVID-19 vaccines or the amount of investment needed for R&D. It is therefore impossible to assess how much the share of public funding is in the development and production of COVID-19 vaccines.

2.1.2. Procurement

The EU vaccines strategy builds on the use of APAs with vaccine producers to secure the availability of vaccines in the EU in a short timeframe, in a sufficient quantity, and at an affordable price. The negotiation of APAs was the first step in the implementation of the EU vaccines strategy. The APAs ensured a united EU approach to the procurement of vaccines with the aim of promoting efficiency, equality, and solidarity among the Member States. As the agreement states, the Commission acquired 'the mandate to conclude, on behalf of the Participating Member States, Advance Purchase Agreements (APA) with vaccine manufacturers with the objective to procure vaccines for the purposes of combatting the COVID-19 pandemic at Union level'. In this way, EU-level APAs contribute towards securing access to vaccines and lowering the risks for the investments with up-front payments. The Agreement is built on the ESI Regulation under which the Commission may grant emergency support in the form of procurement on behalf of the Member States.⁴¹ The APAs also put in place a plan for the distribution of vaccines across the EU Member States, ensuring equal access and doses available based on the population size.

The responsibility for the negotiations with pharmaceutical companies for the conclusion of APAs was attributed to the European Commission's DG SANTE, together with a joint negotiation team formed by representatives from seven EU Member States (Spain, France, Sweden, Germany, the Netherlands, Italy, and Poland) appointed by a Steering Committee in which all EU Member States are represented.

Through APAs, the European Commission conducted exploratory talks, entered into agreements with individual vaccine producers, and purchased or reserved the right to purchase the vaccines in advance.⁴² The negotiation process for the first six COVID-19 vaccine candidates started right after the EU vaccines strategy was issued on 18 June 2020 and finished by the end of 2020 (Table 1). The negotiations for two additional vaccines produced by Novavax and Valneva started later and were concluded in the second half of 2021. Table 1 illustrates key dates of the negotiation process to conclude APAs for COVID-19 vaccines. (Section 2.1.3 on authorisation provides information about the conditional market authorisation of those vaccines.)

⁴⁰ European Court of Auditors, [Special report 19/2022](#): EU COVID-19 vaccine procurement – Sufficient doses secured after initial challenges, but performance of the process not sufficiently assessed, 12 September 2022.

⁴¹ The Emergency Support Instrument (ESI), activated on 2 April 2020, helped Member States respond to the coronavirus pandemic by addressing needs in a strategic and coordinated manner at European level. ESI financed vaccines, treatments, testing, transport of essential goods, medical teams and patients, essential health related products, UV Robots for disinfection of hospitals across Europe, training of healthcare professionals in intensive care skills, EU Digital COVID Certificate, the links among national contact tracing apps. For further information, see European Commission, [Webpage](#) Emergency Support Instrument (Accessed 31 October 2022). See also Chapter 3.1.4.

⁴² HERA is expected to ensure 'swift procurement and distribution of medical countermeasures' in future health emergencies, as stated in its fourth main task. For further information on HERA, see European Commission, Introducing HERA, the European Health Emergency preparedness and Response Authority, the next step towards completing the European Health Union, Communication [COM\(2021\) 576](#), 16 September 2021.

Table 1: Information regarding APAs of COVID-19 vaccines

Vaccine producers	Conclusion of exploratory talks	European Commission approval of APA	Entry into force of APA
Sanofi-GSK	31/07/2020	-	18/09/2020
Janssen	13/08/2020	08/10/2020	21/10/2020
AstraZeneca	-	14/08/2020	27/08/2020
CureVac ¹	20/08/2020	19/11/2020	30/11/2020
Moderna	24/08/2020	25/11/2020	04/12/2020
Pfizer-BioNTech	09/09/2020	11/11/2020	20/11/2020
Novavax	17/11/2020	04/08/2021	-
Valneva	12/01/2021	10/11/2021	-

Source: European Commission's [webpage](#) on questions and answers on COVID-19 vaccination in the EU (information is valid as of 31 October 2022).

Note: ⁽¹⁾ The APA with CureVac was automatically terminated as the company announced it could not develop the vaccine. The boxes filled with “-” refer to the case that a clear date for the conclusion of exploratory talks (AstraZeneca's vaccine), Commission approval of APA (Sanofi-GSK's vaccine), entry into force of APA (Novavax and Valneva's vaccines) cannot be found.

While the Commission secured the right to buy the COVID-19 vaccines in a given timeframe and at a given price, it also paid €2.7 billion to vaccine manufacturers to compensate for their upfront costs.⁴³ The involvement of public money and the need for affordable vaccines stirred up a public debate about whether the manufacturers should keep their intellectual property rights (IPR) during a global pandemic.⁴⁴ In June 2021, the European Parliament called for a temporary lifting of IPR protection for COVID-19 vaccines, aiming to increase the global supply of vaccines.⁴⁵ The Commission took the opposite stance and argued that waiving IPR would not help increase supply.⁴⁶ Manufacturers agreed with the Commission, arguing that waiving IPR would not boost production since the world's production had already peaked, and that it would loosen the control over the safety and quality of the vaccines (see Annex III).

Transparency: procurement contracts

Various EU institutions have raised their concerns about the transparency of the negotiation and publication of the COVID-19 vaccine contracts procured by the European Commission, including the European Parliament, the Ombudsman, and the Court of Auditors. In addition, the European Public Prosecutor's Office informed in October 2021 that it has launched an investigation into the acquisition of COVID-19 vaccines.⁴⁷

In its 21 October 2021 Resolution on EU transparency in the development, purchase and distribution of COVID-19 vaccines, Parliament called on the Commission to publish the non-redacted versions of

⁴³ European Commission, [Webpage](#) EU Vaccines Strategy (Accessed 31 October 2022).

⁴⁴ Kianzad B. and Wested J., “No-One Is Safe Until Everyone Is Safe” – Patent Waiver, Compulsory Licensing and COVID-19, *European Pharmaceutical Law Review*, Vol. 5(2), 2021, pp. 71–91.

⁴⁵ European Parliament, [Resolution](#) of 17 April 2020 on EU coordinated action to combat the COVID-19 pandemic and its consequences (2020/2616(RSP)).

⁴⁶ Walker L., [‘European Parliament and Commission clash on temporary waiver of Covid-19 vaccine patents’](#), *The Brussels Times*, 10 June 2021.

⁴⁷ European Public Prosecutor's Office, Ongoing EPPO investigation into the acquisition of COVID-19 vaccines in the EU, [press release](#), 14 October 2021.

the APAs between the Commission and companies.⁴⁸ Information of public interest includes prices per dose, the number of doses to each country, payments, liability, sanctions in case of breach of contract, sharing of intellectual property rights, disaggregated amount of public spending on vaccine development, and potential breaches of contracts by companies. In April 2022, five Members of the European Parliament submitted an application to the European Court of Justice against the Commission's lack of transparency in sharing access to vaccine procurement documents.⁴⁹

Another actor playing a critical role in advancing the transparency of the COVID-19 vaccine procurement is the European Ombudsman, the EU office working to promote good administration at the EU level. The Ombudsman has opened a series of inquiries into this matter.

- In July 2020, the Ombudsman sent her own-initiative inquiry (Case SI/4/2020/PL of 29 July 2020) to the Commission asking for the Commission's approach to ensuring the integrity of its procurement of medical countermeasures related to the COVID-19 crisis.⁵⁰ In its response on 8 February 2021, the Commission provided several measures it had taken to guarantee the transparency of its procurement procedure.⁵¹ These measures included i) appointing the evaluation members of the JPAs in compliance with the EU's Financial Regulation, ii) publishing up-to-date information on the joint procurement of COVID-19 vaccines⁵², and iii) publishing contract award notices in the Supplement to the Official Journal.⁵³ When the Ombudsman decided to close this inquiry in April 2021, she emphasised that several issues remained inadequately answered by the Commission, in particular on how it assigned the members of the evaluation committees and its monitoring of the negotiation process;
- In addition, in January 2021 the Ombudsman opened a case on information related to the negotiations of APAs with pharmaceutical companies, following the Commission's rejection to grant a CSO access to the vaccine contracts and failure to share the meeting minutes and correspondence related to the negotiations (Case 85/2021/MIG).⁵⁴ In response to the Ombudsman's inquiry, the Commission initially promised to disseminate a first batch of 76 documents to the CSO but failed to deliver it on time. In January 2022, upon the notification of the CSO, the Ombudsman proceeded the second inquiry in the series, urging the Commission to comply with its promise to grant public access to documents concerning the negotiations for the procurement of COVID-19 vaccines (Case 2206/2021/MIG).⁵⁵ The Commission granted the complainant and the public wider access to the APA 'to the extent it deemed possible'. In addition, the Commission also disclosed the agendas and minutes of the Steering Board meetings and correspondences related to the negotiation of the vaccines

⁴⁸ European Parliament, [Resolution](#) of 21 October 2021 on EU transparency in the development, purchase and distribution of COVID-19 vaccines (2021/2678(RSP)).

⁴⁹ The Greens/EFA in the European Parliament, Access to information: five Greens/EFA MEPs launch legal action on vaccine contract transparency, [press release](#), 22 April 2022. The application was submitted to the European Court of Justice on 22 October 2021. [Case T-689/21 Auken and others v Commission](#) is pending.

⁵⁰ Case [SI/4/2020/PL](#) on The European Commission and transparency in the context of the EU response to the COVID-19 crisis.

⁵¹ [Reply of the European Commission](#) to the request for information from the European Ombudsman - Strategic initiative SI/4/2020/PL.

⁵² The European Commission published the information through its [coronavirus response website](#).

⁵³ See the [Tenders Electronic Daily](#) (TED).

⁵⁴ European Ombudsman, [Case 85/2021/MIG](#) - *The European Commission's refusal to give public access to documents concerning the purchase of vaccines against COVID-19*, 22 January 2021.

⁵⁵ European Ombudsman, [Case 2206/2021/MIG](#) - *How the European Commission dealt with a request for public access to documents concerning the negotiations for the procurement of COVID-19 vaccines*, 26 January 2022.

in May 2022, totalling around 350 documents.⁵⁶ Though the Ombudsman has closed this inquiry, she is aware that the complainant is not fully satisfied with the access granted by the Commission, given that a large amount of critical information in the disclosed contracts remains redacted;

- In September 2021, the Ombudsman opened an inquiry into the disclosure of text messages between the President of the Commission and the CEO of Pfizer on the purchase of COVID-19 vaccines (Case 1316/2021/MIG ⁵⁷ of 16 September 2021). The Commission refused to look for the text messages, justifying that this means of communication had a 'short-lived' nature and did not 'fall under its internal criteria for recording'. The Ombudsman took the view that this case constituted 'maladministration'.

In January 2021, the Commission set up a 'reading room' where selected Members of the European Parliament could read the redacted version of the contracts once all negotiations are completed.⁵⁸ This step was considered insufficient as reading rooms are most relevant while negotiations are still ongoing. The Commission published its contracts with AstraZeneca in January 2021⁵⁹, and with Janssen, Pfizer-BioNTech, Moderna, CureVac, Sanofi-GSK, Novavax, Valneva later in 2022.⁶⁰ Even though the contracts have been released, the controversy has not completely waned. Indeed, all the published APAs and contracts contain a considerable number of redactions (i.e. the act of concealing a text before publication) without any justifications. Reportedly, the published minutes of the Steering Board related to the negotiations of the vaccines have also been redacted.

The published version of the contracts was widely redacted, potentially entailing 'partial transparency', as the unknown redacted texts in the contracts might lead to incorrect interpretations based on the unredacted sections. The Center for Global Development (CGD), in their Principles on Commercial Transparency in Public Contracts, suggests that information should only be redacted 'when the public interest in withholding information is greater than the public interest in disclosure' and all redactions should be clearly marked with the reason for redaction.⁶¹ The NGO Transparency International calls on the EU to explore the good practice of the United States, which uses the CGD principles and notes the legal provisions allowing for each redaction in its published vaccine contracts (Transparency International, 2021).⁶² Inspired by the US's practice, the Commission could consider providing justification of the redactions in its vaccine contracts in line with Article 4 the Regulation (EC) No 1049/2001 on public access to EU documents. Providing justifications might allow a fairer evaluation of the balance between commercial confidentiality and public interests.

Pharmaceutical companies have also faced frequent requests to disclose certain economic aspects of their contracts. In a joint pledge, major pharmaceutical companies commit to implementing exceptional transparency measures on COVID-19 vaccines, which include, among other things,

⁵⁶ Ask The EU, [The Vaccines Procurement Steering Committee & the Joint Negotiation Team](#), 2020 (Accessed 31 October 2022).

⁵⁷ European Ombudsman, [Case 1316/2021/MIG – The European Commission's refusal of public access to text messages exchanged between the Commission President and the CEO of a pharmaceutical company on the purchase of a COVID-19 vaccine](#), 16 September 2021.

⁵⁸ European Parliament, COVID-19 vaccines: MEPs call for more clarity and transparency, [press release](#), 12 January 2021.

⁵⁹ European Commission, Vaccines: contract between European Commission and AstraZeneca now published, [press release](#), 29 January 2021.

⁶⁰ Except for the contract with AstraZeneca, the exact publication dates of the other APAs are not available at the Commission's [Vaccines Strategy website](#).

⁶¹ Center for Global Development, [The Principles on Commercial Transparency in Public Contracts](#), 2019.

⁶² An example of a [contract](#) between the US and Moderna is available at the website of the U.S. Department of Health and Human Services. The redactions in the contract follow the redaction code laid out in the [Freedom of Information Act, 5 U.S.C § 552](#).

publishing clinical trial data.⁶³ Commentators consider the joint statement a positive step towards higher transparency, although it focuses on procedures for patients and the regulatory process, and contains no measures to enhance integrity during negotiation.⁶⁴ Another point of discussion is the lack of assertiveness of the European Commission and Member States while negotiating the APAs with pharmaceutical companies. Despite the public funding for COVID-19 vaccines, the negotiations did not touch upon the possibilities of IPR sharing (see Annex III).

The European Court of Auditors (ECA), in its Special Report 19/2022⁶⁵, also reiterated its request to the Commission to share information on its preliminary negotiations for a contract with Pfizer-BioNTech in March 2021. This contract covers 900 million doses to be delivered in 2022 and 2023 and is the biggest vaccine contract signed by the Commission. ECA particularly asked for information on the scientific experts that the Commission consulted, their advice, the timing and records of the discussions, and details of the agreed terms and conditions of the agreement. As of September 2022, ECA indicated not to have received any information about this contract from the Commission. ECA further recommended that the Commission should take lessons learnt, identify good practices in non-EU countries and provide guidelines on pandemic procurement. Such guidelines should be made available one year after the adoption of the Emergency Framework Regulation⁶⁶ (on 24 October 2022) and the revision of the EU's Financial Regulation.

Finally, in the COVI Committee's hearing with the European Ombudsman and health experts on 7 September 2022, transparency continued to be a topic of concern.⁶⁷ In response to the Ombudsman's inquiry No. 1316/2021/MIG (mentioned above), the Commission has acknowledged that work-related text messages must be classified documents under Regulation 1049/2001 on public access to EU documents. It continues, however, to refuse to share the text messages between the Commission President and the CEO of Pfizer. The Ombudsman therefore maintained her conclusion that this case constituted maladministration. The Ombudsman was also aware that the Commission was preparing a new protocol for documenting texts and other short-lived media. Health experts participating in the hearing further asked for the Commission's disclosure of unredacted vaccine contracts, and called on HERA to integrate more conditionality (e.g. in terms of transparency and IP sharing) in future contracts that it signs with pharmaceutical companies.

2.1.3. Authorisation

One major objective of the EU vaccines strategy is to secure timely access to vaccines against COVID-19. To accelerate the authorisation, development and availability of successful vaccines, the regulatory flexibilities allowed by EU legislation have contributed to securing this objective.

The normal authorisation procedure

Under EU law, all medicinal products must be authorised before being brought to market. The EU-centralised evaluation and authorisation of medicinal products normally follow a well-established procedure, set out in Regulation (EC) No 726/2004 on the authorisation and supervision of medicinal

⁶³ IFPMA, PhRMA, EFPIA, Vaccines Europe, BIO, ICBA [Statement](#) on Innovative biopharmaceutical industry comment on COVID-19 vaccines dosing strategies and recommend following the science, 13 January 2021.

⁶⁴ Sciacchitano S. and Bartolazzi A., '[Transparency in Negotiation of European Union With Big Pharma on COVID-19 Vaccines](#)', *Reviews in Science and Technology*, Vol. 9(1), 2021.

⁶⁵ European Court of Auditors, [Special report 19/2022](#): EU COVID-19 vaccine procurement – Sufficient doses secured after initial challenges, but performance of the process not sufficiently assessed, 12 September 2022.

⁶⁶ [Council Regulation \(EU\) 2022/2372](#) of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level.

⁶⁷ European Parliament, COVI Committee's [debate](#) with EU Ombudsman and healthcare experts, 7 September 2022.

products for human use.⁶⁸ Pharmaceutical and biotechnology companies as well as scientists research and develop new medicinal products and can ask EMA for scientific advice to generate robust data on the medicinal product. The developers then submit data to EMA to apply for market authorisation of the medicinal product, containing all the information needed for the evaluation.⁶⁹ The Committee for Medicinal Products for Human Use (CHMP) – EMA's committee responsible for human medicines – then evaluates the applications based on its scientific assessment of the benefits and risks of the medicinal product. Once the CHMP finishes its evaluation, EMA recommends whether to authorise the use of the medicinal product in patients or not to the European Commission. The Commission consults with Member States and takes the final decision on granting the authorisation to the medicinal product within 67 days of receipt of EMA's recommendation. The authorisation is valid in the EU27 as well as in the European Economic Area (EEA) countries, i.e. Iceland, Norway and Liechtenstein.⁷⁰

Flexible regulatory process

The COVID-19 crisis put unprecedented time pressure on making vaccines available to EU citizens while ensuring their safety and efficacy. In response to this challenge, the EU vaccines strategy introduced a flexible regulatory process to expedite the development and authorisation of COVID-19 vaccines *inter alia*. Some of the regulatory flexibility tools were already used by EMA and the Commission before the COVID-19 pandemic, whereas several others were introduced for the first time during this crisis. The EU's fast-track evaluation and authorisation of COVID-19 vaccines showcase an important example of regulatory flexibility during an emergency.⁷¹ A survey with major R&D-based pharmaceutical companies found that tools like rapid scientific advice, the rolling review procedure, and conditional marketing authorisation were highly welcomed by these pharmaceutical companies (Klein et al., 2022).⁷² The COVI Committee's public hearings with representatives of the pharmaceutical companies on 5 September and 10 October 2022 further confirm these findings.⁷³

EMA has been playing a pivotal role in implementing measures for the flexible regulatory processes, notably through the COVID-19 EMA pandemic task force, the rapid scientific advice, the rolling review, and the conditional market authorisation.

COVID-19 pandemic task force

The COVID-19 EMA pandemic task force (subsequently Emergency Task Force) was established on 9 April 2020, bringing together expertise from across the European medicines regulatory network (EMRN). The COVID-19 EMA pandemic task force aimed to bring support for regulatory activities and solidify the EU's response to the COVID-19 pandemic.⁷⁴ It reinforced interactions with the European Commission, vaccine developers and academics, and coordination with other EU agencies (such as the ECDC) during the pandemic. Under the new mandate of EMA, which entered into force in March

⁶⁸ [Regulation \(EC\) No 726/2004](#) of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency.

⁶⁹ EMA provides [guidance](#) for the submission of data for marketing authorisation.

⁷⁰ More information about the different stages of developing and authorising medicines under the EU centralised route see EMA, [Webpage](#) From lab to patient; and EMA, [From laboratory to patient: the journey of a medicine assessed by EMA](#), 2019.

⁷¹ Marinus R. et al, '[Rolling reviews during COVID-19: The European Union experience in a global context](#)', *Clinical Therapeutics*, Vol. 44(3), 2022, pp. 352-363.

⁷² The survey was conducted in May-June 2021 with 17 pharmaceutical companies.

⁷³ See recordings of the COVI meetings of [5 September 2022](#) and [10 October 2022](#).

⁷⁴ EMA, [Mandate, objectives and rules of procedure of the COVID-19 EMA pandemic Task Force \(COVID-ETF\)](#), 20 June 2021.

2022, the Emergency Task Force (ETF) took over the activities of the COVID-19 EMA pandemic task force and became a permanent EMA body.^{75,76,77}

Rapid scientific advice

EMA provided rapid scientific advice for vaccine developers from the early development phases. Its rapid scientific advice follows the general principles of EMA's standard scientific advice (mentioned above), but with adapted milestones to facilitate the acceleration. Unlike CMA and the rolling review (described below), rapid scientific advice was used for the first time for potential COVID-19 vaccines and treatments in 2020, and was formally established in the Regulation (EU) 2022/123 on a reinforced role for EMA.⁷⁸ The rapid scientific advice process allowed for continuous interaction between EMA and vaccine developers, resulting in mutual understanding in a shorter timeframe. EMA also communicated proactively and extensively on the approvals and monitoring of COVID-19 vaccines through the publication of guidelines, organisation of press briefings, and stakeholder meetings.⁷⁹ These exercises are resource-intensive, requiring early and continuous dialogues between EMA, the Commission, and the vaccine developers. According to some experts interviewed for this study, it would be less possible to sustain such efforts in the post-pandemic era, but the success of the process does provide inspiration for future interaction between medicines' regulatory authorities and medicine developers. The fact that the ETF has now become a permanent body of EMA is considered a positive signal. In the future, the EU could consider conducting further evaluation of selected uses of these pathways, which should be less resource-intensive (and so more sustainable during non-emergency periods) but remain fast, robust, and respectful of scientific standards.⁸⁰

Rolling review

EMA approved the start of the rolling review procedure and reviewed scientific data from clinical trials of potential vaccines and therapeutics for COVID-19 as soon as this data was available while development was still ongoing. Once EMA confirms the sufficiency of the data, the developers submit the application for (conditional) market authorisation of the vaccines. The rolling review is not a new concept.⁸¹ For instance, EMA used this process to evaluate the 2009 H1N1 pandemic vaccines.⁸²

While authorisation relies very much on the review of timely and high-quality clinical trial data, the usual practice of clinical trials faced ethical challenges during the COVID-19 pandemic.⁸³ In these trials, participants are usually 'blinded' about whether they received the vaccine or a placebo. During non-emergency situations, placebo-controlled clinical trials are an effective scientific method to evaluate the efficacy and safety of a vaccine in the short run and also in the long run. However, the organisation of clinical trials during the pandemic raised some ethical challenges, especially when

⁷⁵ [Regulation \(EU\) 2022/123](#) of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices.

⁷⁶ EMA, Regulation on EMA's extended mandate becomes applicable, [press release](#), 1 March 2022.

⁷⁷ EMA, [Webpage](#) Emergency Task Force (ETF) (Accessed 31 October 2022).

⁷⁸ EMA, [EMA initiatives for acceleration of development support and evaluation procedures for COVID-19 treatments and vaccines](#), EMA/213341/2020 Rev.4, 14 July 2022.

⁷⁹ Marinus R. et al., '[Rolling reviews during COVID-19: The European Union experience in a global context](#)', *Clinical Therapeutics*, Vol. 44(3), 2022, pp. 352-363.

⁸⁰ Ibid.

⁸¹ Ibid.

⁸² EMA, [Pandemic report and lessons learned: Outcome of the European Medicines Agency's activities during the 2009 \(H1N1\) flu pandemic](#), 2011.

⁸³ Placebo-controlled testing is a clinical trial engaging two (or more) groups of participants, one gets the active treatment (e.g. a vaccine), while the other gets the placebo.

another approved vaccine was available. This was considered an ethical responsibility from the side of the organisers or researchers whether to notify participants to accept another approved vaccine.^{84 85} It highlights the difficulty of recruiting participants in clinical trials during a global pandemic. Nevertheless, subjects moving across groups is not detrimental if the sample is sufficiently large. Studies on vaccine safety are also not seriously affected since the majority of the data on adverse effects following vaccination (AEFIs) is collected through post-market research and surveillance.⁸⁶

In health emergency situations where CMA is required, vaccine developers and authorisers have to consider the compromise between ensuring robust scientific evidence from the trials and the ethical obligation of granting access to vaccines for the trial participants once the vaccines are approved.

Conditional marketing authorisation

The European Commission grants conditional marketing authorisation (CMA) for the vaccines based on EMA's recommendation and consultation with the EU Member States, under the condition that the benefits of the vaccines outweigh their risks. Regulation (EC) No 507/2006 on CMA for medicinal products came into force in 2006, and since then, the Commission has granted three CMAs to address emergency health situations in 2010 and 2016 (all linked to influenza pandemic vaccines) and 38 CMAs for other cases.⁸⁷ During 2017-2019, EMA provided 12 CMA recommendations for human medicines.⁸⁸ Until November 2022, EMA provided market authorisation, standard or conditional, to seven successful COVID-19 vaccine candidates in a timeframe described in Table 2.

Table 2: Dates of vaccine marketing authorisations

Vaccine producer	Conditional Marketing Authorisation	Standard Marketing Authorisation
Pfizer-BioNTech	21/12/2020	10/10/2022
Moderna	06/01/2021	03/10/2022
AstraZeneca	29/01/2021	31/10/2022
Janssen	11/03/2021	23/01/2023
Novavax	20/12/2021	NA
Valneva	NA	24/06/2022
Sanofi-GSK (Booster)	NA	10/11/2022

Source: EMA [webpage](#).

Note: Some vaccines directly received a standard marketing authorisation (Valneva and Sanofi-GSK's vaccines) while for all others a standard marketing authorisation was issued after a CMA (Moderna, Pfizer-BioNTech, AstraZeneca and Janssen's vaccines). The CMA of Novavax is not yet converted into standard marketing authorisation, though it received annual renewals (as of 23/01/2023).

⁸⁴ Cavaleri M. et al., '[Shaping EU Medicines Regulation in the post COVID-19 era](#)', *The Lancet Regional Health – Europe*, Vol. 9, 2021, 100192.

⁸⁵ Cyranoski D., '[Why emergency COVID-vaccine approvals pose a dilemma for scientists](#)', *Nature*, Vol. 588(7836), 2020, pp. 18-19.

⁸⁶ About vaccine safety, ECDC is responsible for collecting and centralising information of cases of side effects, which are registered nationally through an existing reporting mechanism.

⁸⁷ EMA, [Conditional marketing authorisation: Report on ten years of experience at the European Medicines Agency](#), 2017.

⁸⁸ EMA has recommended three CMAs in [2017](#), one in [2018](#) and eight in [2019](#), according to its annual reports 'Human medicines highlights'.

The CMA is valid for one year, renewable and can be converted into a standard market authorisation. The full clinical data do not need to be available at the time of the authorisation, but the holders of CMAs are obliged to share completed clinical data within defined timelines.⁸⁹ The conversion to full authorisation might reinforce citizens' confidence in the quality, safety, and efficacy of the vaccines, thereby increasing vaccine acceptance and vaccine uptake.⁹⁰ EMA issued a standard market authorisation to Moderna's vaccine (Spikevax) on 3 October 2022, to Pfizer-BioNTech's vaccine (Comirnaty) on 10 October 2022, to AstraZeneca's vaccine (Vaxzevria) on 31 October 2022, to Sanofi-GSK's vaccine (Vidprevtyn, as booster only) on 10 November 2022, and to Janssen's vaccine (Jcovden) on 23 January 2023.⁹¹

Compared to an Emergency Use Authorisation (EUA), the CMA remains a formal authorisation, respecting the essential elements of a standard authorisation route. In the case of COVID-19 vaccines, the majority of post-approval elements that need to be monitored are related to the pharmaceutical quality of the vaccine in light of the manufacturing scale-up.⁹² The CMA route has contributed to the remarkable reduction in deaths and hospitalisations in the EU.⁹³

EU authorisation in comparison to other countries

All in all, the use of regulatory flexibility has expedited the regulatory approval of COVID-19 vaccines compared to non-COVID-19 vaccines in the EU. While usually the average timeline of developing a medicinal product from phase 1 clinical trials to approval is around ten years, this process took less than one year for many COVID-19 vaccines.^{94 95}

EMA's fast-track review of the vaccines has contributed to this achievement. EMA has provided its scientific advice within 20 days, compared to 40-70 days under regular conditions.

The rolling review has reduced the timeline leading up to and including the conditional marketing authorisation.⁹⁶ Altogether, these efforts have led to record time in which the vaccines were authorised in the EU as shown in Figure 4: 21 days between Pfizer-BioNTech's application and the EU's issuance of the CMA, 36 days for Moderna, 17 days for AstraZeneca and 23 days for Janssen, compared to the standard EU's review timeline of 210 working days.⁹⁷

⁸⁹ For more details on EMA initiatives for acceleration of development support and evaluation procedures for COVID-19 treatments and vaccines, see EMA [Webpage](#) on COVID-19 guidance: evaluation and marketing authorisation.

⁹⁰ Abbas N. and Babar Z.U.B., 'Marketing Authorisation of COVID-19 Vaccines across UK, EU, and the US: Fact-Checking and the Implications for Future Research', *Journal of Pharmaceutical Policy and Practice*, Vol. 14(1), 2021, p. 110.

⁹¹ See EMA, [Webpage](#) COVID-19 vaccines: authorised (Accessed 23 January 2023).

⁹² EMA, [Press release](#) on recommendation for standard marketing authorisations for Comirnaty and Spikevax COVID-19 vaccines, 16 September 2022.

⁹³ Cavaleri M. et al., 'The European Medicines Agency's EU conditional marketing authorisations for COVID-19 vaccines', *The Lancet*, Vol. 397(10272), 2021, pp. 355–357.

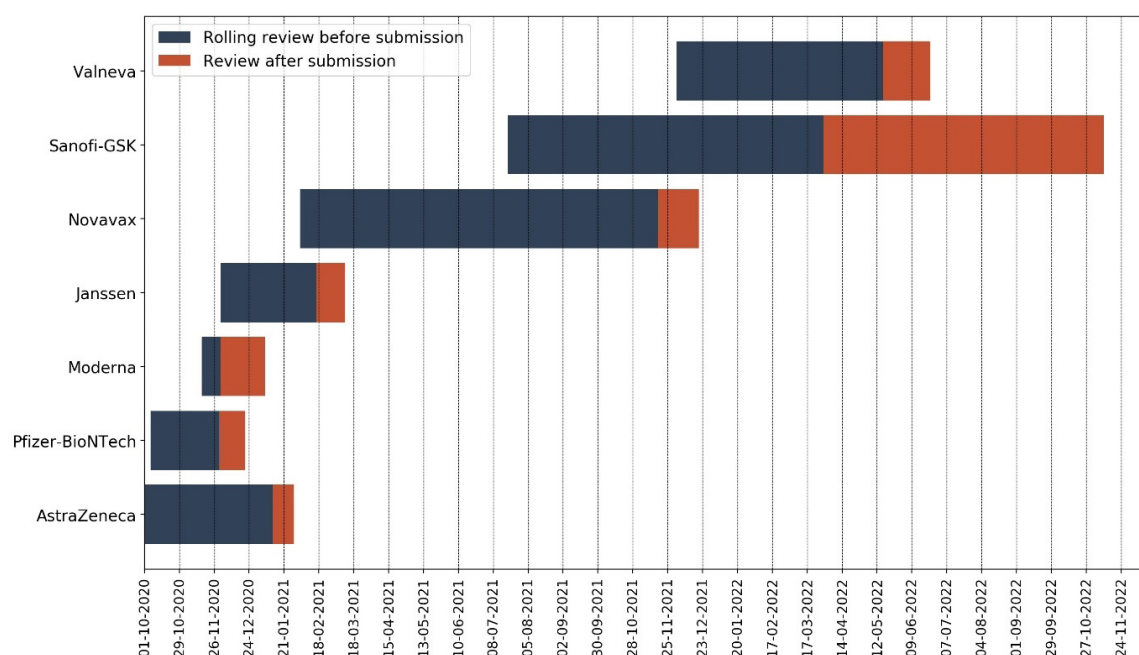
⁹⁴ Marinus R. et al., 'Rolling reviews during COVID-19: The European Union experience in a global context', *Clinical Therapeutics*, Vol. 44(3), 2022, pp. 352–363.

⁹⁵ Cavaleri M. et al., 'The European Medicines Agency's EU conditional marketing authorisations for COVID-19 vaccines', *The Lancet*, Vol. 397(10272), 2021, pp. 355–357.

⁹⁶ Marinus R. et al., 'Rolling reviews during COVID-19: The European Union experience in a global context', *Clinical Therapeutics*, Vol. 44(3), 2022, pp. 352–363.

⁹⁷ EMA, [Webpage](#) The evaluation of medicines, step-by-step (Accessed 31 October 2022).

Figure 4: Timeline of COVID-19 vaccines authorisations in the EU

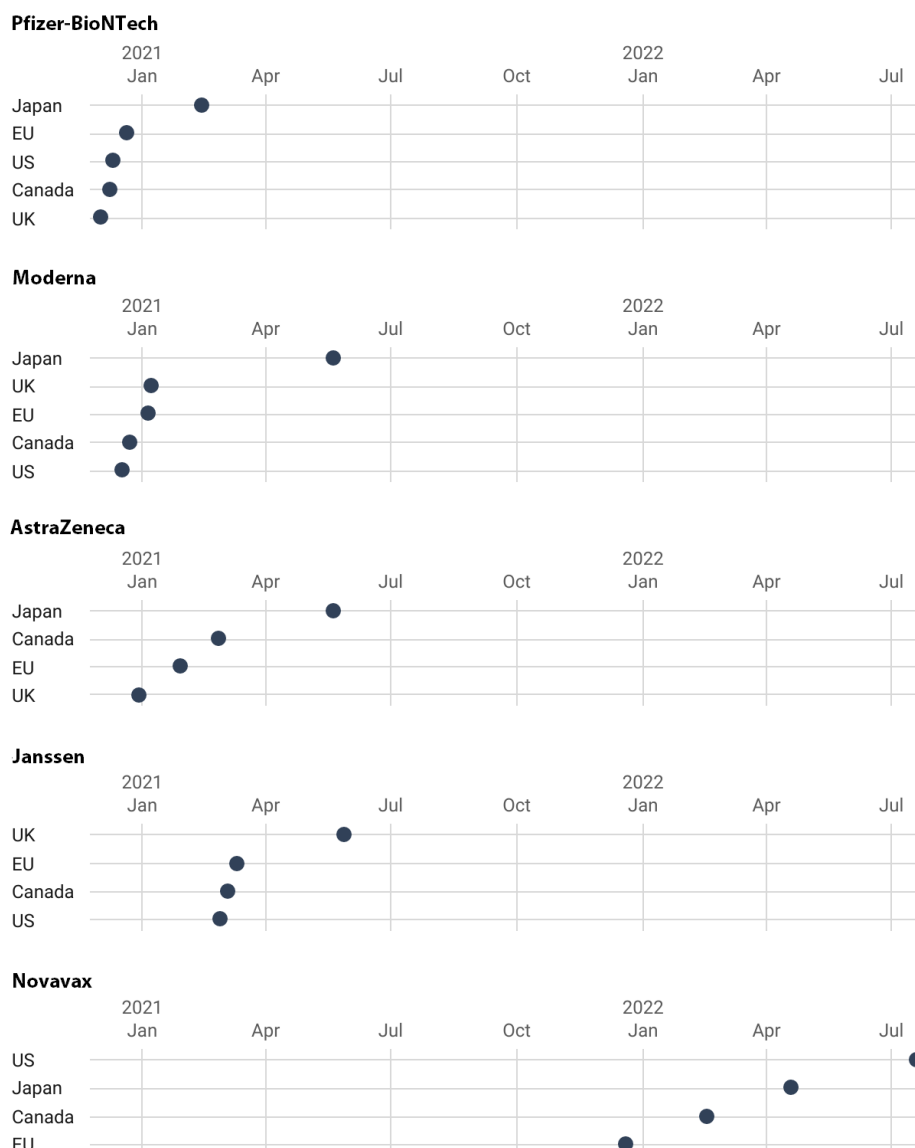


Source: Compiled by the authors.

Note: This Gantt chart shows the timeline of COVID-19 vaccine authorisations in the EU. The chart includes all seven COVID-19 vaccines authorised in the EU to date. The process consisted of two steps; namely, a rolling review before formal submission and a review after formal submission. The first COVID-19 vaccine that began the rolling review process is AstraZeneca, on 1 October 2020, and Pfizer-BioNTech is the first COVID-19 vaccine that received the conditional marketing authorisation, on 21 December 2020. Two vaccines (Valneva and Sanofi-GSK) were directly given a Standard Marketing Authorisation and the others were first given a Conditional Marketing Authorisation (see Table 2). The average time from the start of the rolling review to the issue of a marketing authorisation is 193 days. Considering the first four authorised COVID-19 vaccines, the average time is 87 days. Each vertical gridline refers to another four weeks' (28 days) time.

However, comparing authorisation speed between EU and other countries systematically is difficult. The main reason is that countries followed different authorisation procedures and the beginning of the review process is hard to pin down. As a result, Figure 5 compares only the date of the issue of authorisation for the sake of an easier interpretation.

Figure 5: Dates of marketing authorisations of COVID-19 vaccines: international comparison



Source: Compiled by the authors on the basis of information obtained from [EMA](#) (EU), [PMDA](#) (Japan), [FDA](#) (US), [Health Canada](#), [UK government](#).

Note: This chart compares the dates of (emergency or conditional) marketing authorisation of COVID-19 vaccines across the EU, the US, the UK, Canada, and Japan, which include the five vaccines granted conditional marketing authorisation in the EU. Only Pfizer-BioNTech's vaccine has been approved by all five countries/region. The COVID-19 vaccines by Valneva and Sanofi-GSK are only authorised in the EU as of 10 November 2022 and are excluded from the graph for brevity. This graph is designed using Datawrapper.

The EU's regulatory flexibility aligns with the global trend in authorising COVID-19 vaccines. Other countries in the world that apply a rolling review for COVID-19 vaccine include the US, the UK, Canada, Brazil, Australia, Japan, China, and Singapore.⁹⁸ The UK was the first country in the world to authorise a COVID-19 vaccine (Pfizer-BioNTech) on 2 December 2020, using the rolling review

⁹⁸ Marinus R. et al., 'Rolling reviews during COVID-19: The European Union experience in a global context', *Clinical Therapeutics*, Vol. 44(3), 2022, pp. 352-363.

process and the temporary authorisation for emergency use to approve the vaccines.⁹⁹ The US relies on the procedure of EUA to approve COVID-19 vaccines, and the US Food and Drug Administration (FDA)'s requirement that vaccine developers could apply for EUA only when at least 50% of recipients have completed a two-month follow-up after the administration of vaccines. FDA later converted the EUA of the Pfizer-BioNTech vaccine into full authorisation on 23 August 2021.

Compared to the UK and the US, the EU's scientific evaluation and granting of CMAs of COVID-19 vaccines started later and took more time in some cases. One reason that EMA stresses is the need to ensure the legality of the evaluation process based on the existing conditional marketing authorisation mechanism. Another factor that made a difference in the authorisation dates between the EU and other countries is the date when vaccine developers submitted their application for the approval. In some cases, vaccine developers submitted their application to EMA some weeks later than in the other countries (e.g. the case of Pfizer-BioNTech and Janssen's vaccines). The EU Member States could have opted for faster use of the vaccines through the emergency use at national level but have eventually chosen a more robust, scientific and unified EU-approach relying on the EU's CMA process.¹⁰⁰

The EU, UK, and US have managed to comply with the standards for the vaccines' quality, efficacy and safety when accelerating the authorisation time. To put this in a wider context, the case for accelerated vaccine authorisation was less well established for Russia and China.¹⁰¹ These two countries authorised and used their COVID-19 vaccines without data from phase 3 trials. It was also unclear whether their authorisation took into account the benefit-risk balance recommended by the WHO's Emergency Use Listing (EUL) procedure.^{102,103} The lack of scientific evidence and the ambiguity in the authorisation criteria drew widespread criticism about the safety and efficacy of these vaccines.¹⁰⁴

Transparency: clinical trial data

The European Parliament, in its Resolution of 17 April 2020, highlighted the need to share data and research results on an open science data basis across the scientific community, and emphasised that any public-supported research should 'stay in the public domain'.¹⁰⁵ In its Resolution of 21 October 2021, Parliament raised the concern that most pharmaceutical firms involved in developing COVID-19 vaccines had not published their communicable clinical trial data.¹⁰⁶ Parliament called for the publication of clinical trial protocols and results from vaccine producers. In their joint statement

⁹⁹ Abbas N. and Babar Z.U.B., '[Marketing Authorisation of COVID-19 Vaccines across UK, EU, and the US: Fact-Checking and the Implications for Future Research](#)', *Journal of Pharmaceutical Policy and Practice*, Vol. 14(1), 2021, p. 110.

¹⁰⁰ Cavaleri M. et al., '[Shaping EU Medicines Regulation in the post COVID-19 era](#)', *The Lancet Regional Health – Europe*, Vol. 9(100192), 2021, p. 100192.

¹⁰¹ Abbas N. and Babar Z.U.B., '[Marketing Authorisation of COVID-19 Vaccines across UK, EU, and the US: Fact-Checking and the Implications for Future Research](#)', *Journal of Pharmaceutical Policy and Practice*, Vol. 14(1), 2021, p. 110.

¹⁰² Smith M.J. et al., '[Emergency use authorisation for COVID-19 vaccines: Lessons from Ebola](#)', *The Lancet*, Vol. 396(10264), 2020, pp. 1707-1709.

¹⁰³ Back in 2013-2016, in response to the Ebola outbreak, the WHO developed an Emergency Use Assessment and Listing (EUAL) procedure to expedite the authorisation of vaccines during public health emergency, and later updated the EUAL with the Emergency Use Listing (EUL) procedure in January 2020. The EUL suggests that regulatory authorities make their authorisation decision based on the quality, safety, and performance data, and a risk-benefit analysis of the vaccines.

¹⁰⁴ Smith M.J. et al., '[Emergency use authorisation for COVID-19 vaccines: Lessons from Ebola](#)', *The Lancet*, Vol. 396(10264), 2020, pp. 1707-1709.

¹⁰⁵ European Parliament, [Resolution](#) of 17 April 2020 on EU coordinated action to combat the COVID-19 pandemic and its consequences (2020/2616(RSP)).

¹⁰⁶ European Parliament, [Resolution](#) of 21 October 2021 on EU transparency in the development, purchase and distribution of COVID-19 vaccines (2021/2678(RSP)).

in September 2020, the aforementioned six associations also asked EU regulators to ensure independent, robust, and science-based assessment of the vaccines, and to publish the clinical trial results of the vaccines procured under the EU's joint procurement mechanism.¹⁰⁷

In response to these concerns, EMA has made a remarkable effort to disclose the clinical trial data of COVID-19 vaccines applied for approval in the EU.¹⁰⁸ EMA is one of the two only health authorities in the world which publishes the Clinical Study Reports (the complete, structured report of clinical studies prepared for the regulators), the second one being the Canadian authority (Transparency International, 2021). Despite the general suspension of publication of clinical trials data (due to its move of office from London to Amsterdam during March 2019–January 2020 following Brexit¹⁰⁹), EMA has taken exceptional measures to publish clinical trials data related to COVID-19 medicinal products.¹¹⁰ In addition, EMA's Network Strategy to 2025 also recognises the importance of communication and transparency.¹¹¹ The EU's entry into application of the Clinical Trials Regulation in January 2022 (replacing the Clinical Trials Directive (EC) No. 2001/20/EC) marks another progress towards a more transparent regulatory system (HAI, 2021).¹¹² ¹¹³ Enhancing information-sharing, improving collective decision-making and increasing transparency on clinical trials are among the key benefits of this regulation.¹¹⁴ EMA's transparency during the COVID-19 pandemic was welcomed by the European Parliament and sets high standards for transparency worldwide (Transparency International, 2021).¹¹⁵

The publication of individual participant data is critical as these data allow for detection of biases and patterns of adverse events which occurred during trials, thus ensuring the effectiveness and safety of the vaccines.¹¹⁶ However, there is a high level of uncertainty about the publication of individual-level data by COVID-19 vaccine companies. Based on their statements in trials documents, most vaccine developers would take months, if not years, after the completion of the vaccine studies to publish the individual participant data. Several producers, including Moderna, communicated vague messages around whether they would pledge to disclose this data, whereas others expect to do so but within expanded time frames.¹¹⁷ For example, according to its trial protocol,¹¹⁸ Pfizer will make patient-level data from trials available 24 months after the study's completion. As Pfizer's estimated study completion date is 8 February 2024,¹¹⁹ one can expect that

¹⁰⁷ European Public Health Alliance, [Transparency is needed to reap the full benefits of the EU's investment in its Vaccines Strategy, say health NGOs](#), 18 September 2020.

¹⁰⁸ EMA, [Webpage](#) Clinical data publication (Accessed 31 October 2022).

¹⁰⁹ EMA, [Key achievements in 2020](#).

¹¹⁰ EMA, [Webpage](#) Transparency: exceptional measures for COVID-19 medicines (Accessed 31 October 2022).

¹¹¹ EMA, [Webpage](#) European medicines agencies network strategy (Accessed 31 October 2022).

¹¹² [Regulation \(EU\) No 536/2014](#) of 16 April 2014 on clinical trials on medicinal products for human use.

¹¹³ The Clinical Trials Regulation entered into force in 2014 but has only applied since 31 January 2022. Its entry into application followed the Commission's confirmation that the Clinical Trials Information System (CTIS) – the EU portal and database for submission, assessment and supervision of clinical trials – has met the specifications for functionality stipulated in Article 82(2) of the Regulation (EU) No 536/2014. More information in the Official Journal of the European Union, [Volume 64](#) of 31 July 2021.

¹¹⁴ EMA, [Webpage](#) Clinical Trial Regulation. Webpage (Accessed 31 October 2022).

¹¹⁵ European Parliament, [Resolution](#) of 21 October 2021 on EU transparency in the development, purchase and distribution of COVID-19 vaccines (2021/2678(RSP)).

¹¹⁶ Tanveer S. et al., '[Transparency of COVID-19 vaccine trials: decisions without data](#)', *BMJ Evidence-Based Medicine*, Vol. 27(4), 2021, pp. 199–205.

¹¹⁷ Ibid.

¹¹⁸ Pfizer, A Phase 1/2 Study to Describe the Safety, Tolerability, Immunogenicity, and Potential Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Adults, [Protocol](#), 15 April 2020 (Accessed 31 October 2022).

¹¹⁹ ClinicalTrials.gov, [Study](#) to Describe the Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Individuals. Data as of 31 August 2022.

its patient-level data will only be available in February 2026.¹²⁰ In the COVI public hearing on 10 October 2022, Members raised questions about the availability of data showing whether COVID-19 vaccines have stalled transmission rates of the virus and how long the effects lasted. Most of the pharmaceutical companies attending the hearing were unable to give precise answers to these questions, with AstraZeneca stating that 'there is enough real-life data showing all vaccines dramatically impact the transmission of the virus.'¹²¹

The sharing of raw data is a common challenge across various scientific fields. Open science is supported by the EU (through its Open Science policy) and by international institutions such as the G7's Open Science Working Group, the OECD's Enhanced Access to Data and Models, and the African Research Cloud.^{122 123} However, the realisation of open science still faces challenges, such as the costs of complying with data protection rules, a lack of proper incentives and rewards for researchers, and the impossibility to publish the data due to ongoing competition between different experiments.¹²⁴

Furthermore, the faster authorisation process for COVID-19 vaccines, lacking a sound communication strategy, caused substantial vaccine hesitancy in the EU Member States.¹²⁵ This is discussed in the section below on public opinion (section 2.2.3.). Annex IV provides a brief summary of data sources of vaccine development, funding, procurement, and delivery.

2.2. National vaccination strategies and coverage

After the CMA and joint procurement of COVID-19 vaccines, another hurdle for Member States and the EU has been to roll out the vaccines and to secure broad vaccination uptake. Vaccination strategy implementation is a three-way interaction involving the EU, national (and regional) governments and citizens. EMA authorises the vaccines at the EU level and gives recommendations for the administration of doses and for different groups of people. National governments, taking the recommendations by the ECDC and EMA into consideration, mobilise resources to roll the vaccines out to their populations. Finally, the citizens decide whether or not to get vaccinated against the virus. Many different factors affect the vaccination coverage in a country, and the EU has not had much influence on vaccination uptake.

This section presents a descriptive comparative study on national vaccination strategies and coverage, before explaining determinants behind vaccination performance.

2.2.1. National vaccination strategies

The Commission published a Communication on preparedness for COVID-19 vaccination strategies and vaccine deployment on 15 October 2020, ahead of the start of the vaccination process in the EU.¹²⁶ This communication includes recommendations and proposed actions for 'effective'

¹²⁰ Tanveer S. et al., '[Transparency of COVID-19 vaccine trials: decisions without data](#)', *BMJ Evidence-Based Medicine*, Vol. 27(4), 2021, pp. 199-205.

¹²¹ See recordings of the [COVI hearing](#) of 10 October 2022.

¹²² Burgelman J.C. et al., '[Open science, open data, and open scholarship: European policies to make science fit for the twenty-first century](#)', *Frontiers in Big Data*, Vol.2(43), 2019.

¹²³ It should be however noted that Open Science does not always imply the publication of all research data, e.g. in case the researchers apply for a patent.

¹²⁴ Burgelman J.C. et al., '[Open science, open data, and open scholarship: European policies to make science fit for the twenty-first century](#)', *Frontiers in Big Data*, Vol.2(43), 2019.

¹²⁵ Kassianos G. et al., '[Addressing COVID-19 Vaccine Hesitancy](#)', *Drugs in Context*, Vol. 11, 2022, pp. 1-19.

¹²⁶ European Commission, Preparedness for COVID-19 vaccination strategies and vaccine deployment, [COM\(2020\) 680](#), 15 October 2020.

COVID-19 vaccination strategies: for instance, regarding priority groups or preparedness and monitoring plans. Since the onset of the pandemic, other EU institutions and agencies, notably the ECDC and EMA, have also provided recommendations for Member States to design their own vaccination strategies. For instance, the ECDC has provided scientific evidence and recommendations, through the publication of reports, notably on the use of booster doses¹²⁷ and vaccination of children.¹²⁸ Furthermore, EMA has published a Summary of Product Characteristics (SmPC) for each vaccine product, including information of posology along with recommendations for the timing of administration. Yet, the ECDC guidelines are officially designed as 'options for response' or 'non-binding recommendations' that Member States are free to adopt or not, and the Commission refers to its vaccines strategy as a 'reference point' for Member States to formulate their national vaccination strategies.¹²⁹

The design of national vaccination strategies remains a national competence, and Member States have adapted the EU guidelines to their own epidemiological, institutional, economic, social, cultural, and historical context. While it remains clear that EU guidelines are not binding, some Member States have nevertheless found them challenging to follow. Recommendations were released after short or non-existent consultations with Member States. For instance, one Member State representative expressed in an interview that, sometimes, EU recommendations were made public before national experts had the chance to read them. Consequently, national experts faced difficulties in communicating to their citizens that the national recommendations could differ because they were more tailored to the epidemic situation, to the country's age profile, etc. Another Member State representative argued that the EU recommendations were deemed to be less relevant than the national public health authorities' ones. Yet, for small Member States, the interviews conducted for the purpose of this study revealed that these EU-level recommendations were very valuable, as they have fewer national scientific advisory capacities.

In the end, national vaccination strategies across EU27 varied regarding, among other things, the marketing of different vaccine products, the recommendations for certain age groups and for additional doses, and the implementation of vaccine mandates. This section analyses some of these elements and provides an overview of different strategic choices and their potential consequences on vaccine uptake in the EU.

Vaccines marketed and used

Most of the EU27 Member States have only marketed the vaccines that have been authorised by EMA after submission of a single market authorisation application by pharmaceutical companies. In January 2021, Hungary became the first EU Member State to buy the Russian Sputnik V and Chinese Sinopharm vaccines, following a national approval procedure conducted by the Hungarian Institute of Pharmacy and Nutrition. At the end of March 2021, Hungary also granted an emergency use license to the Convidecia vaccine from Chinese enterprise CanSino, which was however not included in its vaccination plan in September 2022.¹³⁰ Another Member State, Slovakia, has used the Sputnik V vaccine in its vaccination programme. Procurement of the Russian vaccine in Slovakia was highly controversial from the outset and triggered a political crisis in spring 2021 which led to the resignation of then-Prime Minister Igor Matovič. Though Slovakia's drug agency did not authorise the Sputnik V vaccine, the government eventually allowed its use for willing individuals on 26 May 2021. Yet, public interest was low and in the end the use of the Sputnik V vaccine in Slovakia remained marginal, with less than 20,000 doses administered between June and August 2021 (by

¹²⁷ ECDC, [Interim public health considerations for the provision of additional COVID-19 vaccine doses: Guidance](#), 2021.

¹²⁸ ECDC, [Interim public health considerations for COVID-19 vaccination of children aged 5-11 years: Guidance](#), 2021.

¹²⁹ European Commission, [Webpage](#) EU Vaccines Strategy (Accessed 6 December 2022).

¹³⁰ Euractiv, [Hungary approves CanSino Chinese Jab](#), 23 March 2021.

which time approximately 4,000,000 COVID-19 vaccine doses had been administered in Slovakia overall), and four-fifths of the 200,000 purchased doses were sold back to Russia.¹³¹

Not all EMA-authorised vaccines are subsequently used by Member States in their vaccination programmes. In April 2022, only six of the 27 Member States were following EMA's SmPC for all vaccines (Bulgaria, Hungary, Latvia, Lithuania, Poland, Romania), while 19 others recommended specific vaccine products for certain target and/or age groups.¹³² These recommendations for instance relate to the use of AstraZeneca's COVID-19 vaccine whose inclusion in vaccination programmes has been suspended as a precaution in Denmark, Finland, Malta, the Netherlands, and Sweden after blood clot reports. Other countries have only chosen to limit its use to older recipients: in Germany, Italy, and Spain for instance, AstraZeneca's vaccine is only recommended for individuals above 60 years old. Similarly, the Janssen's vaccine has been suspended from vaccination programmes in Denmark, Slovenia, and Sweden because of coagulation disorder reports, and is recommended for older groups of the population in some Member States (e.g. Finland, Germany, Italy). The use of Moderna's vaccine also varies across countries, with some of them recommending it only for individuals above 30 years old (e.g. Austria, France, Germany) because of an elevated but still rare risk in younger people to get myocarditis, an inflammatory heart disease.¹³³

Recommendations for vaccination

Beyond the use of certain COVID-19 vaccine products for certain groups of the population, Member States' national vaccination strategies differ in their schedules for priority groups, recommendations for children vaccination, recommendations for the inoculation of booster doses, and recommendations for the vaccination of previously infected individuals.

Priority groups

In late 2020, the ECDC published two reports to provide the EU27 with information and evidence regarding how the prioritisation of certain population groups may help achieve the objective of vaccination strategies.^{134 135} In October 2020, the WHO's Strategic Advisory Group of Experts on Immunization (SAGE) also released a roadmap for prioritising uses of COVID-19 vaccines in the context of limited supply.¹³⁶ Another ECDC report published in April 2021 identifies different goals for vaccination campaigns (reduction of pressure on the healthcare system, reduction of overall COVID-19 severity and mortality, reopening of society, and disease elimination), which in turn imply different prioritisation strategies.¹³⁷

Based on these guidelines and considering the characteristics of their population and other national factors, Member States have introduced their vaccination schedules from the end of 2020 with the prioritisation of certain vulnerable or key groups of the population. Overall, the priority groups identified by Member States since the beginning of the pandemic have been similar, including residents in long-term care facilities, older people (with different categorisation, e.g. over 85 or 65 years old), healthcare professionals and caregivers, people with chronic diseases or other

¹³¹ See Reuters, [Slovakia sells most Sputnik V vaccine doses back to Russia](#), 2 July 2021.

¹³² Data is missing for Czechia and Slovakia, see ECDC, [Overview of the implementation of COVID-19 vaccination strategies and vaccine deployment plans in the EU/EEA: Technical report](#), 2022.

¹³³ Information about the recommendations of specific vaccine products for different age groups is retrieved from the ECDC, which last published data about recommendations of specific COVID-19 vaccine products to some target or age groups in April 2022 (see ECDC, [Overview of the implementation of COVID-19 vaccination strategies and vaccine deployment plans in the EU/EEA: Technical report](#), 2022). The validity of this information was verified with additional research in December 2022.

¹³⁴ ECDC, [Key aspects regarding the introduction and prioritisation of COVID-19 vaccination in the EU/EEA and the UK: Guidance](#), 26 October 2020.

¹³⁵ ECDC, [COVID-19 vaccination and prioritisation strategies in the EU/EEA: Guidance](#), 2020.

¹³⁶ WHO, [WHO SAGE Roadmap for prioritizing uses of COVID-19 vaccines](#), 2022.

¹³⁷ ECDC, [Objectives of vaccination strategies against COVID-19: Guidance](#), 2021.

comorbidities, and people undertaking critical professions for the functioning of the society and public services. Some Member States also included the relatives of people at high risk into priority groups.

In a comparative analysis of the prioritisation strategies in Israel and European countries, Cylus, Panteli, and van Ginneken (2021) underline that some Member States have first prioritised the vaccination of healthcare workers and/or residents of care homes before any age group of the general population, in line with the SAGE guidance. In Slovakia for instance, health workers, medical students, social service home staff and other 'key' workers have been offered the vaccine in the first round, before individuals above 65 years old and people with chronic diseases were offered it in a second round. The authors also underscore that the age threshold for vaccine prioritisation largely varied across EU countries: while Austria and Germany for instance prioritised individuals of 80 years old and above for primary vaccination (and then moved incrementally to younger age groups), Portugal started with vaccinating all people aged 50 years and older who had a chronic condition.

Vaccination of children

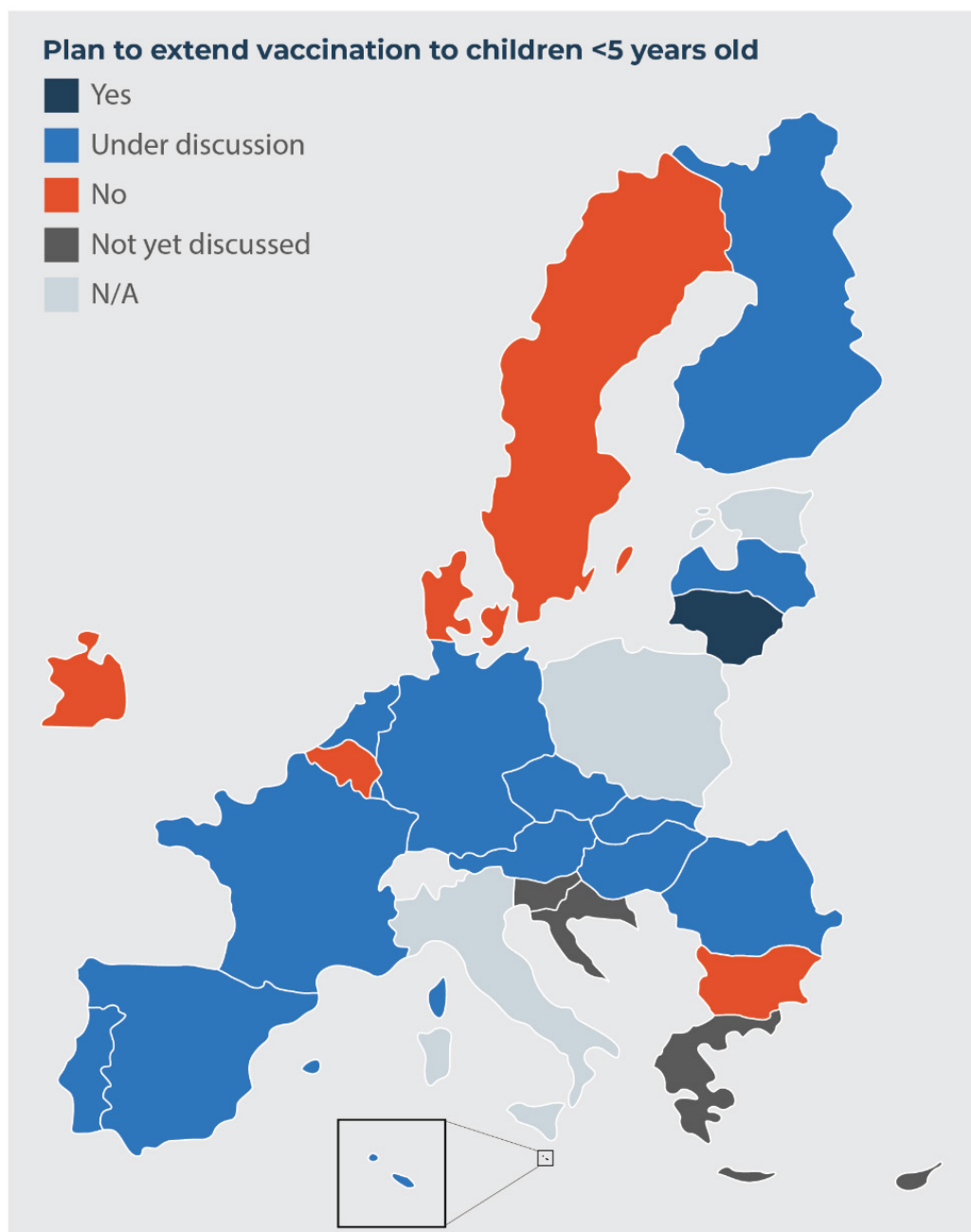
While the vaccination of children (5-17 years old) has been advised by EMA, Member States slightly differ in their recommendations regarding this age group. All 27 Member States were recommending vaccination for all between 12-17 years old in September 2022.¹³⁸ For children aged 5-11 years old, 26 Member States were recommending vaccination for all children, and Sweden only recommended vaccination for 5-11-year-olds with risk factors. In Germany, 5-11-year-olds at risk were recommended a two-dose primary series, while 5-11-year-olds with no underlying disease were only given one dose.

Regarding the vaccination of young children aged between 6 months and 4 years, EMA has started evaluating the use of COVID-19 vaccines in July 2022 and recommended the approval of Pfizer-BioNTech's vaccine and Moderna's vaccine for children from 6 months of age on 19 October 2022. According to an ECDC report published on 8 September 2022, which included a survey relating to the vaccination of children younger than 5 years old, the majority of Member States (Austria, Czechia, Finland, France, Germany, Hungary, Latvia, Luxembourg, the Netherlands, Portugal, Romania, Slovakia, Spain) were at that time discussing an expansion of vaccination to this age category if EMA authorised it (see Figure 6).¹³⁹ Two countries (Lithuania and Malta) were already planning to extend vaccination to this group, while five expressed that they were not planning to do so (Belgium, Bulgaria, Denmark, Ireland, Sweden).

¹³⁸ ECDC, [Overview of the implementation of COVID-19 vaccination strategies and deployment plans in the EU/EEA: Technical report](#), 2022.

¹³⁹ Ibid.

Figure 6: Plans to extend vaccination to children under 5 years old (September 2022)



Data source: [ECDC](#) (September 2022).

Note: N/A refers to countries for which there is no data reported in the ECDC report.

Booster doses

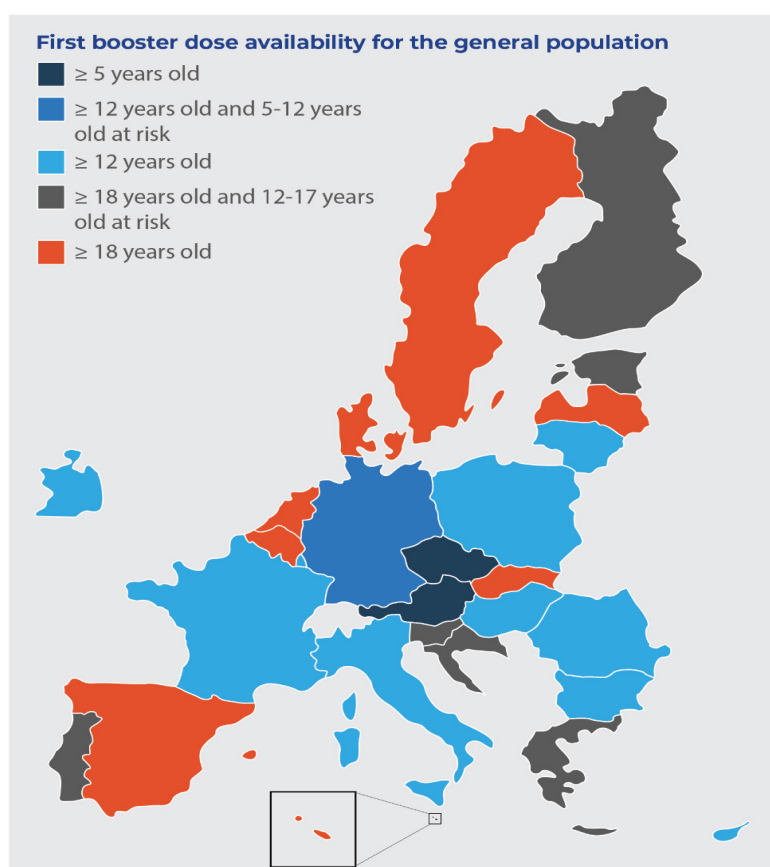
The question of administering third and fourth doses arose in the EU when evidence suggested that the immunisation levels of vaccinated individuals would significantly decrease over time. Recommendations differed for immunocompromised individuals (i.e. those whose immune system is weakened or impaired because of medication or illness), for whom the primary course of vaccination was extended in all Member States to three doses, and immunocompetent individuals (i.e. people with normal capacity to develop an immune response), where the primary course remained two doses. 'Boosters' are understood as doses administered additionally to the primary

vaccination series, and therefore represent third and fourth doses (and so on) of vaccine for immunocompetent individuals, and fourth and fifth doses for people with a weakened immune system.

In September 2022, 24 Member States recommended a first booster dose for immunocompromised individuals following the extended three-dose primary course (fourth dose) - the exceptions being Czechia, Estonia, and Romania.¹⁴⁰ Ten Member States also recommended a second booster for immunocompromised individuals, i.e. a fifth dose. This was recommended only for severe cases in some Member States (e.g. Lithuania) or for adults over 18 years old in others (Belgium, the Netherlands, Sweden).

For the general population, all Member States recommended the administration of a first booster dose for individuals of 18 years old and above, on top of the usual two-dose primary course. As can be seen in Figure 7, most Member States went beyond this by recommending a first booster dose for certain categories of children. In Austria and Czechia for instance, children from 5 years old could receive a booster dose, while this was the case for all children from 12 years and those aged 5-11 in risk groups in Germany.

Figure 7: First booster availability for the general population (September 2022)

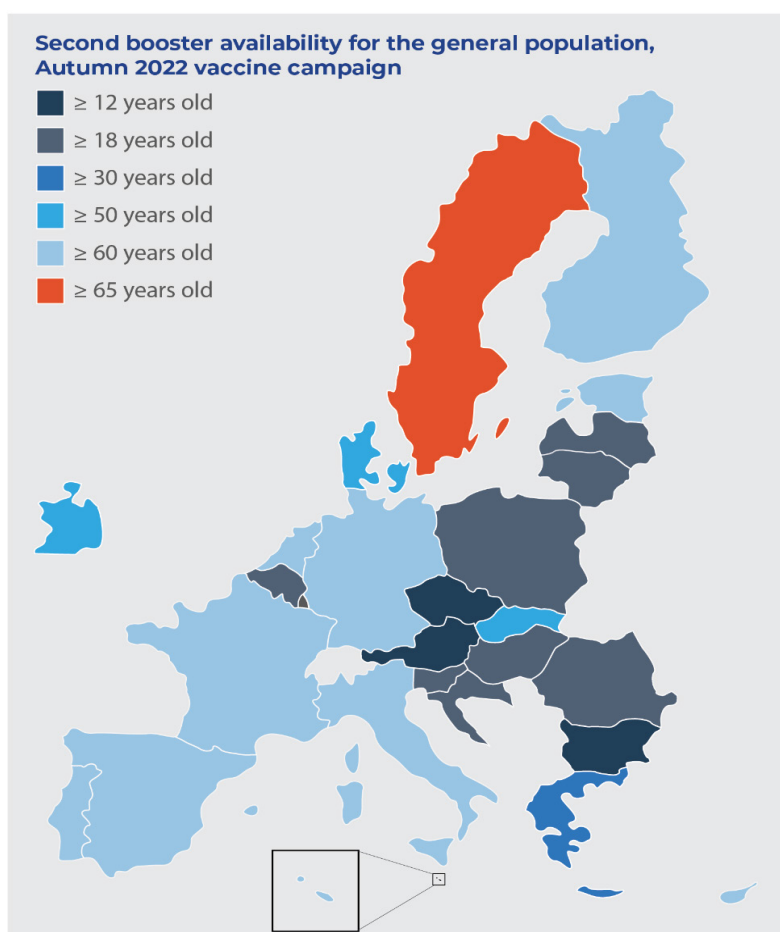


Data source: [ECDC](#) (September 2022) and additional research.

¹⁴⁰ Data for booster doses are retrieved from ECDC, [Overview of the implementation of COVID-19 vaccination strategies and deployment plans in the EU/EEA: Technical report](#), 2022, and verified with additional research.

The recommendations regarding a second booster dose for the general population were evolving rapidly in the autumn of 2022, notably because of uncertainty regarding the evolution of the pandemic given the arrival of winter and the appearance of new variants. Figure 8 displays the state of play in September 2022, as reported by the ECDC in its latest vaccination strategy and deployment report¹⁴¹ and complemented by a desk review of official sources. In September 2022, all Member States were recommending a second booster dose for certain categories of the population. Many Member States had extended the possibility to receive a second booster dose to the broader population: from everyone above 18 years old in Belgium, Croatia, Hungary, Latvia, Lithuania, Poland, Romania, and Slovenia, to everyone above 12 years old in Austria, Bulgaria, and Czechia. Some countries were making the second booster dose available only for older categories of individuals: from above 65 years old in Sweden and 60 years old in Cyprus, Estonia, Finland, France, Germany, Italy, Luxembourg, Malta, the Netherlands, Portugal, and Spain, to above 50 years old in Denmark and Ireland, and 30 years old in Hungary. In these countries, a second booster dose was additionally recommended to different vulnerable groups such as younger age groups at risk, residents of Long-Term Care Facilities (LTCFs), healthcare professionals, pregnant women, relatives of people at risk, or people receiving home care.

Figure 8: Second booster availability for the general population (September 2022)



Data source: [ECDC](#) (September 2022) and additional research.

¹⁴¹ ECDC, [Overview of the implementation of COVID-19 vaccination strategies and deployment plans in the EU/EEA: Technical report](#), 2022.

Mandatory vaccination

Efforts to increase the vaccination uptake in some Member States – as well as EU-wide – have led to discussions around the need to impose mandatory vaccination. On 1 December 2021, Commission President Ursula von der Leyen stated that it was time for the EU to 'think about mandatory vaccination'.¹⁴² Yet, with the declining severity of the new variants such as Omicron, the justification for mandatory vaccination partly lost momentum, as highlighted by European Economy Commissioner Paolo Gentiloni in February 2022.¹⁴³

Up to September 2022, some Member States had imposed a vaccination obligation for certain age groups (for all adults in Austria¹⁴⁴, over 60 years old in Greece and over 50 years old in Italy), and others have made vaccination compulsory for certain types of workers (e.g. healthcare professionals, caregivers, firefighters, public sector employees, etc.) to exercise their professional activities (France, Germany, Greece, Hungary, Italy, Latvia, Poland). In Estonia, employers were given the power to decide for themselves whether to impose a scheme of mandatory vaccination for their employees. These vaccination mandates are summarised below in Figure 9 and Table 3.¹⁴⁵ The sanctions levelled at people who did not respect the mandates mainly consisted of suspension from work (unpaid leave) and no possibility of recruitment for professionals, and resulted in an administrative fine of 100 € in Italy and 100 € per month in Greece for the mandates concerning specific age groups.

It is interesting to note that the countries where vaccination mandates have been introduced were not necessarily the ones where public support for making COVID-19 vaccination compulsory was the highest. Public support for mandatory vaccination in Europe was highest in some Southern European countries (Italy, Spain, Portugal), as well as in Sweden, Finland and Germany, according to the survey Flash Eurobarometer 505 conducted in February 2022.¹⁴⁶ This public support is very much dependent on vaccine acceptance itself: the results from this survey showed that 67% of people supportive of vaccination were also in support of a vaccination mandate, while this is the case for only 15% of individuals demonstrating hesitancy towards vaccination, and 3% of people expressing that they do not want to receive the vaccine.

¹⁴² European Commission, [Commission reiterates calls to step up vaccination, rapid deployment of boosters, vigilance and rapid reaction to Omicron variant](#), 1 December 2021.

¹⁴³ See [COVID digest: Vaccine orders no longer needed – EU official](#), Deutsche Welle (DW), 13 February 2022.

¹⁴⁴ The vaccination mandate in Austria was eventually terminated. More information can be found below in Box 2.

¹⁴⁵ Note: Data about whether these mandatory requirements are still in place in these countries were not retrieved in the present study. This table rather outlines which countries have at some point during the pandemic included any type of vaccination mandate. While the mandate was terminated in Austria, as explained in Box 2, it is for instance set to cease applying on 1 January 2023 in Germany, where a discussion on a potential extension is currently ongoing. In Italy, the mandate was also still in place in autumn 2022 and an extension was set to be discussed in Parliament.

¹⁴⁶ European Commission, [Flash Eurobarometer 505 on Attitudes on vaccination against COVID-19](#), March 2022 (2692 / FL505).

Figure 9: Vaccination mandates since the beginning of the pandemic



Data source: ECPRD¹⁴⁷ and the [EPRS briefing](#) by Diaz Crego et al. (2022).¹⁴⁸

¹⁴⁷ Data from the network of the European Centre for Parliamentary Research and Documentation (ECPRD) have been provided by the EPRS solely for the purpose of this study.

¹⁴⁸ Diaz Crego M. et al., [Legal issues surrounding compulsory Covid-19 vaccination](#), EPRS, European Parliament, 2022.

Table 3: Information about mandatory vaccination

Country	Category of population	Sanction if not respected	Date of entry into force
Austria	All adults	Administrative fine of €600, rising up to €3 600 every 3 months in case of repeated offences	5 February 2022
Estonia	Workers, if employers decide so	Termination of employment contract if no other solution	Since 24 November 2020, COVID-19 is listed as a biological hazard that allows employers to ask their employees for a vaccination certificate
France	Healthcare professionals, caregivers, firefighters	Suspension from work	15 September 2021
Germany	Employees of medical establishments, caregivers	Suspension from the workplace or no possibility to be employed	15 March 2022 until 1 January 2023, with ongoing discussion about an extension
Greece	Healthcare professionals, caregivers, and people over 60 years old	For healthcare professionals and caregivers, suspension from work. For people over 60 years old, administrative fine of 100 € per month	1 September 2021 for healthcare professionals; 16 January 2022 for people over 60 years old
Hungary	Healthcare professionals and employees of state and local government institutions	For healthcare professionals, termination of work. For other employees, unpaid leave up to a year and then termination of work	15 September 2021 for healthcare professionals; 15 December 2021 for employees of state and local government institutions
Italy	Healthcare professionals, school staff, police and army, penitentiary staff, and people over 50 years old	For workers, suspension from work. For people over 50 years old, one-off administrative fine of 100 EUR	1 April 2021 for healthcare professionals; 15 December 2021 for other types of workers; 15 February 2022 for people over 50 years old
Latvia	Employees and officials of State and local government authorities	Suspension from work	15 November 2021
Poland	Healthcare professionals, teachers, and military	Suspension from work	1 March 2022

Source: Compiled by the authors on the basis of data from the ECPRD network,¹⁴⁹ the EPRS [briefing](#) by Diaz Crego et al. (2022)¹⁵⁰ and additional desk research.

Note: This table does not include the expiry date for all the vaccination mandates, as this information is not easily available for all Member States. Rather, this table aims at showcasing the different strategies that Member States have established to mitigate the pandemic, and hence at illustrating different choices and nuances when it comes to mandatory vaccination in the EU.

¹⁴⁹ ECPRD data were shared by EPRS for the purpose of this study.

¹⁵⁰ Diaz Crego M. et al., [Legal issues surrounding compulsory Covid-19 vaccination](#), EPRS, European Parliament, 2022.

Box 2: Compulsory vaccination in Austria

Austria was the first EU Member State to make vaccination mandatory for its adult population, which attracted much international attention. On 22 November 2021, the Austrian government announced plans for establishing a vaccination mandate for all individuals over the age of 18 residing in Austria. The COVID-19 Vaccine Mandate Law¹⁵¹ entered into force on 5 February 2022 and was expected to last until 31 January 2024. The mandate concerned both the primary course of vaccination as well as booster doses. People exempted from the mandate were pregnant women, people unable to get vaccinated because of medical reasons, and people who had been infected with COVID-19 less than 180 days ago. According to § 1 para. 2 Vaccine Mandate Law, compulsory vaccination must not be enforced by direct coercive measures.

Checks of compliance with the law were foreseen to be established from 15 March 2022, the date from which non-vaccination was to be considered an administrative offence. The police were to conduct checks and notify the administration of cases of non-compliance before vaccination data could be entered into a central register which would allow systematic verification of compliance. The administrative fine for non-compliance was set to be at €600, rising up to €3,600 every 3 months in case of repeat offences. The fine was to be lifted by law if the person got vaccinated within two weeks following reception of the penalty order.

However, under § 19 para. 2 Vaccine Mandate Law, the application of the law was suspended as of 12 March 2022 by a regulation of the Austrian government, with the consent of the Main Committee of the National Council.¹⁵² This move was in response to large protests across the country since the announcement of the law, and a recommendation by the expert committee established by the COVID-19 Vaccine Mandate Law. On 9 March 2022, the expert committee's report had been published, which found that the application of the general vaccine mandate was no longer suitable to the epidemiological situation in Austria.¹⁵³ The mandate's interference with fundamental rights was indeed perceived not be proportionate with the current situation, with the Omicron variant being less severe than previous forms of the virus, and with another wave of infections not being expected before autumn 2022. The regulation's original expiry date, 31 May, was extended until 31 August 2022.¹⁵⁴ However, in July 2022, the COVID-19 Vaccine Mandate Law was repealed, along with the regulations based on it.¹⁵⁵

Other countries, such as Croatia, Cyprus, Austria, Slovenia, and Finland required some categories of workers to provide a vaccination, recovery, or test certificate to access the workplace. Similarly, Denmark and Luxembourg allowed employers to impose such a requirement for their employees.

This kind of certificate has also been imposed on the wider public in some Member States. In order to control infections and boost vaccination uptake, a majority of the EU27 have introduced a so-called 'COVID-19 certificate' that would be required in order to access certain public places, which consisted of proof that a person has either been vaccinated against COVID-19, recovered from COVID-19, or received a negative test result. As shown in Figure 10, COVID-19 certificates have been implemented in almost all Member States, also facilitated by the development of a common 'EU digital COVID-19 certificate' that fostered the interoperability of these certificates within the EU.¹⁵⁶

¹⁵¹ Please refer to the [federal law](#) adopted by the Austrian parliament, [amended](#) in March 2022.

¹⁵² Austrian government, Regulation [Vorübergehende Nichtanwendung des COVID-19-Impfpflichtgesetzes und der COVID-19-Impfpflichtverordnung](#), 11 March 2022.

¹⁵³ Austrian government, [Erster Bericht zum begleitenden Monitoring der Impfpflicht gegen COVID-19](#), 8 March 2022.

¹⁵⁴ Austrian government, Regulation [Änderung der Verordnung betreffend die vorübergehende Nichtanwendung des COVID-19-Impfpflichtgesetzes und der COVID-19-Impfpflichtverordnung](#), 25 May 2022.

¹⁵⁵ Austrian federal law [Aufhebung des COVID-19-Impfpflichtgesetzes, der COVID-19-Impfpflichtverordnung und der Verordnung betreffend die vorübergehende Nichtanwendung des COVID-19-Impfpflichtgesetzes und der COVID-19-Impfpflichtverordnung sowie Änderung des Epidemiegesetzes 1950](#), 28 July 2022.

¹⁵⁶ Note: this figure does not provide information for a certain point in time, but rather outlines which measures Member States have adopted throughout the pandemic. For instance, on 9 August 2021 France introduced a COVID-19 certificate named 'pass sanitaire' including vaccination, recovery, and test to access certain venues, which was transformed into a 'pass vaccinal' restricted to vaccination and recovery only on 24 January 2022, before being abandoned on 14 March 2022. Another example is Denmark, where the 'coronapas' including proof of vaccination,

While these certificates were implemented at the national level in most Member States, the decentralised structure of public healthcare in Spain led to a situation where regional authorities had a lot of autonomy to impose sanitary measures during the pandemic, including COVID-19 certificates. These measures adopted by regional authorities had to be ratified by the High Court of the corresponding region before entering into force. On 22 July 2021, Galicia became the first Spanish region to adopt a Decree, which entered into force in September 2021, requiring individuals to hold a COVID-19 certificate to access cafes, bars, and restaurants indoors in its municipalities with high infection rates.¹⁵⁷ By the end of November 2021, 8 Spanish regions had received permission from the courts to impose a COVID-19 certificate to access public spaces,¹⁵⁸ and by mid-2022 only four regions had not implemented one at all (Madrid, Castilla y Leon, Extremadura and Castilla-La Mancha).¹⁵⁹

Moreover, some Member States went a step further and restricted access to certain public places to people who could not show proof of vaccination or recovery, thereby revoking the possibility to provide only a negative test (Czechia, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Luxembourg, Malta, Sweden). This mandate was mainly applied to access to bars, restaurants, and hotels, but also to some types of public transports in France and Italy and was limited to certain types of high-capacity events in Hungary. This approach has raised many questions and debates about its legal and ethical basis, as it was understood by some as a not-openly-admitted vaccination mandate. At the cut-off date in September 2022, the use of COVID-19 certificates has been terminated in all Member States.

This section demonstrated the differences related to the national vaccination strategies of the EU Member States. Despite the recommendations provided at EU level by the ECDC, national health authorities introduced different measures related to the rollout of vaccines in their own national territories. National governments have maintained their autonomy in designing their own national vaccination strategies, though sharing some common approaches.

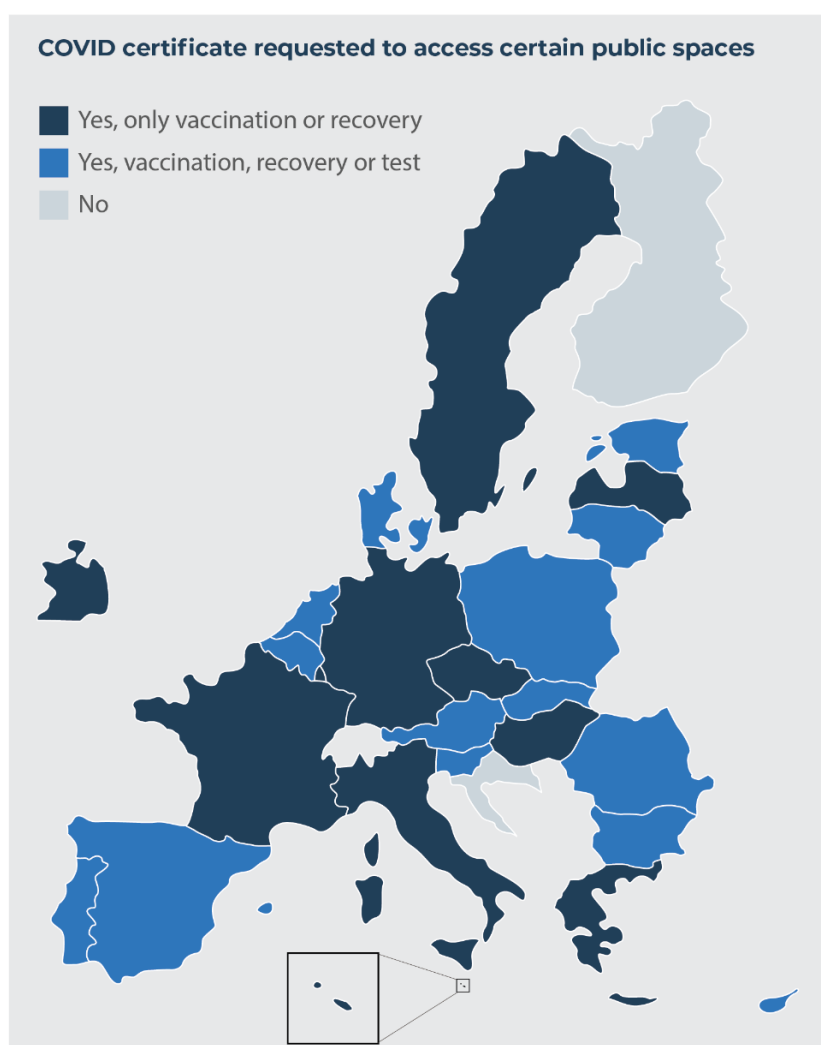
recovery or test is no longer effective but has been running from April 2021 to September 2021 and from November 2021 to January 2022.

¹⁵⁷ Galician region, [DOG Núm. 139-Bis](#), 22 July 2022.

¹⁵⁸ El País, [Covid passports in Spain: A region-by-region breakdown of where they are required, and for which activities](#), 26 November 2021.

¹⁵⁹ Morales Sancho, G. A., '[Pasaporte COVID a Examen: Nudging y Derechos Fundamentales](#)', *Revista de Derecho Publico*, Vol. 115, 2022, pp. 171-293.

Figure 10: COVID-19 certificate required to access certain public spaces



Data source: [EPRS briefing](#) by Diaz Crego et al. (2022) and additional desk review of official sources.

2.2.2. National vaccination coverage over time

Apart from the development and manufacturing of vaccines, the EU vaccines strategy aimed to accelerate the deployment of vaccines against COVID-19. The main task by the Commission at the EU level is to make sure that Member States are prepared for the roll-out safely and effectively. However, vaccination coverage in a country over time depends on multiple factors that could or could not be influenced or controlled at the Union level or even by the national government. While the government tries to vaccinate the population as quickly, extensively, and safely as possible, vaccination coverage also depends on the individual's willingness to get vaccinated, complicated with the circulation of misinformation and disinformation (as discussed in section 2.2.3), and the country's specific political atmosphere and cultural background. Multiple intertwining factors make an analysis of vaccination coverage particularly difficult.

Before studying the determinants driving vaccination coverage, this section will present a descriptive overview of the vaccination coverage over time of 30 European countries (27 EU Member States and the three EEA countries Iceland, Liechtenstein and Norway) with a cut-off date at the end

of September 2022.¹⁶⁰ The analysis employs two main indicators. The first one is vaccination coverage, which refers to the proportion of the population who have received a certain number of doses of COVID-19 vaccine. The second is national vaccination progress, which refers to the number of doses administered per 100 persons. Although the two indicators are similar, they yield different information. Vaccination coverage shows the proportion of the population protected, while national vaccination progress shows the overall speed of vaccination. For instance, a vaccination coverage of 50% of the population with two doses (and 0% with only one dose) is equal to a vaccination progress of 100 doses per 100 persons. The same value of national vaccination progress is found in a country where 100% of the population have received one dose and none received a second dose. These two countries will probably experience a very different epidemic curve and mortality rates but their vaccination progress or speed is the same, showing that the differences in epidemiological circumstances are not due to low capacity or poor logistics of vaccine roll-out.

The analysis is built upon the vaccination data from COVID-19 Vaccine Tracker, provided by the ECDC.¹⁶¹ The dataset documents the weekly numbers of doses administered across 27 EU Member States plus three EEA countries since the beginning of vaccine deployment in Europe (the end of 2020) until October 2022.¹⁶² The analysis is divided into three groups of population: namely, the whole population, older people (i.e. age ≥ 60) and children (i.e. age < 18). For each group, the study presents information in two graphs: the number of doses of vaccines administered per 100 persons, and the number of weeks needed to vaccinate 50% of the whole population and of the older population, and to vaccinate 1% of the under 18 years old population.

Whole population

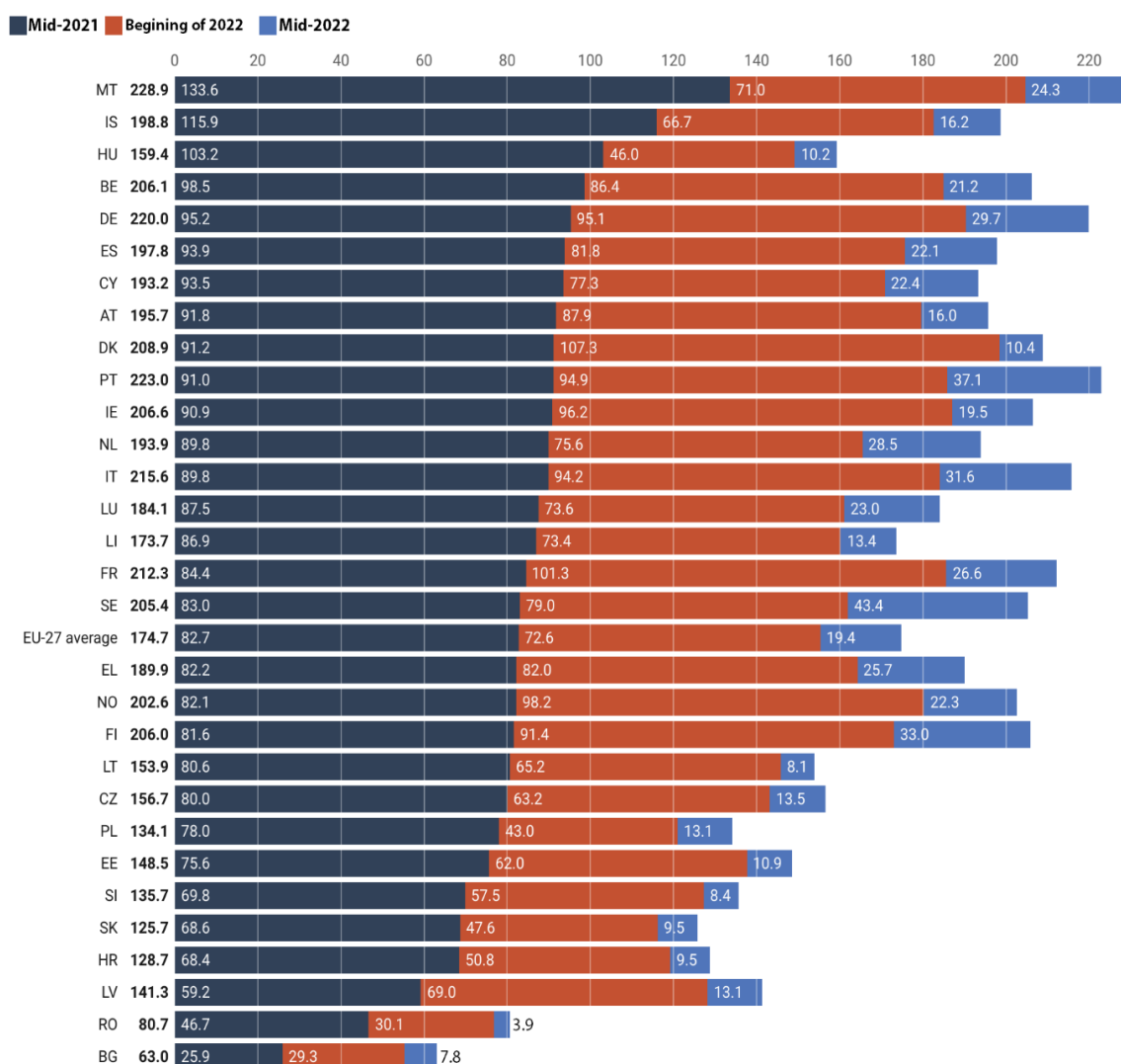
Figure 11 illustrates the number of COVID-19 vaccine doses administered per 100 persons in the EU27 plus three EEA countries, which are ranked according to their vaccination progress by mid-2021. As the primary course of vaccination for two of the main COVID-19 vaccines (Pfizer-BioNTech and Moderna) consists of two doses, and one or two booster doses are recommended in most Member States, the number of administered vaccine doses per 100 persons can exceed 100.

¹⁶⁰ On top of the 27 EU Member States, EEA countries are also covered by the ECDC in its data collection. The analysis uses the data updated on 24 October 2022.

¹⁶¹ ECDC, [COVID-19 Vaccine Tracker](#), 2021.

¹⁶² ECDC keeps updating the dataset after this date. As the data of October 2022 are incomplete in the dataset, the research team chose the end of September as the cutoff date. The dataset solely contains the information about these 30 countries.

Figure 11: Vaccination progress by country (vaccine doses administered per 100 persons)



Data source: [ECDC Vaccine Tracker](#) (version 24 October 2022).

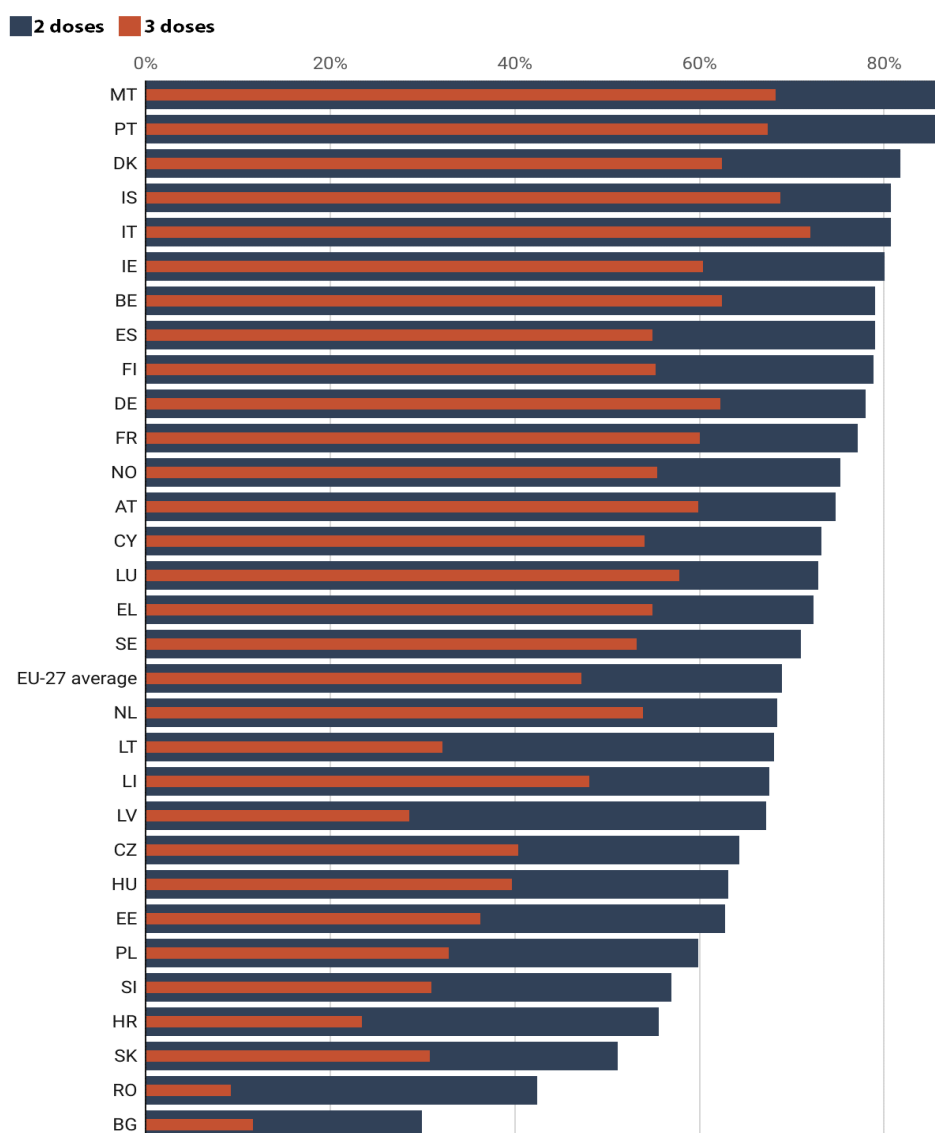
Note: The bars show the progress of vaccine doses administered by mid-2021, the first week of 2022 and mid-2022. Progress is measured by the number of vaccine doses administered (in each period) per 100 persons. The stacked bars thus measure the overall progress since the beginning of the vaccination. This graph is designed using Datawrapper.

The graph shows a substantial variation between countries: by mid-2021, the country with the slowest progress represented only one-fifth of the progress in the best-performing country. Subsequent developments did not significantly affect their relative progress, albeit with some notable drops in vaccination progress (e.g. Hungary) as well as catch-ups (e.g. Latvia). The second half of 2021 saw a general decline in vaccination progress with some exceptions. Vaccination progress in general plateaued during the first half of 2022, as most of the population had already been double-jabbed. By mid-2022, most of the countries were able to vaccinate a large part of their population, with 25 of EU27 countries reaching above 100 doses per 100 persons and 9 of EU27 reaching above 200 doses per 100 persons.

Figure 12 shows the vaccination coverage of EU27 + 3 EEA countries. 5 countries achieved 80% coverage of 2 doses and 18 countries achieved 50% coverage of 3 doses. Figure 13 shows the number of weeks since January 2021 needed for a country to vaccinate 50% of the population twice

and to administer a third dose for 50% of the population.^{163 164} Malta was the quickest in vaccinating 50% of the population twice, taking only 23 weeks. Among the EU27, Denmark was the quickest in boosting its population, reaching 50% of population boosted in the first week of 2022, closely followed by Austria, Belgium, Germany, Ireland, and Italy.

Figure 12: Vaccination coverage by the end of September 2022



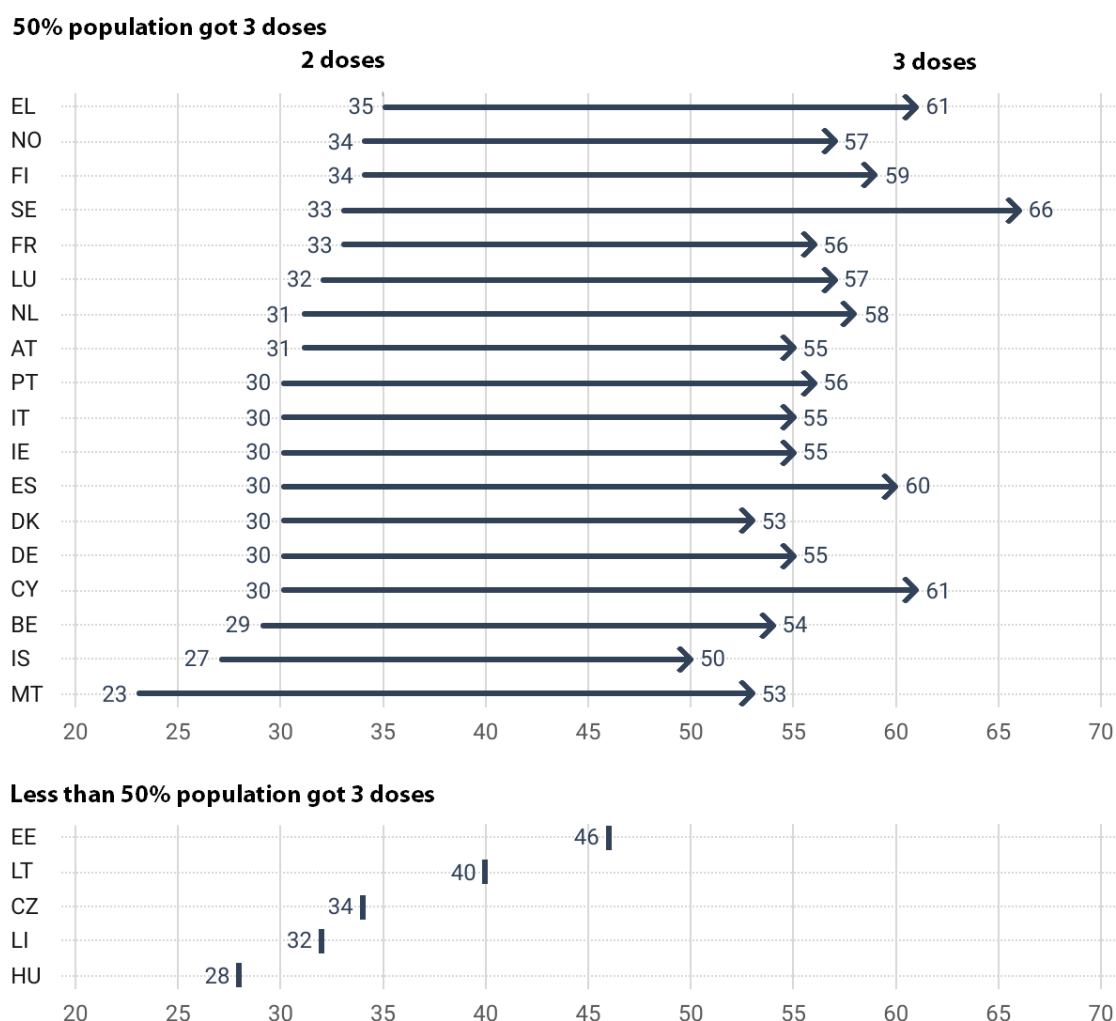
Data source: [ECDC Vaccine Tracker](#) (data version 24 October 2022).

Note: This chart shows the proportion of each Member State's population vaccinated twice or three times. This graph is designed using Datawrapper.

¹⁶³ Countries did not all begin their vaccination programmes the same week. While some had already vaccinated a very small number of individuals in the last weeks of 2020, the more general roll-out began in the beginning of 2021.

¹⁶⁴ The ECDC webpage also provides information of 'fully vaccinated', which is slightly different from having two doses of a COVID-19 vaccine because Janssen's Jcovden was designed and administered as a single-dose vaccine. Since Janssen's share in the actual roll-out of COVID-19 vaccines is relatively small, we acknowledge the difference but do not account for it.

Figure 13: Number of weeks needed to achieve two vaccination coverage goals



Data source: [ECDC Vaccine Tracker](#) (version 24 October 2022).

Note: This chart shows the numbers of weeks since the beginning of 2021 a country needed to achieve two vaccination goals, namely, 50% of the population double-jabbed and 50% of the population triple-jabbed. This graph is designed using Datawrapper.

Older people (aged 60 and above)

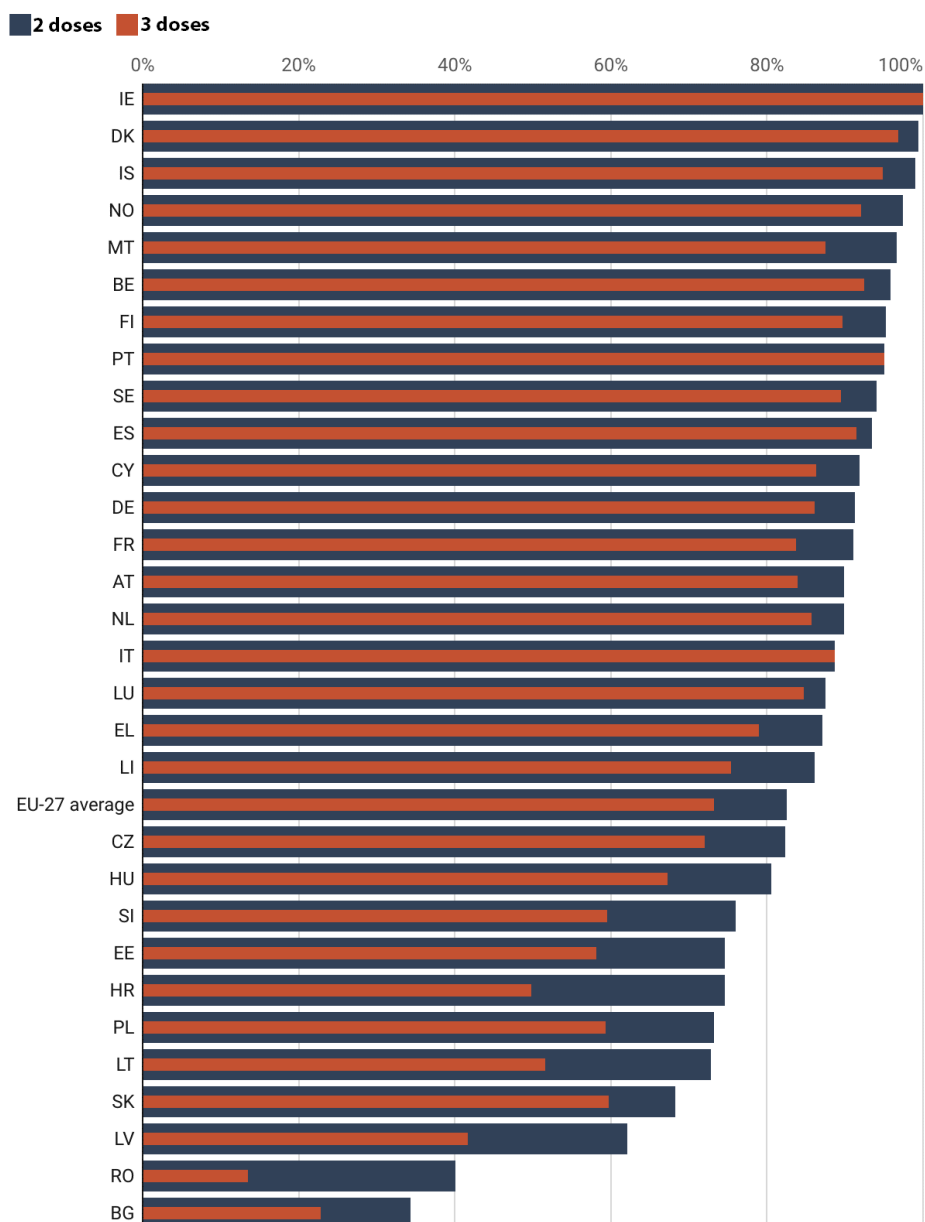
As older people were among the first groups to receive the vaccine, all Member States began their vaccination around the same time. The range in Member States' start dates of vaccinating older people are within two to three weeks from each other and are believed to be due to delivery times and countries' administrative capacity rather than governments' intention to vaccinate. This section will evaluate the vaccination coverage of the older population. By older, this study refers to the population aged 60 and above.¹⁶⁵

Figure 14 shows the vaccination coverage by the end of September 2022. It shows that 15 EU Member States have succeeded in vaccinating more than 80% of those above 60 years with 2 doses. Eastern European countries are lagging behind their Western peers.

¹⁶⁵ The research team is aware that in some countries or cultures being aged above 60 is not considered 'older' in a strict sense. However, for the sake of consistency and easier communication, the team refers the group as older people.

Figure 15 plots the number of weeks (since the beginning of 2021) needed to vaccinate 50% of older populations. It shows that, apart from Bulgaria, Latvia, and Romania, EU Member States succeeded in vaccinating those older than 60 years with 2 doses within 25 weeks. Additionally, most of them were able to provide booster doses to their older population within a year.

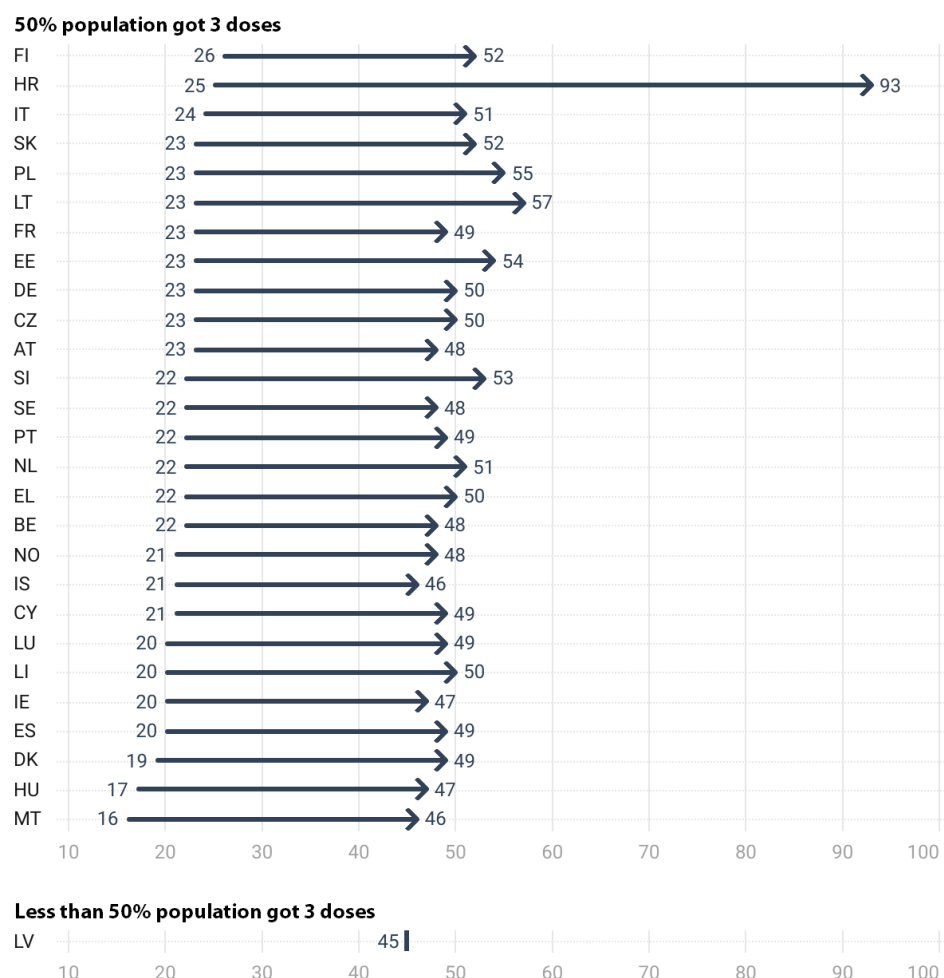
Figure 14: Vaccination coverage by the end of September 2022 (aged 60 and above)



Data source: [ECDC Vaccine Tracker](#) (version 24 October 2022).

Note: This chart shows the proportion of the population over 60 years of age vaccinated twice or three times. This graph is designed using Datawrapper.

Figure 15: Number of weeks needed to achieve two vaccination coverage goals for 60+ years old



Data source: [ECDC Vaccine Tracker](#) (version 24 October 2022).

Note: This chart shows the numbers of weeks (since the beginning of 2021) a country needed to achieve two vaccination coverage goals; namely, 50% of those aged 60+ years double-jabbed and 50% of those aged 60+ years vaccinated with three doses. Bulgaria and Romania have not managed to see 50% of their older population double-jabbed. Bulgaria, Latvia, and Romania have not reached 50% of the population aged 60+ years vaccinated with three doses. This graph is designed using Datawrapper.

Children (aged below 18)

While the older populations were amongst the first to get vaccinated, the youngest were last. The extension of vaccination programmes to children was gradual and began from the oldest children to the youngest. At the time of writing (1 November 2022), only three vaccines (Pfizer-BioNTech, Moderna and Novavax) are authorised for use on children by EMA.

Table 4: COVID-19 vaccines approved for children

Vaccine Producer	EMA recommendation date ¹⁶⁶	Age group
Pfizer-BioNTech	28 May 2021	12-15 years ¹⁶⁷
	25 November 2021	5-11 years
	19 October 2022	6 months - 4 years
Moderna	23 July 2021	12-17 years
	24 February 2022	6-11 years
	19 October 2022	6 months - 5 years
Novavax	23 June 2022	12-17 years

Source: [EMA](#) (as of 1 November 2022).

On the basis of the recommendation by EMA, it is up to Member States to decide whether to begin the roll-out of vaccines to children. Meanwhile, it is deemed likely that COVID-19 is generally less severe in children¹⁶⁸ and so parents are more hesitant to vaccinate their children. As a result, there is much more variation in both the starting date of vaccination for children as well as the time needed to reach a certain coverage goal. By defining the time needed since authorisation to vaccinate 1% of an age group as the reaction time of the Member State to extend the coverage to a certain age group, data shows that Member States' reaction time improved along with the extension. It took at least 17 weeks to begin mass-vaccination of children aged 15-17 even though Pfizer-BioNTech had been authorised for use in those 16 years old and above. This is however not surprising, since governments prioritised older people, frontline workers, and vulnerable groups before healthy adults and children. The reaction time towards the extension of recommendations to those aged 12-15 in Week 22 2021 (end of May/beginning of June 2021) is 6.5 weeks on average.¹⁶⁹ The time needed to cover 1% of the population aged 5-9 is even shorter. It took on average 3.5 weeks following the recommendation of extension which was announced in Week 48 2021.¹⁷⁰ The improvement of the reaction time could be due to several reasons. First, governments became familiar with and wiser in rolling out vaccines. Second, towards the end of 2021, most of the population who were willing to receive a vaccine had been vaccinated at least once, leaving resources free for children.

¹⁶⁶ The date listed in the table is the date when EMA announced the recommendation on its website, which may not be the actual approval date of the use of the vaccine.

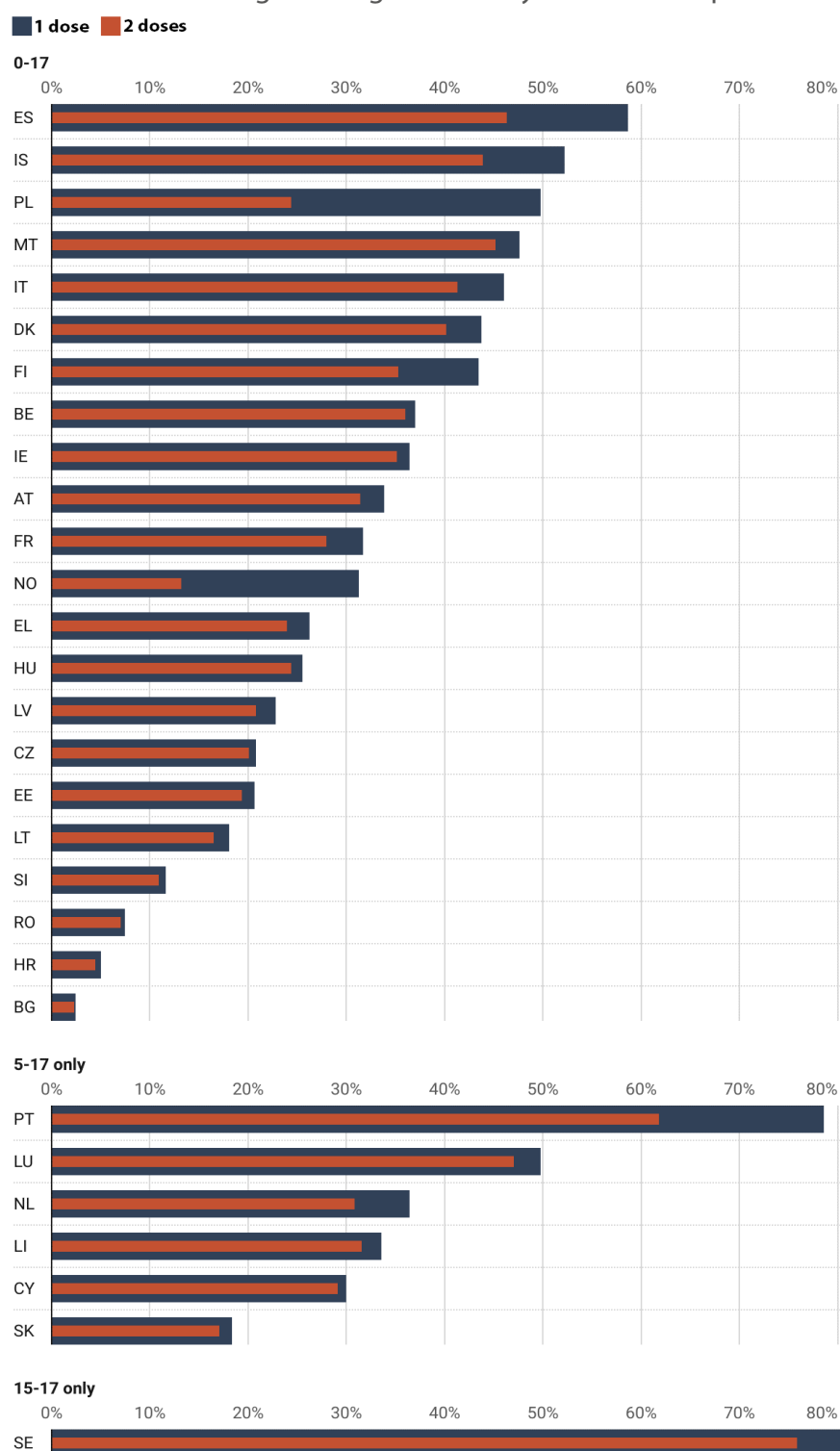
¹⁶⁷ Pfizer-BioNTech (Comirnaty) has been approved for use in adolescents aged 16 and above along with the approval for adults.

¹⁶⁸ Sinaei R. et al., '[Why COVID-19 is less frequent and severe in children: A narrative review](#)', *World Journal of Pediatrics*, Vol. 17(1), 2021, pp. 10-20.

¹⁶⁹ It is the average value of the reaction time of 18 countries where data are available.

¹⁷⁰ It is the average value of the reaction time of 17 countries where data are available.

Figure 16: Vaccination coverage among children by the end of September 2022



Data source: [ECDC Vaccine Tracker](#) (version 24 October 2022).

Note: There are no data for the age group 0-4 for Cyprus, Lithuania, Luxembourg, the Netherlands and Portugal; and for Sweden, there are no data for the age group below 15. This graph is designed using Datawrapper.

Vaccination coverage of children is far behind that of older people. Figure 16 shows the vaccination coverage among children by the end of September 2022. As five countries have not reported data about the population aged 4 and below and Sweden has no data released about its population aged 14 and below, these countries are separated from the rest in the graph because the denominators

of vaccination coverage are therefore not comparable. No country has reached 50% of its population aged 18 and below double-jabbed and the coverage of a third dose is even lower (not shown in the chart).

2.2.3. Key variables determining vaccination coverage

This section will explore reasons behind vaccination coverage differences among Member States. The variables that could determine vaccination coverage studied in this section are national vaccination programmes, public opinion, infodemics, and trust.

National vaccination programmes

The impact of different vaccination strategies on vaccination coverage is not straightforward. A large part of the content of national vaccination strategies, which was presented in section 2.2.1., is not directly aimed at increasing vaccination coverage per se, but rather endeavours to design vaccine deployment in the most efficient and safe manner. For instance, this is the case regarding the recommendations for booster doses. Initially, most COVID-19 vaccines (except Janssen) were designed/developed as a two-dose immunisation for the general adult population. Because of the quicker waning of immunity granted by COVID-19 vaccines than anticipated, as well as of the appearance of more contagious variants of the virus, booster doses have come to be suggested, which governments recommended with different schedules. Data shows that some countries were quick in administering third doses, such as Croatia, Ireland, and Poland, though with limited coverage, while many other countries waited until the second half of 2021 following the recommendation by the ECDC and EMA on the use of first booster dose.¹⁷¹ The decision to begin the administration of boosters depended very much on national circumstances and some governments were focussed on fostering the uptake of the second dose while others chose to boost immunity of those already twice vaccinated with boosters. Overall, recommendations for booster doses might have led to some countries choosing to administer additional doses earlier than others, but they are not important determinants of a country's vaccination coverage.¹⁷² The same conclusions can be reached about recommendations for previously infected individuals, or the categorisation of priority groups: while these recommendations might have impacted the patterns of vaccination in different countries, they are not key determinants of their overall vaccination coverage.

Additionally, some countries' vaccination strategies included measures directly aimed at increasing vaccination coverage, such as vaccination mandates or COVID-19 certificates to enter public places.

Although some countries made vaccination mandatory for specific groups of the population, data does not show that this pushed up vaccination coverage rates significantly. Since January 2022, compulsory vaccination for instance applies to individuals over 60 years old in Greece. The vaccination data from the ECDC shows that the announcement of this order on 30 November 2021 led to a small increase in vaccination uptake among older people in Greece, from an average weekly growth of 0.41% in the two months preceding the announcement to 1.33% in the following month. Yet, this increase is relatively small, and Greece is still not among the best performing countries when it comes to the vaccination of those aged 60+ years.

¹⁷¹ ECDC, ECDC and EMA highlight considerations for additional and booster doses of COVID-19 vaccines, [press release](#), 2 September 2021.

¹⁷² The research team attempted to correlate vaccination progress of Member States with their different vaccination strategies but found no support that earlier booster administration led to wider coverage or faster progress. Very often, earlier booster administration is associated with low coverage and slow progress. The causality is very likely the opposite: slower vaccination made governments more willing to expand the reach by including more age groups and to start booster vaccination earlier.

The use of COVID-19 certificates in some countries is believed to be a reason behind vaccination coverage surges. In France, for instance, President Emmanuel Macron's announcement of the establishment of a COVID-19 certificate (requiring either proof of vaccination, recovery, or negative test) for accessing most public spaces on 12 July 2022 appears to have triggered a rise in vaccination appointment website visits and bookings.¹⁷³ A study on six countries that implemented certification (Denmark, Israel, Italy, France, Germany, and Switzerland) also showed that COVID-19 certificates could increase vaccine uptake considering pre-existing levels of vaccine uptake and hesitancy, the certificate design, and the epidemiological situation.¹⁷⁴

National vaccination campaigns were designed to cover the whole population, but in some cases certain groups of people may not have been reached. For example, in some parts of Italy, the online booking platforms required a person's social security number to complete the booking, which is only available for legally residing people. Some efforts by local NGOs in collaboration with the local administration were directed to vaccinate undocumented people but were limited by human resources and also the availability of suitable vaccines.¹⁷⁵ Homeless people are another major group that have been very often neglected. Research shows that they are not necessarily hesitant towards vaccines, but often lack information about vaccination or do not have the means to travel to a vaccination centre.¹⁷⁶ The findings suggest that by better designing a vaccination campaign, vaccines can actually reach a wider population, and low vaccination progress in a country may not be due solely to vaccine hesitancy or misinformation.

Public opinion

Public opinion towards vaccination is an important determinant of vaccine uptake. Willingness to get the COVID-19 vaccine has varied across EU Member States as well as during the different stages of the pandemic. A study in eight European countries in spring 2021¹⁷⁷ revealed striking differences across countries, with 6.4% of Spanish adults and 61.8 % of Bulgarians reporting being hesitant towards vaccination against COVID-19. The two Flash Eurobarometers about attitudes on vaccination against COVID-19 conducted in May 2021 and February 2022, as well as some of the Standard Eurobarometer editions conducted since the onset of the pandemic¹⁷⁸, also provide valuable information about this issue.

Figures 17 and 18 display the evolution of vaccine hesitancy and refusal from February/March 2021¹⁷⁹ (at the beginning of the deployment of vaccine campaigns in the EU) to February 2022¹⁸⁰. Specifically, the question asked to respondents in February/March 2021 was: "If a vaccine against

¹⁷³ Karaivanov A. et al., '[COVID-19 vaccination mandates and vaccine uptake](#)', *Nature Human Behaviour*, Vol. 6, 2022, pp. 1615–1624.

¹⁷⁴ Mills M.C. and Rüttenauer T., '[The Effect of Mandatory COVID-19 Certificates on Vaccine Uptake: Synthetic-Control Modelling of Six Countries](#)', *The Lancet Public Health*, Vol. 7(1), 2022, pp. e15–e22.

¹⁷⁵ Bentivegna E. et al., '[Access to COVID-19 vaccination during the pandemic in the informal settlements of Rome](#)', *International Journal of Environmental Research and Public Health*, Vol. 19(2), 2022, 719.

¹⁷⁶ McCosker L.K. et al., '[Strategies to Improve Vaccination Rates in People Who Are Homeless: A Systematic Review](#)', *Vaccine*, Vol. 40(23), 2022, pp. 3109–3126.

¹⁷⁷ Steinert J.I. et al., '[COVID-19 vaccine hesitancy in eight European countries: Prevalence, determinants, and heterogeneity](#)', *Science Advances*, Vol. 8(17), 2022.

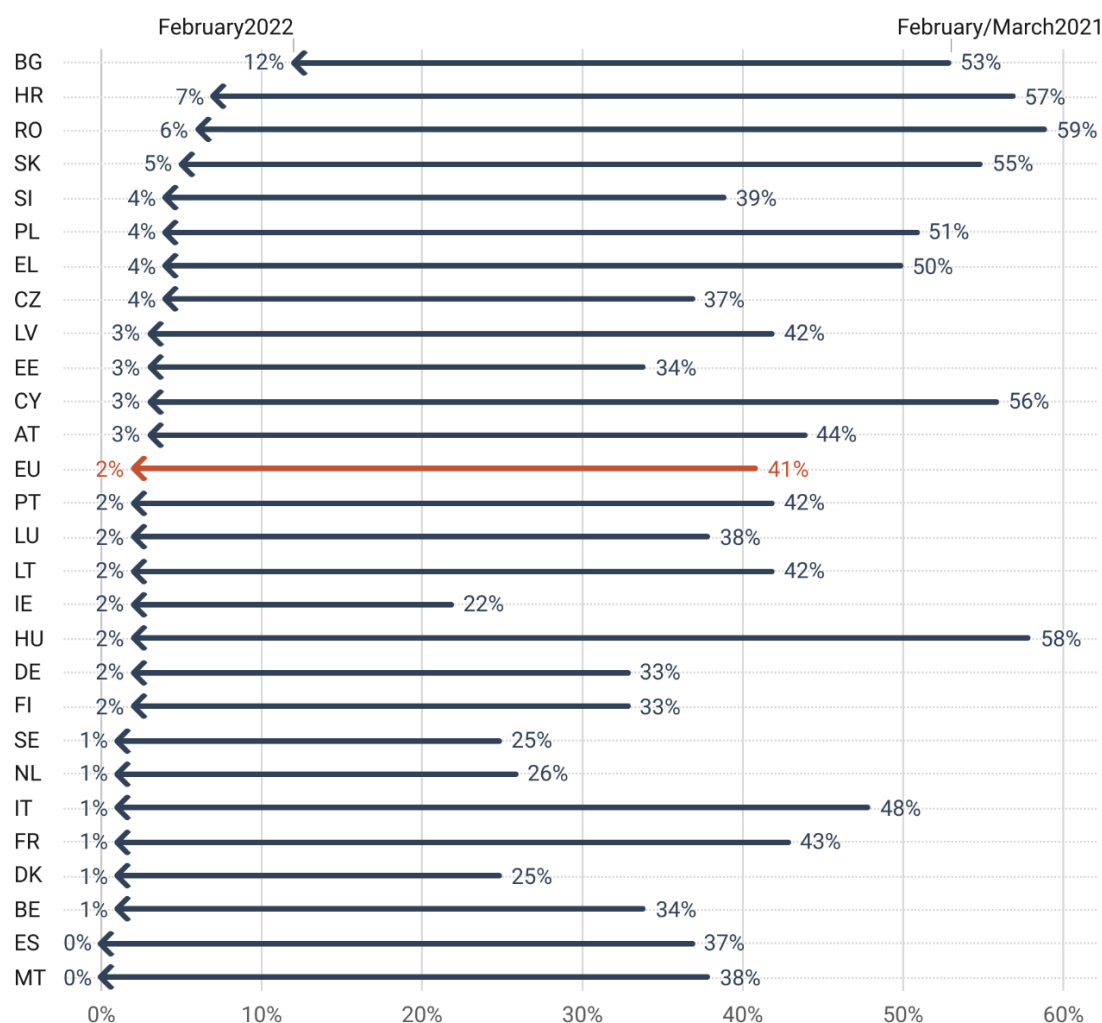
¹⁷⁸ See European Commission, [Flash Eurobarometer 494](#) (2512 / FL494 – fieldwork conducted in May 2021) and [Flash Eurobarometer 505](#) (2692 / FL505 – fieldwork conducted in February 2022). The Standard Eurobarometer published since the onset of the pandemic include [Standard Eurobarometer 94](#) (2355 / STD94 - fieldwork conducted in February and March 2021), [Standard Eurobarometer 95](#) (2532 / STD95 – fieldwork conducted in June and July 2021) and [Standard Eurobarometer 96](#) (2553 / STD96 – fieldwork conducted in January and February 2022). [Standard Eurobarometer 97](#) (2693 / STD97 – fieldwork conducted in June and July 2022) is not included in this study because it had not yet been published at the time of writing.

¹⁷⁹ As reported in the [Standard Eurobarometer 94](#) – Winter 2020-2021 (2355 / STD94).

¹⁸⁰ As reported in the latest version of the Flash Eurobarometer on Attitudes on vaccination against COVID-19 published in March 2022 with the field trip having been conducted in February 2022 ([2692 / FL505](#)).

COVID-19 (coronavirus) is authorised by public authorities and available for you, when would you like to get vaccinated?”, and in February 2022: “Have you been vaccinated against COVID-19 (coronavirus)? And when would you like to get vaccinated against COVID-19 (coronavirus)?”. The answers to this question are categorised between unvaccinated respondents who are vaccine-hesitant, i.e. answering “sometime in 2021”, “sometime in 2022” or “later”, and unvaccinated respondents who are against vaccination, i.e. answering “never”. While reported intentions do not always translate into vaccination uptake, the Flash Eurobarometer conducted in February 2022 indicates that the proportion of respondents indicating that they have already been vaccinated

Figure 17: Percentage of respondents being hesitant to getting a COVID-19 vaccine



Data source: [Standard Eurobarometer 94](#) (February/March 2021) and [Flash Eurobarometer 505](#) (February 2022).

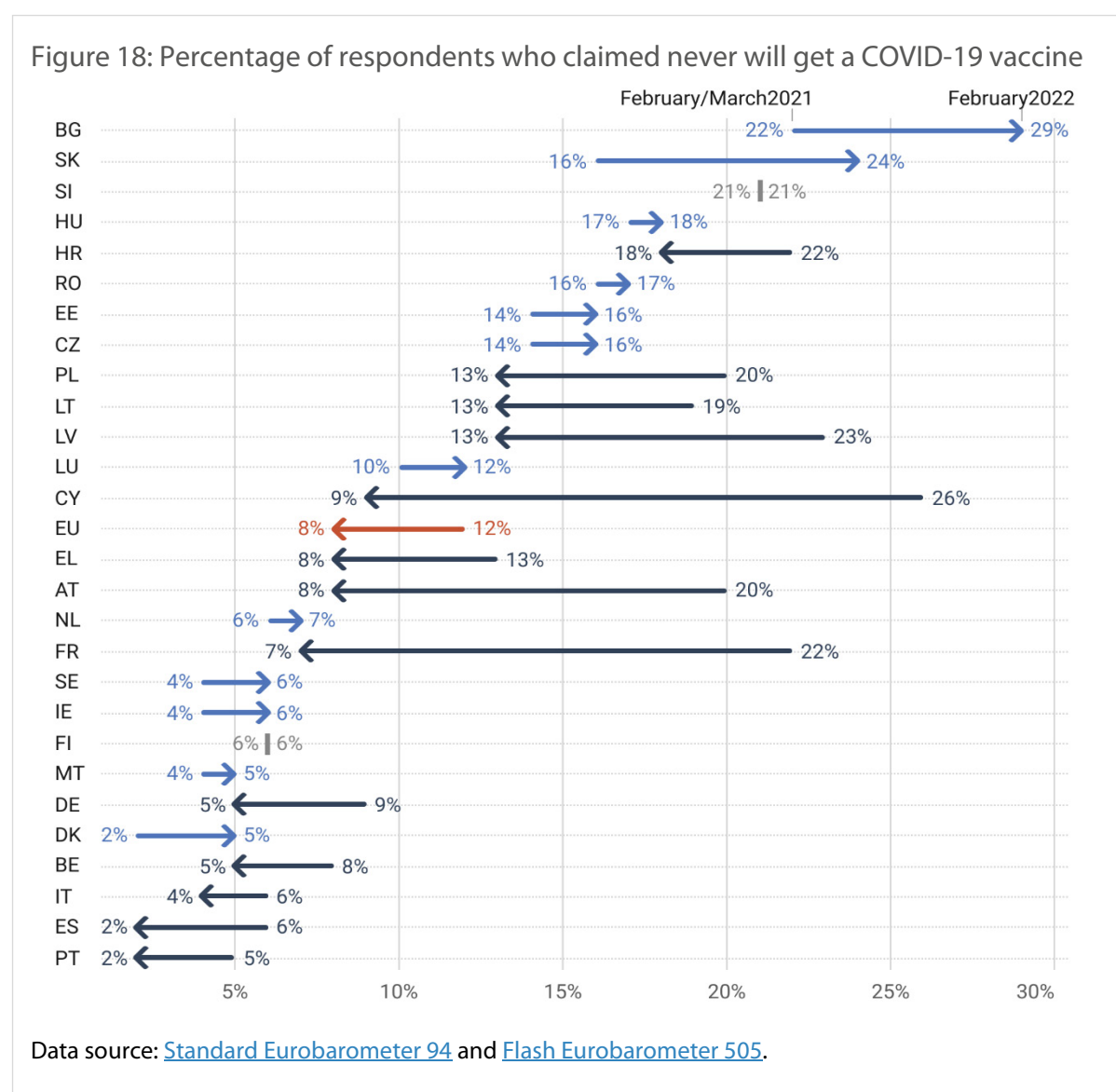
broadly mirrors the actual vaccination rates in Member States at the time the survey was conducted (except for Romania, due to potential bias in the surveyed sample).

Note: This chart shows the percentage of respondents to the surveys expressing that they are hesitant to get a COVID-19 vaccine. The arrows show the change of percentage points from February-March 2021 to February 2022. The EU average is highlighted in orange.

Figure 17 shows the percentage of respondents who are hesitant in taking a COVID-19 vaccine. Understandably, the percentage drops significantly from February/March 2021 to February 2022, since the vaccination campaigns throughout Europe had been relatively successful and many people had already taken the vaccines. The remaining respondents were either accepting or

rejecting the vaccines completely. In February 2022, the proportion of vaccine-hesitant individuals remained highest in Bulgaria (12%), Croatia (7%), Romania (6%) and Slovakia (5%).

Figure 18 depicts the percentage of respondents claiming that they have not taken a COVID-19 vaccine and that they will not get one in the future. While this proportion decreased in most of the Member States, it increased in some, such as Bulgaria, Slovakia, Estonia, and Czechia. In February 2022, the proportion of people stating that they would never get vaccinated against COVID-19 was highest in Bulgaria (29%), Slovakia (24%) and Slovenia (21%), and lowest in Portugal (2%), Spain (2%) and Italy (4%). The graph also shows that in February/March 2021 Cyprus, Latvia, Austria, and France had a relatively high percentage of their population expressing that they would never want to get vaccinated (>20%), but that this proportion had dramatically decreased by February 2022 (10 or more percentage points decrease). This could be linked to the establishment of COVID-19 certificates to access certain places, which were introduced in all four aforementioned countries, or to changing public opinion towards vaccination for other purposes, e.g. following public health information campaigns.



Note: This chart shows the percentage of respondents to the Eurobarometer surveys which expressed that they did not get a vaccine and never intend to get one in the future in February/March 2021 and February 2022. The arrows represent the change over time: arrows in dark blue are countries where this percentage decreased in the studied period, arrows in light blue are those where it increased, those in grey are those where it did not change, and the one in orange represents the EU average.

The two Flash Eurobarometers about attitudes on COVID-19 vaccination also investigate the reasons for people being reluctant (or refusing) to get vaccinated. It appears that the two main reasons are related to vaccine safety: individuals think that COVID-19 vaccines have not been sufficiently tested yet (90% of respondents thinking this is an important reason in May 2021, 85% in February 2022), and they are worried about the side effects of COVID-19 vaccines (82% in May 2021, 84% in February 2022). The usefulness of vaccines is also increasingly put into question throughout the pandemic, with respondents believing that COVID-19 vaccines are not effective (60% in May 2021, 80% in February 2022), that the risk posed by COVID-19 is exaggerated (57% in May 2021, 62% in February 2022), and that the pandemic will be over soon (49% in May 2021, 61% in February 2022). In both surveys, less than half of respondents (41% in May 2021 and 32% in February 2022) stated that they did not want to get vaccinated against COVID-19 because they were against vaccines in general.

These findings are consistent with the literature on the factors associated with COVID-19 vaccine hesitancy. A study on vaccine hesitancy in Portugal¹⁸¹ found that vaccine refusal and delay were associated with low confidence in the vaccine and the health service response during the pandemic, as well as bad perception of government measures¹⁸² also show that low trust in the quality and efficacy of the COVID-19 vaccines spurred vaccine hesitancy, with for instance major concerns about the lack of evidence regarding the long-term effect of the COVID-19 vaccines as well as concerns about the speed with which vaccines had been developed. Other studies about vaccine hesitancy also point at the fact that vaccine hesitancy and refusal are associated with a lower perceived severity of COVID-19.^{183 184} Gerretsen et al. (2021) found that the mistrust of vaccine benefit and lower perceived seriousness of COVID-19 were the principal determinants of vaccine hesitancy, and that sociodemographic aspects explained a lower proportion of the variance in vaccine hesitancy.¹⁸⁵ According to a meta-analysis of 15 peer-reviewed journal articles, some sociodemographic factors that influence vaccine acceptance include ethnicity, working status, religiosity, political orientation, education, age, and income.¹⁸⁶ This is somehow reflected in the results of the Flash and Standard Eurobarometers, where vaccine acceptance is seen to be dependent on age and occupation, while differences in terms of level of education and urbanisation are identified as small and tend not to be statistically significant.

All respondents were also asked what would make them more eager to get vaccinated. 7% of respondents answered that they would not get vaccinated anyway, which is consistent with the EU average of people answering “never” to the question of when they will get vaccinated against COVID-19. The main reasons which people would get more eager to get vaccinated for relates to the safety and efficacy of vaccines, for instance if they see that there are more serious forms of COVID-19 among unvaccinated people (around 30%) and if more people are already vaccinated, and that it works with no-side effects (around 29.5%). The number of people getting vaccinated around them is also important for respondents: 15% on average answered that they would be more eager to get vaccinated if they saw more people doing it, and another 17% that they would be more motivated if the people that recommend the vaccines were vaccinated themselves. The issue of vaccine development is also key: the fact that there is full clarity on how vaccines are being developed, tested, and authorised would be a driver for COVID-19 vaccination for 27% of the

¹⁸¹ Soares P. et al., '[Factors associated with COVID-19 vaccine hesitancy](#)', *Vaccines*, Vol. 9(3), 300, 2021.

¹⁸² Steinert J.I. et al., '[COVID-19 vaccine hesitancy in eight European countries: Prevalence, determinants, and heterogeneity](#)', *Science Advances*, Vol. 8(17), 2022.

¹⁸³ Fridman A., Gershon R. and Gneezy A., '[COVID-19 and vaccine hesitancy: A longitudinal study](#)', *PLOS ONE*, Vol. 16(4), 2021.

¹⁸⁴ Schwarzinger M. et al., '[COVID-19 vaccine hesitancy in a representative working-age population in France: A survey experiment based on vaccine characteristics](#)', *The Lancet Public Health*, Vol. 6(4), 2021, pp. e210-e221.

¹⁸⁵ Gerretsen P. et al., '[Individual determinants of COVID-19 vaccine hesitancy](#)', *PLOS ONE*, Vol.16(11), 2021, p. e0258462.

¹⁸⁶ Troiano G. and Nardi A., '[Vaccine hesitancy in the era of COVID-19](#)', *Public Health*, Vol. 194, 2021, pp. 245-251.

respondents, and the fact that vaccines are developed in the EU for 11.5% of them. Finally, medical advice seems to be an important driver of vaccination, as receiving their doctor's recommendation to get vaccination would make 22% of respondents more willing to get the vaccine.

Infodemic

As defined by the WHO, an infodemic relates to too much information (be it false or misleading) online and offline during a disease outbreak, which causes confusion and endangers health behaviours.¹⁸⁷

Results from the Flash Eurobarometer on attitudes on COVID-19 vaccination reflect that finding trustworthy information sources about COVID-19 vaccines is a high concern among EU citizens, and that it is also correlated with one's willingness to vaccinate.¹⁸⁸ Overall, 46% of respondents agree that it is difficult to find information they can trust about COVID-19 (while 48% disagree) – but this proportion rises to 73% among people that refuse vaccination and to 75% among vaccine-hesitant individuals. Health professionals and national health authorities are the most trusted sources of information among respondents, while the least trusted are the mass media, websites, and online social networks. Yet, respondents that are against vaccination are somewhat more likely to trust websites, online social networks, and people around them as trustworthy sources of vaccination.

In fact, misinformation about vaccines has long been a factor in unwillingness to vaccinate over the world, even before the COVID-19 pandemic. Anti-intellectual attitudes have long been documented and associated closely with political movements and politicians.¹⁸⁹ Lack of scientific knowledge increases distrust in medical institutions and pharmaceutical companies.¹⁹⁰ Such a sentiment is growing fast on social media, which is the breeding ground of misinformation where users could easily find echo chambers.¹⁹¹ Unfortunately, confirmation bias¹⁹², which connotes the seeking of information that is consistent with one's expectation, and the Dunning-Kruger Effect¹⁹³, which refers to the observation that those who possess little subject knowledge are those who fail to recognise their knowledge deficiency, reinforce one's belief. Research showed that high vaccine hesitancy is driven by belief in conspiracy theories, poor trust in medical science and institutions, and also low objective vaccine knowledge.¹⁹⁴

Apart from being associated with common vaccine conspiracies, COVID-19 vaccines have been put under a microscope because of the unprecedented nature of the COVID-19 pandemic. Death cases or serious reactions some days after vaccination were often reported by online and even traditional media outlets. When such reports pile up, they form the impression of COVID-19 vaccines being unsafe in one's knowledge space. Research has attempted to document the extent of misinformation about COVID-19 vaccines across countries. Roozenbeek et al. (2020) using survey

¹⁸⁷ WHO, 'Infodemic' (Accessed 1 December 2022).

¹⁸⁸ European Commission, Eurobarometer, [Flash Eurobarometer 494](#) – (2512 / FL494), June 2021, and [Flash Eurobarometer 505](#) – (2692 / FL505), March 2022.

¹⁸⁹ Motta M., 'The dynamics and political implications of anti-intellectualism in the United States', *American Politics Research*, Vol 46(3), 2018, pp. 465-498.

¹⁹⁰ Allum N. et al., 'Science knowledge and attitudes across cultures: A meta-analysis', *Public Understanding of Science*, Vol. 17(1), 2008, pp. 35-54.

¹⁹¹ Del Vicario M. et al., 'Echo chambers: Emotional contagion and group polarization on Facebook', *Scientific Reports*, Vol. 6(1), 2016, p. 37825.

¹⁹² Nickerson R.S., 'Confirmation bias: A ubiquitous phenomenon in many guises', *Review of General Psychology*, Vol. 2(2), 1998, pp. 175-220.

¹⁹³ Dunning D., 'The Dunning-Kruger effect: On being ignorant of one's own ignorance', *Advances in experimental social psychology*, Vol. 44, 2011, pp. 247-296.

¹⁹⁴ Milošević Đorđević J. et al., 'Links between conspiracy beliefs, vaccine knowledge, and trust: Anti-vaccine behavior of Serbian adults', *Social Science & Medicine*, Vol. 277(1), 113930, 2021.

data, found a substantial number of individuals believing to a certain extent some misinformation.¹⁹⁵ Unsurprisingly, they found that those who get information from social media and those who do not trust scientists showed a higher susceptibility to misinformation.

Several authors reported spread of misinformation and disinformation during the COVID-19 pandemic^{196 197} especially through social media.¹⁹⁸ In the meantime, tools for fact checking have been developed.^{199 200} A systematic monitoring facility of narratives circulating online and offline is necessary to measure the extent of misinformation across countries and also its impacts on potential future public health emergencies.

Trust

Trust in public authorities has been mentioned as a key factor behind vaccine acceptance or refusal.^{201 202} A survey study of eight European countries²⁰³ found that trust in government is a crucial factor influencing one's willingness to get vaccinated, and that it is highly related to one's political preference. A study in Austria found that only 46.2% of those who were hesitant towards a COVID-19 vaccine trusted the Austrian government to provide safe vaccines, and that vaccine hesitancy was higher among those who voted for the opposition parties.²⁰⁴

Figure 19 displays the relationships between trust in national government (y-axis), level of vaccine reluctance including both vaccine refusal and vaccine hesitancy (x-axis), and number of doses administered per 100 persons as of 24 October 2022 (size of the dot).²⁰⁵ The dots in dark blue refer to the values recorded in winter 2020-2021 and the ones in blue in winter 2021-2022. A negative correlation between trust in national government and vaccine reluctance level can be observed, which is consistent with what has been found in the literature. As already illustrated above, vaccine reluctance fell from 2020 to 2021 while most of the population has received a COVID-19 vaccine. However, it is not clear that low trust in government must lead to low vaccination rate. Most of the highly vaccinated countries align at around 10% of vaccine reluctance in the winter 2020-2021, while their trust levels vary from 25 to 65. It suggests that trust in government is not a definitive factor of vaccination progress. Meanwhile, the Eurobarometer does not point at a general increase or decrease of trust in national government during the pandemic up to the winter 2021-2022.

¹⁹⁵ Roozenbeek J. et al., '[Susceptibility to misinformation about COVID-19 around the world](#)', *Royal Society Open Science*, Vol. 7(10), 2020.

¹⁹⁶ Tagliabue F., Galassi L. and Mariani P., '[The "Pandemic" of disinformation in COVID-19](#)', *SN Comprehensive Clinical Medicine*, Vol. 2(9), 2020, pp. 1287-1289.

¹⁹⁷ Das R. and Ahmed W., '[Rethinking fake news: Disinformation and ideology during the time of COVID-19 global pandemic](#)', *IIM Kozhikode Society & Management Review*, Vol. 11(1), 2022, pp. 146-159.

¹⁹⁸ Gisondi M.A. et al., '[A deadly infodemic: Social media and the power of COVID-19 misinformation](#)', *Journal of Medical Internet Research*, Vol. 24(2), 2022, p. e35552.

¹⁹⁹ Hossain T. et al., '[COVIDLies: Detecting COVID-19 Misinformation on Social Media](#)', in *Proceedings of the 1st Workshop on NLP for COVID-19 (Part 2) at EMNLP 2020*, Online, Association for Computational Linguistics.

²⁰⁰ Kolluri N.L. and Murthy D., '[CoVerifi: A COVID-19 news verification system](#)', *Online Social Networks and Media*, Vol. 22(1), 100123, 2021.

²⁰¹ Prickett K.C. and Chapple S., '[Trust in government and Covid-19 vaccine hesitancy](#)', *Policy Quarterly*, Vol.17(3), 2021, pp. 69-71.

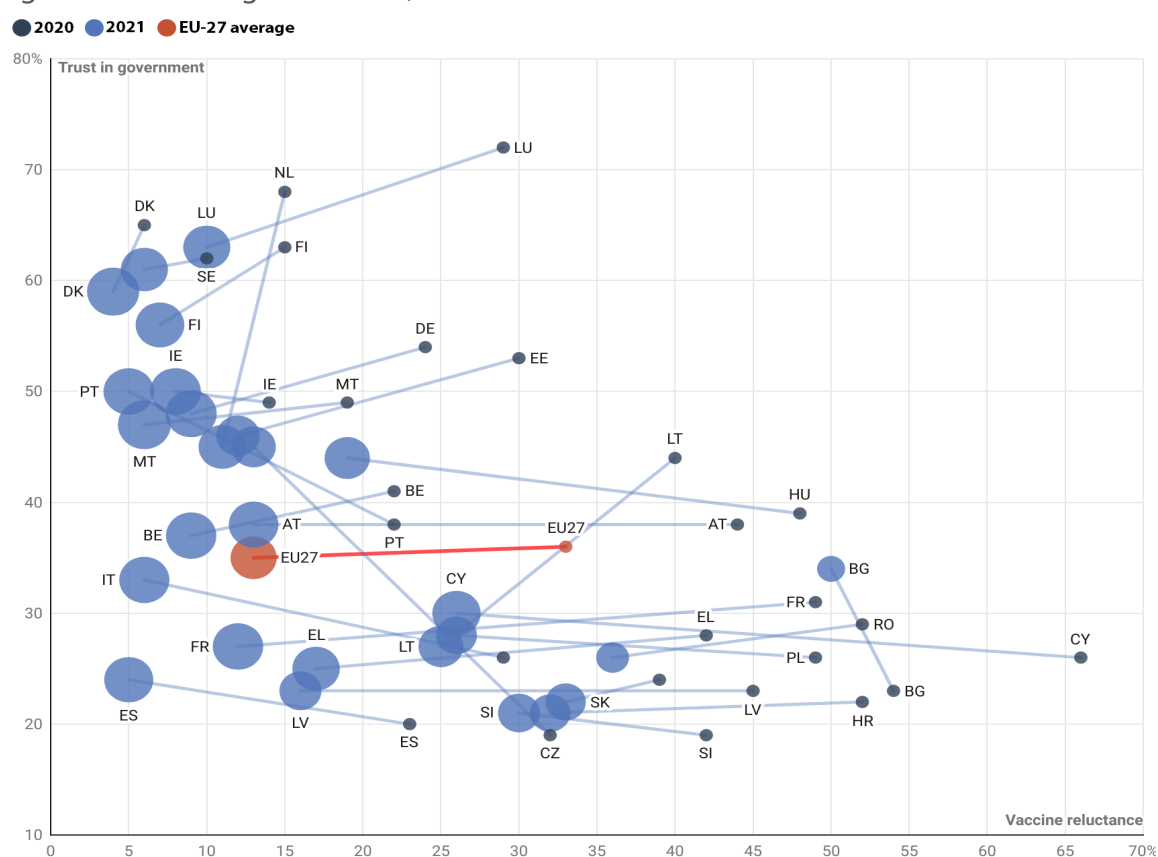
²⁰² Trent M. et al., '[Trust in government, intention to vaccinate and COVID-19 vaccine hesitancy: A comparative survey of five large cities in the United States, United Kingdom, and Australia](#)', *Vaccine*, Vol. 40(17), 2022, pp. 2498-2505.

²⁰³ Steinert J.I. et al., '[COVID-19 vaccine hesitancy in eight European countries: Prevalence, determinants, and heterogeneity](#)', *Science Advances*, Vol. 8(17), 2022.

²⁰⁴ Schernhammer E. et al., '[Correlates of COVID-19 vaccine hesitancy in Austria: Trust and the government](#)', *Journal of Public Health*, Vol. 44(1), 2022, pp. e106-e116.

²⁰⁵ Based on the responses to the Eurobarometer surveys, the vaccine reluctance level is computed by adding up the proportions of respondents who are hesitant to take a COVID-19 vaccine and those who plan to refuse vaccination.

Figure 19: Trust in government, vaccine reluctance and vaccination rate



Data source: [Standard Eurobarometer 94](#) (winter 2020/2021, fieldwork conducted in early 2021) and [Standard Eurobarometer 96](#) (winter 2021-2022, fieldwork conducted in early 2022) and the [ECDC Vaccine Tracker](#) (version 24 October 2022).

Note: This chart shows trust in national government and vaccine reluctance. Vaccine reluctance is measured by the sum of the proportion of respondents who would be hesitant or refuse to have a COVID-19 vaccine. The size of the dot corresponds to the overall vaccination progress at 1) 2021 Week 4 (range: 0-1.7) and 2) 2022 Week 4 (range: 55.1-204.6). This graph is designed using Datawrapper.

2.3. Vaccine effectiveness

By vaccine effectiveness, this study refers to how effective a vaccine is towards preventing infection or reducing the severity of an infection, observed in epidemiological or observational studies (the goal of such studies is usually to evaluate how vaccination prevents death, symptoms requiring admission to intensive care or hospital admission). A closely related concept is vaccine efficacy. Vaccine efficacy rate is measured in clinical trials in which participants are randomly assigned treatment or a placebo.

This section first summarises the scientific evidence of vaccine efficacy from peer-reviewed clinical trials of the three main authorised COVID-19 vaccines in the EU. Secondly, the research team also collected scientific evidence of vaccine effectiveness based on epidemiological methods. The main difference from clinical trials is that researchers do not administer the vaccination of the participants but use observational data to analyse vaccine effectiveness in a real-world setting. Comparatively, clinical trials are not numerous as they usually involve pharmaceutical companies, and the continuous monitoring of subjects in the trial locations could be costly. Epidemiological studies are more common and can be conducted in various settings. Both types tell important information about vaccine effectiveness. Clinical trials are experimental and precede vaccine authorisation. They

investigate efficacy in individuals while epidemiological studies assess vaccine effectiveness in defined populations. Such trials use very different methodologies and are subject to very strict standardised protocols and regulations. Meanwhile, epidemiological studies are usually independently conducted without participation of the vaccine manufacturer. Their results are therefore useful for verifying the claims from clinical trials. Finally, this section will end with a short analysis of excess mortality during the pandemic in the EU, trying to present an overview of the relationship between vaccinations and public health, which is of course determined also by other health-related and social factors.

This brief summary of evidence should not be considered as a comprehensive meta-analysis in the strict sense, which would deserve a full-length research paper. Instead, this summary attempts to document the results, in a systematic way, of some more prominent studies. The literature, especially the epidemiological studies of COVID-19 vaccines, is growing fast and this brief summary will inevitably miss some of the evidence produced by researchers worldwide.

2.3.1. Clinical trials

The COVID-19 pandemic led to a rise in interest in understanding clinical trials and scientific evidence. The production of scientific evidence of vaccines, and any medicinal products, is however a subject of its own and not intellectually accessible to the general public.

Clinical trials are generally classified into three phases. While phase II focusses on safety and dose-effect relationship, phase III is the larger and more important one as it tries to measure the safety and efficacy of the drug or vaccine. To perform an acceptable phase III trial, the researchers will test the vaccine with a large group of people (typically 1,000-3,000), which is called the 'sample'. The simplest setting is to divide the sample randomly into two groups, namely, the control group and the intervention group. The vaccine to be tested is administered in the intervention group while a placebo vaccine (or sometimes a vaccine for another disease) is used for the control group. The participants are 'blinded', meaning they do not know what they received between the real and the placebo vaccines, and in a 'double blinded' study the researchers themselves also do not know until the so-called 'code' is broken. Finally, the researchers determine infection rates in both groups (also called attack rates) and calculate the vaccine efficacy. In the meantime, they keep record of any side-effects of all subjects and medical complications of those infected subjects.

The basic formula to compute vaccine efficacy is the following:

$$VE = \frac{ARU - ARV}{ARU} \times 100\%$$

where VE refers to vaccine efficacy, ARU the attack rate of unvaccinated subjects and ARV the attack rate of vaccinated subjects. For example, in an evenly divided sample of 1,000 subjects, 100 of those in the control group and 25 in the treatment group are tested positive on COVID-19. The efficacy rate is 75%. A common misunderstanding is that it does not imply that with the vaccine the probability of not getting infected is 75% - rather that vaccinated people were at 75% lower risk of contracting COVID-19 than those in the placebo group.

Table 5 shows 11 peer-reviewed clinical trial studies of four EU/EEA approved COVID-19 vaccines. These studies include the four clinical trials listed by the ECDC in its review of efficacy of authorised COVID-19 vaccines.²⁰⁶ The list is however not exhaustive and may have missed some existing clinical trial studies. A study may have several trials targeting different groups of people, which are listed in the 'Objective' column. The trials were finished at different points of the pandemic and thus their targeted variants may differ, but this research paper does not take this into account.

²⁰⁶ ECDC, [Efficacy, effectiveness and safety of EU/EEA-authorised vaccines against COVID-19: living systematic review](#), 2022.

Table 5: Summary table of clinical trials for COVID-19 vaccines

No.	Authors	Journal	Publication date	Manufacturer	Objective	Efficacy rate (%)	95% CI lower	95% CI higher	Doses and evaluation time	Side-effects
1	Voysey et al.	The Lancet	09/01/2021	AstraZeneca	Against infection (adults)	62.1	41.0	75.5	2 standard doses	no pattern of serious adverse events
						90.0	67.4	97.0	a low dose followed by a standard dose	
2	Voysey et al.	The Lancet	19/02/2021			66.7	57.4	74.0	2 doses with an interval of 4-12 weeks, evaluation 14 days after the second dose	no mention of serious adverse effects
						81.3	60.3	91.2	longer prime boost interval	
						55.1	33.0	69.9	shorter prime boost interval	
						73.0	46.0	86.0	2 doses against Zeta (P.2) variant 4 to 12 weeks apart	
69.0	55.0	78.0	2 doses against B.1.1.28 variant 4 to 12 weeks apart							
3	Clemens et al.	Nature Communications	06/10/2021			88.2	5.0	99.0	2 doses against B.1.1.33 variant 4 to 12 weeks apart	
						69.0	-2.0	87.0	2 doses against Gamma (P.1) variant 4 to 12 weeks apart	
4	Falsey et al.	New England Journal of Medicine	16/12/2021			Against infection (>65)	74.0	63.5	80.5	2 doses 28 days apart
					83.5		54.2	94.1		

No.	Authors	Journal	Publication date	Manufacturer	Objective	Efficacy rate (%)	95% CI lower	95% CI higher	Doses and evaluation time	Side-effects
5	Sadoff et al.	New England Journal of Medicine	10/06/2021	Janssen	Against infection (adults)	66.9	59.0	73.4	14 days after administration	injection-site pain, headache, fatigue, myalgia, nausea
						66.1	55.0	74.8	28 days after administration	
					Against severe condition (adults)	76.7	54.6	89.1	14 days after administration	
						85.4	54.2	96.9	28 days after administration	
6	Baden et al.	New England Journal of Medicine	04/02/2021	Moderna	Against infection (adults)	94.1	89.3	96.8	2 doses 28 days apart	injection-site pain, erythema, tenderness
7	Creech et al.	New England Journal of Medicine	11/05/2022		Against infection (children 6-11)	88.0	70.0	95.8		injection-site pain, erythema
8	Polack et al.	New England Journal of Medicine	12/10/2020	Pfizer	Against infection (>15)	95.0	90.3	97.6	7 days after 2 doses	injection-site pain, fatigue, headache, fever
9	Frenck et al.	New England Journal of Medicine	27/05/2021		Against infection (children 12-15)	100.0	78.1	100.0	7 days after 2 doses administered 21 days apart	injection-site pain, headache, fatigue
10	Thomas et al.	New England Journal of Medicine	15/09/2021		Against infection (>12)	91.3	89.0	93.2	2 doses 21 days apart	decreased appetite, lethargy, asthenia, malaise, night sweats, hyperhidrosis
					Against severe disease (>12)	96.8	80.3	99.9	After 1 dose	
					Against infection (>12)	100.0	53.5	100.0	against Beta variant	
11	Walter et al.	New England Journal of Medicine	09/11/2021		Against infection (children 5-11)	90.7	66.7	98.3	7 days after 2 doses	injection-site redness, swelling, fever, chills

Focusing on the point estimate of efficacy rate, all four vaccines provide sufficient protection against infection with an average of 80.2%. The average efficacy rate of Janssen and Pfizer-BioNTech's vaccines against severe conditions is 86.3%. No severe side-effects are noted in the 11 studies, and with no death related to the vaccine in trial. Note that surveillance of side-effects is a long process. EMA as well as national authorities have been collecting evidence of side-effects and will update their recommendations when necessary. In short, it requires more than clinical trials to deter side-effects. Generally speaking, the clinical trial studies show that the four COVID-19 vaccines produce very satisfactory protection against either infection or severe complications. Note that all clinical trials listed above, as expected, involved at least one employee of the manufacturer as one of the authors.

The difficulty of recruiting a sufficient number of participants led to the lack of results for specific vulnerable groups of people such as pregnant women, breastfeeding mothers, and patients with chronic diseases, which is complicated by ethical concerns of recruiting vulnerable people as participants.

Conducting a clinical trial study during a pandemic is extremely difficult with many possible complications. Researchers require the participants who took either the vaccine in trial or a placebo to act and live normally while the virus is spreading across their communities. This raises ethical concerns since participants who receive the placebo may instead want to take the available COVID-19 vaccine that might offer protection. Most of the clinical trials were conducted in the United States and South America, with a few of them in the United Kingdom. The choices were very likely driven by regulatory restrictions and the epidemiological situations of the sites.²⁰⁷

2.3.2. Epidemiological studies

Studying vaccine effectiveness could also be based on epidemiological research methods in which researchers observe some health-related outcomes of a sample of individuals who have or have not taken the vaccine in study. The study design can be of different types (e.g. case control or cohort studies) that are either prospective or retrospective, but never imply the administration of vaccines to subjects. Vaccine effectiveness is usually defined as the per cent reduction in the frequency of COVID-19 among vaccinated people compared to people not vaccinated, or as the per cent reduction in the hospitalisation or death due to COVID-19.

For the analysis, 16 epidemiological studies have been selected, all published since February 2021, and 43 result entries are summarised in Table 6. The selection of these studies is based on several criteria; namely, the general prominence of the journal and current citation count. Another criterion is the comparativeness of the methods and results. The research team did not select the papers based on how effective the vaccine is. Yet, the list may not be a representative random sample from the vast literature.

²⁰⁷ For further information about ethical concerns of clinical trials during the COVID-19 pandemic, see Bierer B. et. al., [Ethical Challenges in Clinical Research During the COVID-19 Pandemic](#), *Bioethical Inquiry* 17, 2020, pp. 717–722.

Table 6: Summary of epidemiological studies

No.	Authors	Journal	Publication date	Manufacturer	Objective	Efficacy rate (%)	95% CI lower	95% CI higher	Doses and evaluation time
1	Katikireddi et al.	The Lancet	20/12/2021	AstraZeneca	Against hospitalisation and deaths (adults)	83.7	79.7	87.0	2-3 weeks after 2 doses
						63.7	59.6	67.4	18-19 weeks after 2 doses
2	Mazagatos et al.	Eurosurveillance	16/06/2021	Moderna	Against hospitalisation (older people)	88.4	74.9	94.7	2 doses
					Against death (older people)	97.0	91.7	98.9	
3	Dagan et al.	The New England Journal of Medicine	24/02/2021	Pfizer	Against infection (≥ 16)	92.0	88.0	95.0	7 days after second dose to end of the follow-up
					Against symptomatic infection (≥ 16)	94.0	87.0	98.0	
					Against hospitalisation (≥ 16)	87.0	55.0	100.0	
					Against severe condition (≥ 16)	92.0	75.0	100.0	
					Against symptomatic infection (>70)	98.0	90.0	100.0	
					Against symptomatic infection (pre-existing conditions)	89.0	68.0	98.0	
					Against symptomatic infection (obesity)	98.0	91.0	100.0	
					Against symptomatic infection (Type2 diabetes)	91.0	68.0	100.0	
					Against symptomatic infection (hypertension)	95.0	84.0	100.0	
4	Hall et al.	The Lancet	23/04/2021		Against infection (HCW)	85.0	74.0	96.0	7 days after second dose
5	Haas et al.	The Lancet	15/07/2021		Against hospitalisation (≥ 16)	97.2	96.8	97.5	7 days after second dose

No.	Authors	Journal	Publication date	Manufacturer	Objective	Efficacy rate (%)	95% CI lower	95% CI higher	Doses and evaluation time
					Against death (>=16)	96.7	96.0	97.3	
6	Olson et al.	MMWR. Morbidity and mortality weekly report	22/10/2021		Against hospitalisation (12-18)	93.0	83.0	97.0	14 days after second dose
7	Olson et al.	The New England Journal of Medicine	12/01/2022		Against hospitalisation (12-18)	94.0	90.0	96.0	illness onset after 14 days of two doses
					Against severe condition (12-18)	98.0	93.0	99.0	
					Against need of life support (12-18)	98.0	92.0	100.0	
8	Price et al.	The New England Journal of Medicine	30/03/2022		Against hospitalisation (5-11)	68.0	42.0	82.0	median 34 days after second dose
					Against hospitalisation (12-18)	40.0	9.0	60.0	median 162 days after second dose
					Against severe condition (12-18)	79.0	51.0	91.0	
9	Tan et al.	The New England Journal of Medicine	20/07/2022		Against infection (5-11)	65.3	62.0	68.3	7 days after the second dose
					Against hospitalisation (5-11)	82.7	74.8	88.2	
10	Rudan et al.	The Lancet Regional Health - Europe	22/09/2022		Against symptomatic infection (16-17)	95.6	77.0	99.1	Delta period at 2-5 weeks after second dose
						65.5	56.0	73.0	Omicron period at 2-5 weeks after second dose
					Against symptomatic infection (12-15)	81.2	77.7	84.2	
11	Nanduri et al.	MMWR. Morbidity and mortality weekly report	18/08/2021	Moderna	Against infection (nursing home residents)	50.6	45.0	55.7	14 days after second dose, delta variant
				Pfizer	52.4	48.0	56.4		
12	Self et al.		24/09/2021	Janssen	Against hospitalisation (>=18)	71.0	56.0	81.0	full sample period

No.	Authors	Journal	Publication date	Manufacturer	Objective	Efficacy rate (%)	95% CI lower	95% CI higher	Doses and evaluation time
		MMWR. Morbidity and mortality weekly report		Moderna		93.0	90.0	95.0	median 66 days after second dose
				Pfizer		91.0	88.0	93.0	median 69 days after second dose
13	Pilishvili et al.	The New England Journal of Medicine	16/12/2021	Moderna	Against infection (HCW)	88.9	78.7	94.2	1 dose
						96.3	91.3	98.4	2 doses
				Pfizer		77.6	70.9	82.7	1 dose
						88.8	84.6	91.8	2 doses
14	Paris et al.	Clinical Microbiology and Infection	13/07/2021	Pfizer, Moderna, AstraZeneca	Against infection (HCW)	94.6	61.0	99.2	14 days after second dose
15	Thompson et al.	The New England Journal of Medicine	15/07/2021	Pfizer, Moderna	Against infection (HCW and other frontline workers)	91.0	76.0	97.0	2 doses
16	Tenforde et al.	MMWR. Morbidity and mortality weekly report	28/01/2022		Against hospitalisation (>=18)	82.0	77.0	86.0	2 doses
						97.0	95.0	99.0	3 doses
					Against hospitalisation (>=18 with immunocompromising conditions)	69.0	67.0	78.0	2 doses
						88.0	81.0	93.0	3 doses

Table 7: Summary of epidemiological studies

Objective	Average effectiveness rate (%)	Lowest value	Highest value	No. of results
Against infection	84.5	50.6	98	20
Against hospitalisation/ severe condition	83.6	40	98	21
Against death	96.9	96.7	97	2

Source: Compiled by the authors on the basis of the results of the 16 studies.

Note that epidemiological studies are less comparable among themselves (since they may have applied different methods and adopted different effectiveness measures) than clinical trials that focus on the efficacy against infection using a randomised experimental design. This summary table does not include all results of these 16 studies but selects those results that are timely for the current situation. For example, the summary excludes those results testing the effectiveness of partial vaccination (i.e. one dose of a two-dose course) and focuses instead on the effectiveness towards preventing more severe conditions (i.e. hospitalisation and deaths) since infections have already become widespread. The summary also attempts to specify the objective of a specific test or the outcome measure of a result entry. Yet, minor differences among results remain. For instance, while most of the research define 'adults' as those aged above 18, some research also includes those aged above 15 in the adult sample. Despite these differences, 43 results are categorised into 3 types, namely, against infection, against hospitalisation, and against death. Table 7 summarises the results by showing the average value, the lowest, and the highest values among the results of each type of objectives.

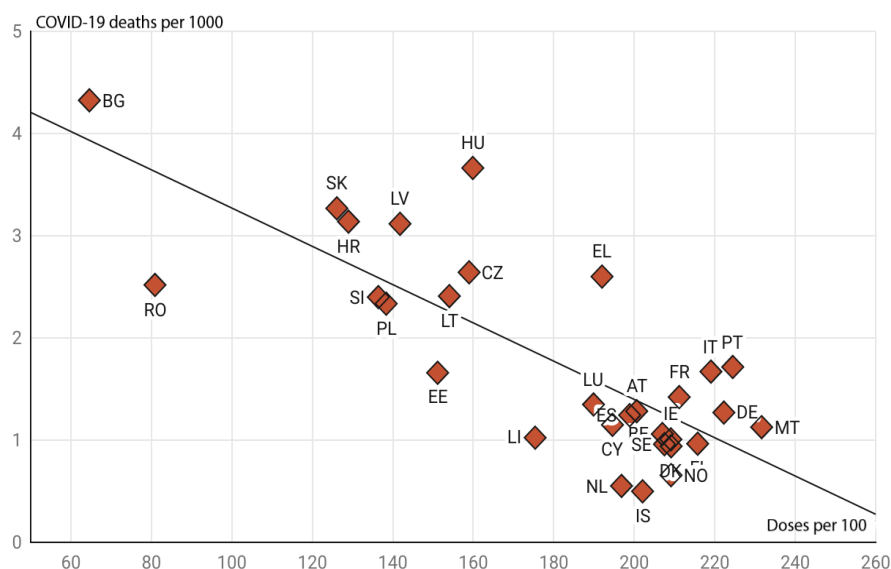
Generally speaking, the COVID-19 vaccines inspected are very effective in preventing infection, hospitalisation, and death.²⁰⁸

2.3.3. A correlation analysis of vaccine effectiveness

Clinical trials and epidemiological studies overwhelmingly point towards the same direction: COVID-19 vaccines help avoid infections, hospitalisations, and ICU admissions for more or less serious complications and deaths. While clinical trials and epidemiological studies are useful in identifying the causal links between vaccinations and some health outcomes within a short timeframe, this research paper aims to give a bigger picture to check if a highly vaccinated society tends to cope better with the COVID-19 pandemic on a longer term. Figure 20 plots 30 countries' (EU27+3 EEA) cumulative COVID-19 deaths per 1,000 persons in a country (from January 2021 up to August 2022) against the total doses administered per 100 persons (up to August 2022). As COVID-19 vaccination programmes began roughly in January 2021 across Europe, it is convenient to pick January 2021 as the starting point. Since the COVID-19 death counts do not include those that happened in 2020, the result is not complicated by the possibility that countries with higher COVID-19 mortality rates in 2020 were also slow in vaccination in 2021 and 2022. A negative correlation between them is found, which points to the same conclusion that COVID-19 vaccines helped suppress the severity of the virus.

²⁰⁸ WHO [recommends](#) requiring an approved vaccine to have an efficacy rate higher than 50%.

Figure 20: COVID-19 vaccines administered per 100 persons/COVID-19 mortality rate



Source: Authors' visualisation based on the [ECDC Vaccine Tracker](#) (version 24 October 2022).

Note: This scatter plot shows the relationship between COVID-19 vaccine doses administered per 100 persons in a country (cumulative doses until August 2022) and COVID-19 mortality rate (cumulative COVID-19 deaths per 1,000 persons from January 2021 to August 2022). A linear trend line is added. This graph is designed using Datawrapper.

Figure 21: COVID-19 vaccines administered per 100 persons and excess mortality rate



Source: Authors' visualisation based on the [ECDC Vaccine Tracker](#) (version 24 October 2022) and [Eurostat](#) (data available up to August 2022).

Note: This scatter plot shows the relationship between COVID-19 vaccine doses administered per 100 persons in a country (cumulative doses until August 2022) and excess mortality rate (average monthly excess mortality rate between January 2021 and August 2022). A linear trend line is added. This graph is designed using Datawrapper.

Another way to study the impact of vaccination is to employ the measure of excess mortality.²⁰⁹ Eurostat has computed monthly excess mortality rates for the same list of countries, which is defined as 'the number of deaths from all causes measured during a crisis, above what could be observed under "normal" conditions'.²¹⁰ According to Eurostat, the reference is the average monthly deaths from 2016 to 2019. Excess mortality rate is thus the percentage difference versus the average monthly deaths. Figure 21 shows a negative correlation between excess mortality rate and doses administered per 100 persons. In other words, a more vaccinated country is associated with lower excess mortality rate during the period from January 2021 to August 2022.

This simple correlation analysis is less precise, being unable to establish a direct causal impact of vaccines but provides some additional findings. First, excess death rates remain high even in 2022. Explaining this phenomenon requires some attention from governments and researchers. Finding out the reasons behind it will help all stakeholders better understand the effectiveness and safety of the approved COVID-19 vaccines and also identify the correct non-pharmaceutical interventions for future pandemics. Second, it is not guaranteed that a more vaccinated country tends to suffer from fewer excess deaths. This finding points to a bigger question that asks what the determinants are. One important driver is the behaviour of individuals. A vaccinated person may make more risky decisions due to feeling protected against the virus. Policies could also be a reason. Governments might have substantially relaxed measures because of their high vaccination rate. Researchers should also pay attention to the long-term safety of the COVID-19 vaccines and also closely monitor the impacts of Long COVID. The COVI committee asked pharmaceutical companies for information on Long COVID but did not receive concrete answers. An observational cohort study in the Netherlands found that 12.7% of patients diagnosed with COVID-19 developed at least one long COVID symptom with moderate severity. Meanwhile, many patients with chronic diseases have not been given adequate treatments, and diagnoses of cancer were delayed.²¹¹ Climate should also be taken into account. The heatwave in the summer of 2022 could have contributed to some death cases. Finally, this correlation analysis from a macro-perspective does not capture other economic and institutional factors that could influence the outcome.

Most importantly, the data shows to policymakers that vaccination alone is insufficient in protecting the population. Evidence-based relaxation of containment policies, well-supported healthcare systems, long-term recovery plans for the economy and patients suffering from Long COVID, scientific surveillance systems for viruses and diseases, and cooperative behaviours by the public are all necessary for lowering a country's death rate back to its pre-pandemic level.

2.4. EU added value of vaccine and vaccination strategies

This section will attempt to perform an EU added value test as defined in the Better Regulation Toolbox.²¹² In short, this section studies the EU's and Member States' actions by asking if an EU action would have been better achieved at Member State level, or if a national action would have been better achieved at Union level.

The development of COVID-19 vaccines was exceptionally fast compared to other vaccines. A typical vaccine development process could take 5 to 10 years.²¹³ Before the first COVID-19 vaccine was announced, experts had been pessimistic about whether an effective vaccine could be ready in 2020

²⁰⁹ Unsurprisingly, COVID-19 death rate and excess death rate are strongly and positively correlated. The correlation coefficient between them is 0.62.

²¹⁰ Eurostat, [Excess mortality – statistics](#).

²¹¹ Metzger et al., [Treatment delay and tumor size in patients with oral cancer during the first year of the COVID-19 pandemic](#), *Head and Neck*, Vol. 43(11), 2021, pp. 3493-3497.

²¹² See European Commission, [Better regulation: guidelines and toolbox](#), 2021.

²¹³ Johns Hopkins, [Webpage](#) Vaccine Research & Development: How Can COVID-19 Vaccine Development Be Done Quickly and Safely?

or even in 2021. In retrospect, neither the EU nor other big nations could have done more to accelerate their development. The manufacturing capacity of pharmaceutical and biotech companies expanded rapidly as they received public support from the EU and national governments. The establishment of the Task Force for Industrial Scale-Up of COVID-19 vaccines allowed an increased production of COVID-19 vaccines in the EU. In this regard, decentralised investment in vaccine development and production would have been less efficient as duplications of efforts will be highly likely.

Decentralised procurement has been the norm where Member States negotiate contracts of purchases for vaccines with pharmaceutical companies. The largest contribution of the EU, agreed by almost all the experts and officials interviewed, were the Advance Purchase Agreements (APAs) for COVID-19 vaccines and the Joint Procurement Agreements (JPAs) that avoided a scramble for vaccines and other medicinal products within the EU and ensured even distribution of vaccines among EU countries, albeit not globally. The experts consulted for this study agree that EU procurement is needed since many EU countries alone would not be able to compete with global players. Representatives from pharmaceutical companies such as Pfizer, Moderna, or GSK also praised the use of APAs and JPAs at COVI committee hearings on 5 September and 10 October.²¹⁴

However, HIPRA, a Spanish pharmaceutical company, noted that signing large APAs with single providers could dissuade competition and innovation at other companies or for differing vaccination technologies. Moreover, civil society members raised some concerns about the transparency of the negotiation process with the vaccine manufacturers and the details of the contracts. Despite the fact that the norm is decentralised procurement, it is unclear whether centralisation of vaccine procurement would have led to a higher level of transparency. As long as pharmaceutical companies maintain their will to protect their business secrets and hold the veto power of disclosing any information of the contracts, the release of information will still be limited. However, democratic pressure by citizens might have been able to push for more direct responses from governments. The handling of procurement might not have been optimal, but the centralised effort has avoided a potential scramble at vaccines among Member States, which could have damaged the harmony and solidarity of the internal market.

The fast-track authorisation process provided by EMA shortened the approval time of COVID-19 vaccines from on average a year to within a month, valid for all 27 EU Member States. This has been valuable for all Member States to start their vaccination campaigns rapidly, and especially for smaller Member States who probably could not have accomplished this accelerated process on their own. EMA's work during the COVID-19 pandemic for the authorisation of COVID-19 vaccines was appreciated by the experts interviewed and was based on a close collaboration with the pharmaceutical companies that applied for a conditional marketing authorisation for their COVID-19 vaccine. Although some criticised that EMA was comparatively slow²¹⁵, the fact that EMA did not apply an emergency mechanism for COVID-19 vaccines approval, like the UK and the US did, ensures higher trust in the quality and safety of the COVID-19 vaccines. It is worth noting that Member States retain authority over vaccine marketing within their own countries. Hungary and Slovakia rolled out vaccines beyond those recommended by the EMA. Yet, independent national authorisations would have consumed applicants' time and attention, causing unnecessary delays and duplications of efforts.

EU influence on Member States in the deployment of vaccines was understandably small. The main contribution in this regard comes from the ECDC and EMA, which provide recommendations on the use of vaccines, and the European Commission, which provided guidance in its October 2020 Communication on Preparedness for COVID-19 vaccination strategies and vaccines deployment. Yet designing the vaccination strategy remains a Member State competence, which implies that

²¹⁴ See recordings of the COVI meetings of [5 September 2022](#) and [10 October 2022](#).

²¹⁵ See Reuters, [Europe's vaccine hesitancy](#), 1 April 2021.

national (or sub-national) authorities make the final decisions about who to vaccinate, when, and how. This caused heterogeneous vaccination strategies across Member States, with sometimes significant differences in the timeline or scope of vaccine administration. In that sense, the added value of the EU in vaccination strategy mainly relies on non-binding recommendations as well as data collection and analysis.

Though Member States have full competence on establishing their vaccination strategy, the recommendations of EMA and the ECDC, e.g. in terms of vaccine administration and timing, have been a useful resource on which to base these strategies. This is true especially for small Member States, which valued the work of EMA and the ECDC and the possibility to have access to knowledge and expertise at EU level as they did not necessarily have the internal research capacity. Yet, for other Member States, the added value of EU-level recommendations was less evident, with some relying completely on their own national health authorities' recommendations. In the area of competence, the opinions of interviewees and desk research by the team do not find consistent views. Centralisation of recommendation at Union level might have avoided confusions but could have ignored national epidemiological and demographic differences.

The collection and analysis of data was another aspect where the value the EU provided was most appreciated by Member States. For instance, the work of the ECDC to provide unbiased scientific evidence was mentioned as an added EU value to the work of Member States to build their national vaccination strategies and to provide a comparative overview of the epidemiological evolution and vaccination progress of the 27 Member States. This benefit was somehow limited by the urgency of the situation, where Member States needed to proceed rapidly and take decisions while the work of the ECDC was lagging behind. The ECDC's budget and its number of employees were indeed considered to be insufficient to manage the tasks for which the ECDC is responsible for during the crisis (Anderson & Mossialos, 2020; Forman & Mossialos, 2021). In that sense, the ECDC's extended mandate adopted by the European Parliament and the Council in November 2022 will allow the ECDC to play a bigger role in improving European preparedness and response.²¹⁶ For example, the new mandate endows the ECDC the competence to 'monitor the level of vaccination coverage' (Article 5a(4)) and 'collects new information, use the relevant data collected by competent bodies, or both' to coordinate post-marketing monitoring of the effectiveness and safety of vaccine, together with EMA (Article 5a(5)).

2.5. Main findings

Impacts of the EU vaccines strategy

- The EU vaccines strategy contributed to speeding up vaccine development by establishing selection criteria for vaccine candidates, introducing a derogation on the legislation on GMOs and providing flexibility in labelling and packaging requirements.
- The EU and Member States have also provided funding to support the R&D of COVID-19 vaccines. However, the use of public money and the need of affordable vaccines stirred up a public debate of whether the manufacturers should keep the intellectual property rights during a global pandemic.
- The EU also helped accelerate the production of COVID-19 vaccines through the establishment of the Task Force for Industrial Scale-up of COVID-19 vaccines, and subsequently the Commission Directorate-General HERA. The forthcoming initiative 'EU FAB' would further strengthen the vaccine production capacity of the EU.
- EU-level APAs ensured a united EU approach to the procurement of vaccines and contributed to securing access to vaccines for its Member States.

²¹⁶ [Regulation \(EU\) 2022/2370](#) of 23 November 2022 amending Regulation (EC) No 853/2004 establishing a European Centre for Disease Prevention and Control.

- The flexible regulatory process under the EU vaccines strategy (notably the COVID-19 EMA pandemic task force, the rapid scientific advice, the rolling review, and the Conditional Marketing Authorisation) expedited the development and authorisation of COVID-19 vaccines in the EU. These tools were however resource-intensive and would be less sustainable during the post-pandemic period.
- The implementation of clinical trials faced significant difficulties during a global pandemic, such as participants from a control group taking an approved COVID-19 vaccine for protection, impacting the scientific conclusions of the trials.
- The EU's authorisation of COVID-19 vaccines started later, took more time, and followed different procedures from the UK and the US. Yet, the EU's conditional marketing authorisation is a well-established and systematic regulatory mechanism, ensuring positive benefit-risk balance and rigid post-approval safeguards and controls.
- During the COVID-19 crisis, concerns about transparency have become prominent. The Commission has so far failed to disclose detailed information on the public spending on vaccine development. The published APAs and contracts contain a considerable number of redactions without any justifications.
- To ensure a high level of transparency, EMA has taken exceptional measures to publish clinical trials data related to COVID-19 medicinal products.

National vaccination strategies and coverage

- Based on the recommendations made at EU level, national health authorities introduced their different national vaccination strategies, though sharing some common approaches. Some Member States have found the EU's recommendations on vaccination challenging to follow as the EU released them with short or non-existent consultations with Member States, while being deemed helpful by small Member States with fewer scientific capacity.
- Most of the EU27 Member States have only marketed the vaccines that have been authorised by EMA. However not all EMA-authorised vaccines are subsequently used by Member States in their vaccination programmes. Member States' national vaccination strategies also differ in their vaccination schedules for priority groups, recommendations for children vaccination, recommendations for the use of additional doses ('boosters'), and recommendations for the vaccination of previously infected individuals.
- Some Member States have imposed a vaccination mandate for certain age groups; others have made vaccination compulsory for certain types of workers to exercise their professional activities. The majority of the EU27 have introduced a so-called 'COVID-19 certificate' to access certain public places to control infections and boost vaccination uptake. The 'EU digital COVID-19 certificate' further fostered the interoperability of these certificates across the EU.
- By mid-2021, the country with slowest progress represented only one-fifth of the progress in the best-vaccinated country. Vaccination progress in general plateaued during the first half of 2022. By mid-2022, most of the countries were able to vaccinate a large part of their population, with 25 of the 27 EU countries reaching above 100 doses per 100 persons and 9 of EU27 reaching above 200 doses per 100 persons.
- As of September 2022, 15 EU Member States have succeeded in vaccinating more than 80% of their older population with 2 doses. Eastern European countries are lagging behind their Western peers.
- Children were the last groups to get vaccinated. As of 1 November 2022, only three vaccines (Pfizer-BioNTech, Moderna, and Novavax) are authorised for use in children by EMA. By the end of September 2022, no EU Member State has reportedly reached 50% of its population aged 18 and below double-jabbed, and the third-dose coverage is even lower.
- The key variables determining vaccination coverage studied in this research paper are national vaccination programmes, public opinion, infodemics, and trust in public authorities.
- Vaccine hesitancy dropped significantly from February/March 2021 to February 2022 in the EU, and vaccine refusal also decreased in most of the Member States. The two main factors

influencing vaccine hesitancy are the availability of scientific evidence about the effectiveness, and the safety of the vaccines.

- Misinformation and disinformation during the COVID-19 pandemic especially spread through social networks and have been key drivers of vaccine hesitancy. Trust in government is another crucial factor influencing one's willingness to vaccinate, especially in the initial phase of vaccination.
- The impact of national vaccination strategies on vaccination coverage is not obvious, as many of them do not directly aim to increase the national vaccination coverage per se, but to plan vaccine deployment in the most efficient and safe manner. Vaccination mandates for specific groups of population do not ramp up vaccination rates significantly, while the use of COVID-19 certificates in some countries is believed to be a reason behind surges in vaccination progress.
- Some countries' vaccination campaigns did not include certain groups of population, e.g. the population without social security number or homeless people.

Vaccine effectiveness

- The study of 11 peer-reviewed clinical trial studies of four EU/EEA approved COVID-19 vaccines (AstraZeneca, Janssen, Moderna, and Pfizer-BioNTech) shows sufficient protection of these vaccines against infection.
- These studies did not find severe side effects. However, it is noted that the surveillance of side effects is a long-term process that goes well beyond clinical trials.
- The difficulty of recruiting a sufficient number of participants for clinical trials led to the lack of results for specific vulnerable groups of people, such as pregnant women, breastfeeding mothers, and patients with chronic diseases.
- The analysis of the 16 epidemiological studies showed that on average the COVID-19 vaccines inspected are very effective in preventing infection, hospitalisation, and death.
- The data shows a negative correlation between COVID-19 deaths and overall vaccination progress. While excess mortality has still been high in 2022 across the EU, it is also negatively correlated with the overall vaccination progress.

3. EU Public health response to COVID-19 (Pillar 3)

The COVID-19 pandemic put unprecedented strain upon the health systems and economies of EU Member States, and presented the opportunity for a central role for the EU in the coordination and management of responses to the unfolding public health crisis. Member States reported similar sets of challenges, such as severe capacity strain on hospitals and intensive care units (ICUs) and acute shortages of essential medical countermeasures.²¹⁷ The resulting devastation was clear evidence that unilateral measures taken at the level of the individual Member States to address and ameliorate the crisis at hand were largely inadequate compared to the magnitude of the crisis.²¹⁸ It called for a collective and multilateral approach, coordinated at the EU level, towards ensuring secure medical supply chains for vaccines, medicines and other countermeasures,²¹⁹ and a managed path towards socio-economic recovery.²²⁰

The administration of public health, which includes the provision of public health services, healthcare systems and associated decision-making, is essentially a national competence that lies firmly within Member States' purview.²²¹ Even so, at the start of the COVID-19 pandemic, the EU had the legal and institutional basis needed to respond to the public health emergency as well as organising and coordinating necessary action. These stemmed from Decision 1082/2013/EU on cross-border health threats, giving the European Commission the broader power to recognise a public health emergency at Union level.²²² The decision provided the basis for Union action to cover the 'monitoring, early warning of, and combating serious cross-border threats to health', complementary to Member State policies. It also included a provision for establishing a Health Security Committee (HSC) to coordinate national health responses to serious cross-border health threats through communication and sharing of best practices on national preparedness activities. Decision 1082/2013/EU was superseded by Regulation (EU) 2022/2371 on serious cross-border threats to health, adopted on 23 November 2022,²²³ which draws on the lessons learned from the COVID-19 pandemic.

Box 3: Definition of serious cross-border threats to health

"serious cross-border threat to health" means a life-threatening or otherwise serious hazard to health of biological, chemical, environmental or unknown origin [...], which spreads or entails a significant risk of spreading across the national borders of Member States, and which may necessitate coordination at Union level in order to ensure a high level of human health protection.'

Source: [Regulation \(EU\) 2022/2371](#) on serious cross-border threats to health, Article 3(1).

The EU's capacity for coordinated health action was facilitated through its specialised agencies – the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA) – and through policy mechanisms such as the Joint Procurement Agreement (JPA). Established in 2005, the ECDC is the EU's public health agency responsible for strengthening EU

²¹⁷ Anderson M., Mckee, M. and Mossialos E., '[Editorial: Covid-19 exposes weaknesses in European responses to outbreaks](#)', *British Medical Journal*, 368, 2020.

²¹⁸ Beaussier A. and Cabane L., '[Improving the EU response to pandemics: key lessons from other crisis management domains](#)', *E-international relations*, 2021.

²¹⁹ OECD, '[The face mask global value chain in the COVID-19 outbreak: Evidence and policy lessons](#)', *OECD Policy Responses to Coronavirus (COVID-19)*, 2020.

²²⁰ Mauer N. et al., '[Towards a European Health Union: new instruments for stronger and more resilient health systems](#)', *Eurohealth*, Vol. 28(1), 2022, pp. 57-61.

²²¹ Forman R. and Mossialos E., '[The EU Response to COVID-19: From Reactive Policies to Strategic Decision-Making](#)', *Journal of Common Mark Studies*, Vol. 59(S1), 2021, pp. 56-68.

²²² [Decision No 1082/2013/EU](#) of 22 October 2013 on serious cross-border threats to health, para. 1.

²²³ [Regulation \(EU\) 2022/2371](#) of 23 November 2022 on serious cross-border threats to health.

defences against infectious diseases.²²⁴ Under its founding regulation,²²⁵ the ECDC is tasked with the mission to 'identify, assess, and communicate current and emerging threats to human health from communicable diseases'. EMA, founded in 1995, and like the ECDC a decentralised EU agency, is responsible for the scientific evaluation, supervision and safety monitoring of medicines in the EU, including vaccines.²²⁶ The European Joint Procurement Agreement is a centralised, multilateral procurement system for the emergency provision of vaccines, antivirals and medical countermeasures against cross-border health threats.²²⁷

In addition, the EU coordinated its immediate emergency response to the COVID-19 pandemic through a set of civil protection and financial instruments that provided emergency assistance and structural support to Member States. These include the Emergency Support Instrument (ESI)²²⁸ and unspent cohesion policy funds through the Coronavirus Response Investment Initiative (CRII and CRII+).²²⁹ The immediate emergency response was designed to offer liquidity to Member States in their pandemic-related spending and to shore up support for the priority sectors in healthcare, Small and Medium Enterprises (SMEs), and labour markets. The union civil protection mechanism (UCPM) operates the rescEU reserve for coordinating and providing emergency medical stockpiles and relief.

EU longer-term response mechanisms to the COVID-19 pandemic underpin investments for recovery, and strengthen preparedness for future health shocks. These include the Recovery and Resilience Facility, which is at the core of Next Generation EU, with about €37 billion allocated to health investments through the national recovery and resilience plans. The EU4Health programme, cohesion policy funds and Horizon Europe play a critical role in the long-term perspective.

Chapter 3 will first examine the EU's framework for coordinating the public health response to COVID-19, and focus then on the policy instruments and competences that were deployed towards public health response and crisis management. Making use of the Better Regulation guidelines, subsequent sections will conduct an ex-post assessment of the EU's public health response to the COVID-19 pandemic, covering the following criteria: effectiveness (section 3.2), coherence (section 3.3), and the EU added value (section 3.4).

The discussion on 'effectiveness' will consider how successful the EU public health intervention was in achieving its stated objectives and, conversely, the extent to which the progress towards the objectives can be attributed to the policy intervention.²³⁰ Next, the section on 'coherence' will consider how well different interventions and policy instruments work together at the EU, national, and international levels.²³¹ Accordingly, the analysis will either highlight the synergies that improved overall performance or alternately point towards possible points of tension, e.g. objectives which are potentially contradictory, or inefficient approaches. Finally, the section on 'EU added value' will reflect on changes that can be reasonably attributed to EU intervention beyond what can be reasonably expected of or attributed to national actions by the Member States.²³²

It is still too early to carry out a full evaluation of the EU's COVID-19 response in line with the Better Regulation Guidelines. Moreover, key proposals of different initiatives were not accompanied by an impact assessment due to the urgency to act. In light of these constraints, findings in this chapter

²²⁴ ECDC, '[What we do](#)' (Accessed 15 November 2022).

²²⁵ [Regulation \(EC\) No 851/2004](#) of 21 April 2004 establishing a European Centre for disease prevention and control.

²²⁶ EMA, '[Who we are](#)' (Accessed 15 November 2022).

²²⁷ European Commission, [Webpage](#) Joint Procurement of medical countermeasures. Ensuring Proper Preparedness.

²²⁸ [Council Regulation \(EU\) 202/521](#) of 14 April 2020 activating the emergency support under Regulation (EU) 2016/369, and amending its provisions taking into account the COVID-19 outbreak.

²²⁹ European Commission, [Questions and answers](#): European coordinated response to corona, 13 March 2020.

²³⁰ European Commission, [Better Regulation Toolbox, Tool #47: Evaluation criteria and questions](#), 2021, pp. 403-404.

²³¹ European Commission, [Better Regulation Toolbox, Tool #47: Evaluation criteria and questions](#), 2021, pp. 408-409.

²³² European Commission, [Better Regulation Toolbox, Tool #47: Evaluation criteria and questions](#), 2021, pp. 409-411.

are based on interviews with stakeholders conducted for the purpose of this study. Altogether, 23 interviews with 30 persons took place during autumn 2022 (see Annex II). These interviews provide a cross-section of views from stakeholders involved in or affected by the EU's response to the COVID-19 pandemic.

3.1. The EU's policy response to COVID-19: instruments and strategies

The EU's public health response to the COVID-19 pandemic involved the deployment of policies and strategies aimed at addressing the immediate health crisis as well as social and economic recovery over the long term. The EU's policy response to COVID-19 will be discussed in section 3.1 with a specific focus on the European Health Union (section 3.1.1), the Joint Procurement Agreement (section 3.1.2), civil protection through rescEU (section 3.1.3), financial support through ESI and CRII/CRII+ (section 3.1.4), and EU contributions to global health through the Team Europe Initiative (section 3.1.5). To allow for an ex-post assessment, the background, objectives, and key initiatives for each initiative will be outlined in detail.

Whereas the first four sections focus respectively on COVID-19-related measures in public health, civil protection, and financial support coordinated and delivered by the EU, the last section will address the EU's contributions to global health and to EU partner countries through the 'Team Europe' Initiative (TEI).²³³ TEI is a collaborative initiative, that combines the resources from EU institutions, EU Member States and European financial institutions, such as the European Investment Bank (EIB) and the European Bank for Reconstruction and Development (EBRD) – to support and assist EU partner countries in dealing with the impacts of the COVID-19 pandemic.²³⁴

3.1.1. European Health Union

Background

The European Health Union (EHU) is a set of legislative measures designed to improve the coordination of the EU's response to COVID-19 pandemic, and more generally, to strengthen the EU's resilience against and preparedness for (present and future) cross-border health threats. It was launched on 11 November 2020 in the European Commission's Communication on 'Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats',²³⁵ which outlined the first building blocks of the European Health Union.

The agenda for the EHU was presented in the context of a worldwide resurgence in COVID-19 infections and the second wave in Europe, exacerbated by the highly transmissible Alpha (B.1.1.7) variant.²³⁶ In November 2020, death rates peaked in Europe due to COVID-19-related cases. According to figures from Eurostat, 2020 was a period of 'excess mortality'²³⁷ with over 45,000 *more deaths* occurring in the EU between March and November 2020, compared with the same period in

²³³ European Commission, Commissioner Urpilainen: Team Europe with our partners against Covid-19, [press statement](#), 28 March 2020.

²³⁴ European Commission (2022), Covid-19: Team Europe has delivered EUR. 47.7 billion to help its partners address the pandemic and its consequences. [Press release](#), 13 September.

²³⁵ European Commission, Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats, Communication [COM\(2020\) 724](#), 11 November 2020.

²³⁶ Walker A.S. et al., '[Tracking the Emergence of SARS-CoV-2 Alpha Variant in the United Kingdom](#)', *New England Journal of Medicine*, Dec. 30, 385, pp. 2582-2585.

²³⁷ 'Excess mortality' refers to the number of deaths from all causes during a crisis, in comparison to previous years. It is used in epidemiology and public health as a comprehensive measure of the total impact of a pandemic on deaths, accounting for misdiagnosis and under-reportage. Giatto C. et al., '[Excess Mortality during the Coronavirus pandemic \(COVID-19\)](#)', *Our World in Data*, University of Oxford, 12 November 2022.

2016-2019.²³⁸ In absolute numbers in November 2020, the daily COVID-19 infection rate was 200,000-260,000 across Europe, with a daily death rate of 4,000-6,000; in comparison, the recorded global daily infections were 480,000 and global daily death rates ranged from 8,000-11,000.²³⁹

At the same time, there was a growing recognition that the COVID-19 pandemic was symptomatic of an interconnected viral age. Present-day globalisation, including global environmental change (e.g. loss of biodiversity, climate change) and demographic transition (e.g. population mobility), is causally linked to infectious disease burden²⁴⁰ and found to contribute to the risk of disease outbreaks caused by new, emerging, and re-emerging diseases.²⁴¹ Moreover, demographic factors within Europe, in particular ageing populations with associated health vulnerabilities and disease patterns are expected to inflate healthcare demand and associated public expenditure.²⁴²

Accordingly, the EHU agenda aims to strengthen the EU-level protection, prevention, preparedness, and response to cross-border health threats through improved global health security. This is to be achieved and delivered through investments into resilient national health systems, swift and agile decision-making, and the provision of appropriate and assured funding under the EU4Health programme. The EHU's specific provisions will be outlined in the discussion of key initiatives below.

Objectives

The EHU's objectives are to improve the EU-level 'protection, prevention, preparedness, and response against human health hazards'.²⁴³ The Commission's Communication defined that the primary purpose of a strong Health Union is to prepare the EU to 'prevent, prepare for and manage health crises both at the EU and global level' and to support long-term recovery. The EHU emphasises coordination and joint actions, including joint procurement between Member States – both during health crises (response) and for underlying health conditions (preparedness). In so doing, the EHU was expected to contribute to 'a more resilient EU internal market and a sustained economic recovery'.²⁴⁴

Key initiatives

The key initiatives for the EHU were presented and developed in three consecutive sets of actions from November 2020 to November 2022. The first set of actions was articulated in the Commission's Communication of 11 November 2020. It contained three legislative proposals, or the 'first building blocks', for the EHU: (1) an upgrade of Decision 1082/2013/EU on serious cross-border health threats; (2) a strengthening of the ECDC's mandate; and (3) an extension of the mandate of EMA. As the Communication clarified, the proposals were designed to raise 'a robust and cost-effective framework' to enable EU Member States to respond collectively to future health crises. The Communication followed Commission President Ursula von der Leyen's 2020 State of the Union

²³⁸ Eurostat, [Excess mortality in 2020 reached its peak in November](#), 16 February 2021.

²³⁹ Figures from the Institute of Health Metrics and Evaluation (IHME), University of Washington School of Medicine, cited in: Deol T., [Covid-19: Europe is back to November 2020 numbers, severe cases higher](#), *DownToEarth*, 23 November 2021.

²⁴⁰ Saker L. et al., [Globalization and Infectious Disease: a review of the interlinkages](#), Social, Economic and Behavioural (SEB) Research, Special Topics No. 3, UNICEF/ UNDP/World Bank/WHO, 2004.

²⁴¹ Medialdea Carrera R., [The importance of cross-border pandemic preparedness](#), *Eurohealth*, 26, 34, 2020.

²⁴² Suk J.E. and Semenza J.C., [Future Infectious Disease Threats to Europe](#), *American Journal of Public Health*, Vol. 101(11), 2011, pp. 2068-2079.

²⁴³ European Commission, Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats, Communication [COM\(2020\) 724](#), 11 November 2020.

²⁴⁴ Ibid.

address, calling on Europe to embrace the lessons from the pandemic and 'build a European Health Union'.²⁴⁵

The second set of actions concerned the creation of a European Health Emergency Preparedness and Response Authority (HERA) in September 2021, as a key milestone of the EHU. It was announced in the 2021 State of the Union speech as part of a 'new health preparedness and resilience mission for the whole of the EU'.²⁴⁶ Finally, the third and most recent set of actions stems from the EU global health strategy, which was presented on 30 November 2022, comprising the EHU's external dimension. Especially the latter sets of actions build on the lessons the European Commission identified in the June 2021 Communication 'Drawing the early lessons from the COVID-19 pandemic'.²⁴⁷

Overall, the EHU revolves around the following seven key initiatives:²⁴⁸

- a revised legal framework for serious cross-border health threats;
- the establishment of HERA;
- revised mandates of the ECDC and EMA;
- the creation of a European Health Data Space;
- a Pharmaceutical Strategy for Europe;
- Europe's Beating Cancer Plan;
- and the EU global health strategy.

1. Regulation (EU) 2022/2371 on serious cross-border threats to health, adopted on 23 November 2022,²⁴⁹ provides an upgraded legal framework to combat serious cross-border health threats and repeals the framework set out in Decision No. 1082/2013/EU. The regulation's main objective is to bolster Union-level preparedness and response capacity for all cross-border health threats, thereby drawing on the early lessons from the COVID-19 pandemic.

With regard to EU preparedness, the regulation creates the Union prevention, preparedness and response plan on health crises (Article 5), which is complementary to the respective plans at Member States level. In terms of EU response, the regulation provides for the adoption of temporary public health measures (Article 22) whose activation is triggered by recommendations by the ECDC and the WHO, or the independent advisory committee established under Article 24 of the regulation. Moreover, the regulation provides for the recognition of public health emergencies at Union level (Article 23).

The legal framework includes the provision to adopt case definitions for surveillance of novel threats and provides for the establishment of a network of EU reference laboratories as well as a network to support monitoring of disease outbreaks that are relevant to substances of human origin. It includes a solid legal mandate for the Health Security Committee to coordinate national responses to cross-border health risks and crisis communication, and provisions for increased international cooperation and global action.

²⁴⁵ European Commission, [State of the Union Address by President von der Leyen at the European Parliament Plenary](#), 16 September 2020.

²⁴⁶ European Commission, [State of the Union Address by President von der Leyen](#), 15 September 2021.

²⁴⁷ European Commission, Drawing the early lessons from the COVID-19 pandemic, Communication [COM\(2021\) 380](#), 15 June 2021.

²⁴⁸ European Commission, [Webpage](#) European Health Union.

²⁴⁹ [Regulation \(EU\) 2022/2371](#) of 23 November 2022 on serious cross-border threats to health.

Further cornerstones of the regulation include:

- provisions that broaden information sharing and reporting requirements and analysis regarding health systems indicators, and increased cooperation between Member States and Union agencies and bodies (in particular the ECDC and EMA), and international organisations, such as the WHO;
- provisions for a rapid alert system (the EU Early Warning and Response System or EWRS) for notification of serious cross-border health threats, activation of a coordinated response at the EU-level, improved risk assessment and management of cross-border health threats;
- and a joint procurement mechanism for medical countermeasures (Article 12).

2. A second key initiative comprises the establishment of the European **Health Emergency Preparedness and Response Authority (HERA)**²⁵⁰ as a separate Commission Directorate-General on 16 September 2021. Its specific mission is to prevent, detect, and respond rapidly to health emergencies. Its activities cover a full range of responsibilities, from intelligence gathering to building response capacities through the development, production, and distribution of medicines, vaccines, and other medical countermeasures.²⁵¹

In so doing, HERA is expected to provide an 'agile, robust, and sustainable health security structure' towards ensuring the timely development, procurement, and equitable distribution of essential medical countermeasures.²⁵² Similar to other EHU initiatives, the organisational structure and remit of HERA are underwritten by the early lessons from the COVID-19 pandemic. These concern significant vulnerabilities in global medical supply chains and fragmented intelligence gathering, both of which were found to have delayed and inhibited the Union-level response to the COVID-19 pandemic.²⁵³ As the fulcrum of the Union-level response to cross-border health threats, HERA is meant to operate during both preparedness and crisis.

Accordingly, HERA's activities follow two distinct impact logics, or 'operating modes', corresponding respectively to preparedness and emergency response.²⁵⁴ In the preparedness phase (before the crisis), HERA will work closely with Member States to analyse, identify, and prioritise possible health threats. In this capacity, HERA will support research on new and emerging pathogens and develop the industrial capacity to produce and supply essential medical countermeasures and technologies. These include diagnostics, vaccines, and therapeutics. A crucial aspect of preparedness efforts is geared towards building European capabilities in clinical trials. The 'HERA Incubator' constitutes a central facet of the EU's bio-defence preparedness plan. A tangible achievement towards this comprised the clinical research network VACCCELERATE, which was launched as part of the HERA Incubator to coordinate and conduct COVID-19 clinical trials.²⁵⁵ With regards to building industrial capacities in the manufacturing of medical countermeasures, HERA is expected to build on EU FAB

²⁵⁰ European Commission, Introducing HERA, the European Health Emergency preparedness and Response Authority, the next step towards completing the European Health Union, Communication [COM\(2021\) 576](#), 16 September 2021.

²⁵¹ European Commission, European Health Emergency preparedness and Response Authority (HERA): Getting ready for future health emergencies, [press release](#), 16 September 2021.

²⁵² Proposal for a Council Regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level, Communication [COM\(2021\) 577](#), 16 September 2021.

²⁵³ Ibid.

²⁵⁴ European Commission, [Public Health: HERA](#).

²⁵⁵ Vaccelerate, ['Who we are'](#) (Accessed 15 November 2022).

as a multi-technology production capacity for vaccines and medicines manufacturing at the European level.²⁵⁶

In emergency response, HERA will receive stronger powers for swift decision-making and implementation of emergency measures. In such a scenario, HERA will operate under a Health Crisis Board and have recourse to emergency funding to launch mechanisms for monitoring and the targeted development, procurement, and purchase of medical countermeasures and raw materials. In an emergency, the EU FAB facilities will serve as hub for emergency research and innovation plans in dialogue with Member States and the production base and inventory for countermeasures.²⁵⁷

In order to carry out the full remit of its operations, HERA has been allocated multi-source funding of €30 billion, which is sourced from different financial instruments such as NextGenerationEU, EU4Health, Horizon Europe, the Union Civil Protection Mechanism (UPCM), the European Defence Fund, the Recovery and Resilience Facility, REACT-EU, and the Neighbourhood, Development and International Cooperation Instrument.²⁵⁸ In addition, HERA may also draw on private funding, national budgets of Member States, and multi-country projects, e.g. the planned IPCEI (Important Projects of Common European Interest) Health.²⁵⁹

3. A third set of initiatives towards the constitution of the EHU concerns the *extended mandates of the ECDC and EMA* (see also section 4.2). The first of these stems from Regulation (EU) 2022/2370²⁶⁰ of 23 November 2022, which amends Regulation (EC) No 851/2004 establishing a European Centre for Disease Prevention and Control (ECDC). The new regulation is geared towards redress of the gaps identified to have undermined the effectiveness of the ECDC's response to the COVID-19 pandemic: specifically, these concerned data gaps, i.e. the dearth of complete and comparable data, and communication with the public. For example, the European Ombudsman's strategic enquiry (OI/3/2020/TE) dated 5 February 2021 highlighted challenges in the ECDC's data gathering functions, with attendant consequences for the ECDC's ability to provide timely advice to the public.²⁶¹ Under the revised Regulation, the ECDC is provided capacities to support preparedness, surveillance, risk assessment, and early warning and response to future health emergencies.²⁶² As part of its expanded mandate, the ECDC plans to take a 'One Health' approach (Box 4) and thus consider the interlinkages between the health of humans, animals, and the environment.

In parallel with the changes to the ECDC, the mandate of European Medicines Agency (EMA) was also strengthened to facilitate a coordinated Union-level response. The changes to EMA are set out in Regulation (EU) 2022/123 of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices.²⁶³ Similar to many other EHU aspects, the EMA Regulation is informed by the early lessons of the

²⁵⁶ European Commission, European Health Emergency preparedness and Response Authority (HERA): Getting ready for future health emergencies, [press release](#), 16 September 2021.

²⁵⁷ Ibid.

²⁵⁸ Ibid.

²⁵⁹ European Commission, Website Public health, [Funding](#).

²⁶⁰ [Regulation \(EU\) 2022/2370](#) of 23 November 2022 amending Regulation (EC) No 851/2004 establishing a European Centre for Disease Prevention and Control.

²⁶¹ European Ombudsman, [Executive summary of strategic inquiry OI/3/2020/TE into how the ECDC performed during the COVID-19 crisis](#).

²⁶² European Commission, Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 851/2004 establishing a European Centre for disease prevention and control, Communication [COM\(2020\) 726](#), 11 November 2020.

²⁶³ [Regulation \(EU\) 2022/123](#) of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices.

COVID-19 pandemic. Specifically, these concern COVID-19-related supply difficulties and serious shortages of medical devices, occasioned by the surge in demand for ventilators, surgical masks, and COVID-19 test kits.²⁶⁴ In other words, the experience of COVID-19 underscored the urgency to establish long-term structures that provide a 'more solid and effective monitoring of shortages of medical devices' that can occur during a public health emergency and the mechanisms to coordinate and manage those shortages. As noted in Regulation (EU) 2022/123, this will require various measures, including 'increased and early dialogue with the medical devices industry and healthcare professionals' to prevent and mitigate those shortages.

Accordingly, EMA's enhanced capabilities include monitoring and mitigating the risk of shortages of critical medicines and medical devices; the provision of scientific advice on medicine to treat, prevent and diagnose diseases; coordination of studies to monitor the safety and effectiveness of vaccines; and the coordination of clinical trials.²⁶⁵

Box 4: Definition of the One Health approach

'One Health' is an integrated and unifying approach intended to balance and optimise the health of people, animals, and the environment. Accordingly, the 'One Health' approach designs and implements programmes, policies, legislation, and research in which multiple sectors communicate and work together to achieve better public health outcomes.

Source: WHO, [One Health](#).

4. The European Health Data Space (EHDS) constitutes a milestone in the EU's digital transformation. It builds on rigorous data privacy, interoperability, and security requirements to improve healthcare delivery across the EU and provide research and industry with high-quality health data for product development.²⁶⁶

The European Commission's Proposal for a European Health Data Space (EHDS), released in May 2022, is the first proposal for a domain-specific common European data space.²⁶⁷ A distinction between health data for primary use and secondary use is central to the EHDS. To this end, as the European Commission's proposal clarifies, the EHDS Regulation aims to improve individuals' access to and control of their electronic personal data (primary use), while facilitating data re-use for societal good across the EU (secondary use).

The EHDS comprises a health-specific ecosystem comprising of rules, common standards and practices, infrastructures, and a governance framework for empowering individuals to access and control their personal health data, and to provide consistent and reliable health data for research, innovation, policy-making, and regulatory activities.²⁶⁸

The creation of an EU-wide health data space has been called for and supported by the European Parliament, as voiced in a number of resolutions. In February 2019 the European Parliament adopted a resolution on the implementation of the Cross-border Healthcare Directive, emphasising that eHealth interoperability should be made a priority to improve global patient records and continuity

²⁶⁴ Ibid.

²⁶⁵ Ibid.

²⁶⁶ European Commission, [Questions and Answers](#): EU Health: European Health Data Space (EHDS), 3 May 2022.

²⁶⁷ European Commission, Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space, Communication [COM\(2022\) 197](#), 3 May 2022.

²⁶⁸ European Commission, [Webpage](#) European Health Data Space.

of care in alignment with patient privacy.²⁶⁹ A resolution adopted in December 2019²⁷⁰ on the digital transformation of health in the Digital Single Market stressed that citizens have the right to access and share their personal health data in accordance with the General Data Protection Regulation (GDPR) to obtain better healthcare.²⁷¹ Furthermore, in November 2021, the Parliament welcomed the initiative of building an interoperable digital infrastructure for the European Health Data Space.²⁷²

The European Council's conclusions of 21 and 22 October 2021 (EUCO 17/21) stressed the importance of making rapid progress on other existing and future initiatives to unlock the value of data in Europe, notably through a comprehensive regulatory framework that facilitates data portability and fair access to data and ensures interoperability.²⁷³

5. The Pharmaceutical Strategy for Europe is designed to fulfil patient needs and support a competitive and innovative pharmaceutical industry in Europe through diversified and secured supply chains, environmental sustainability, and crisis preparedness.²⁷⁴ It was adopted on 25 November 2020.

The Pharmaceutical Strategy addresses the specific areas of concern highlighted by the COVID-19 pandemic – i.e. the procurement of vaccines and wider supply chain issues – together with reconciling patient priorities with the economic needs of the pharmaceutical sector. The former refers to the rising burden of diseases brought on by ageing European populations, access to affordable treatments for chronic, debilitating, and rare diseases (e.g. neuro-degenerative diseases, paediatric cancers, rare and orphan diseases),²⁷⁵ and the rising challenges of anti-microbial resistance (AMR) and climate change.²⁷⁶ The EU is the second largest market in the world for pharmaceuticals, with a competitive industry marked by SMEs and large companies. The EU pharmaceutical sector generates a trade surplus of €109.4 billion and employs over 800,000 people (figures for 2020).²⁷⁷ Until the 1990s, the EU pharmaceutical industry was dominated by 'big companies' more interested in developing therapeutics for common diseases with a high market potential.²⁷⁸ In contrast, at present, the EU's pharmaceutical sector is characterised by the active role of SMEs, with a strong focus on the development of new medicines in under-served therapeutic areas such as biological approaches, potential pandemics, and rare and infectious diseases.²⁷⁹

A competitive and resilient pharmaceutical industry is therefore of strategic interest to patient's needs, jobs and economic growth, and better equipping the EU and its Member States for crisis

²⁶⁹ European Parliament, [Resolution](#) of 12 February 2019 on the implementation of the Cross-Border Healthcare Directive, 2018/2018 (INI).

²⁷⁰ European Parliament, [Resolution](#) of 18 December 2019 on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society (2019/2804(RSP)).

²⁷¹ Evroux C., [European health data space](#), EPRS, European Parliament, September 2022.

²⁷² European Parliament, [Resolution of 24 November 2021](#) on a pharmaceutical strategy for Europe (2021/2013(INI)).

²⁷³ European Council, Special meeting of the European Council, 21 and 22 October 2020, (EUCO 17/20), [Conclusions](#), 2 October 2020.

²⁷⁴ European Commission, Pharmaceutical Strategy for Europe, Communication [COM\(2020\) 761](#), 25 November 2020.

²⁷⁵ European Commission, Joint evaluation of Regulation (EC) No 1901/2006 on medicinal products for paediatric use and Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products, [SWD\(2020\) 163](#), 11 August 2020.

²⁷⁶ European Commission, Pharmaceutical Strategy for Europe, Communication [COM\(2020\) 761](#), 25 November 2020.

²⁷⁷ Ibid.

²⁷⁸ European Commission, Joint evaluation of Regulation (EC) No 1901/2006 on medicinal products for paediatric use and Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products, [SWD\(2020\) 163](#), 11 August 2020.

²⁷⁹ European Federation of Pharmaceutical Industries and Associations (EFPIA), [SMEs in Europe – Biopharmaceutical SMEs and their role in the industry](#).

response. Medicinal shortages have long been recognised as an area of ongoing and serious concern in the EU, aggravated by the COVID-19 pandemic. These concerns surrounding the challenges to European strategic autonomy have been highlighted by different EU institutions. The European Council (EUCO 13/20)²⁸⁰ had already recognised in 2020 that 'achieving strategic autonomy in the field' was a key EU objective. The Council, in its conclusions of 5 April 2022, reiterated this imperative,²⁸¹ highlighting the avoidance of excessive reliance on third-country financial institutions and infrastructures as a priority. Similarly, the European Parliament's resolution of 17 September 2020²⁸² linked the European dependence in the health sector to the relocation of production to third countries, mainly in China and India.

Pharmaceutical manufacturing and supply chains are complex, intensely globalised, and found to be insufficiently diversified.²⁸³ The EU pharmaceutical industry is, for instance, heavily reliant on global supply chains and global markets for raw pharmaceutical materials, intermediates, and active pharmaceutical ingredients (APIs), as it is for STEM specialists and a skilled workforce.²⁸⁴ Although Europe maintained a strong manufacturing footprint, the supply chain still relies heavily on subcontractors to produce pharmaceutical raw materials outside the EU, where labour costs and environmental standards are lower. According to a recent estimate, approximately 40% of medicinal products marketed in the EU originate in third countries, mainly in China and India, and 60-80% of active chemical ingredients are manufactured outside the EU (figures for 2020).²⁸⁵

The Pharmaceutical Strategy addresses the structural issues within the pharmaceutical sector through regulatory action. In recognition of these strategic priorities, the Pharmaceutical Strategy encompasses four work strands or pillars of action:²⁸⁶

- ensuring access to affordable medicines for patients and fulfilling unmet medical needs;²⁸⁷
- support competitiveness, innovation, and sustainability of the EU's pharmaceutical sector;
- enhanced resilience through diversified and secure supply chains to address medicines shortages, environmental sustainability, and crisis preparedness;²⁸⁸
- promote high standards of medical products globally.²⁸⁹

The Commission is expected to present a first set of proposals based on the pharmaceutical strategy during the first quarter of 2023.²⁹⁰

6. Europe's Beating Cancer Plan,²⁹¹ presented in February 2021, outlines actions for structural improvements to the prevention, treatment, and care of cancer. It also seeks to address the negative impact the COVID-19 pandemic had on cancer care. The Plan rests on four actions that address risk

²⁸⁰ [European Council Conclusions of 2 October 2020](#) (EUCO 13/20).

²⁸¹ Council of the European Union, Council adopts conclusions on strategic autonomy of the European economic and financial sectors, [press release](#), 5 April, 2022.

²⁸² European Parliament, [Resolution](#) of 17 September 2020 on the shortage of medicines – how to address an emerging problem (2020/2071(INI)).

²⁸³ Yu D.E.C., Razon L.F. and Tan R.R., 'Can global pharmaceutical supply chains scale up sustainably for the COVID-19 crisis?', *Resources, Conservation and Recycling*, 2020;159:104868.

²⁸⁴ European Commission, Pharmaceutical Strategy for Europe, Communication [COM\(2020\) 761](#), 25 November 2020.

²⁸⁵ European Parliament, [Resolution](#) of 17 September 2020 on the shortage of medicines – how to address an emerging problem (2020/2071(INI)).

²⁸⁶ European Commission, Pharmaceutical Strategy for Europe, Communication [COM\(2020\) 761](#), 25 November 2020.

²⁸⁷ European Commission, [Webpage](#) Making medicines more affordable.

²⁸⁸ European Commission, [Webpage](#) Structured dialogue on security of medicines supply.

²⁸⁹ European Commission, Pharmaceutical Strategy for Europe, Communication [COM\(2020\) 761](#), 25 November 2020.

²⁹⁰ For details on these initiatives, see the European Commission's work programmes for [2022](#) and [2023](#).

²⁹¹ European Commission, Europe's Beating Cancer Plan, Communication [COM\(2021\) 44](#), 3 February 2021.

factors and promote a healthy lifestyle. These are (1) prevention; (2) early detection to improve access, diagnostics, and support; (3) diagnosis and treatment, to ensure an integrated and comprehensive cancer and improve healthcare access; and (4) quality of life of cancer patients and survivors.

The Europe's Beating Cancer Plan taps into a broad array of EU policies, such as digitalisation, research and innovation, and disease prevention, to include actions and flagship initiatives that cover the entire disease pathway.²⁹² The lessons from the COVID-19 pandemic, and most pertinently vaccine development, were clear evidence of the progress to be made from pooling resources, clear goal setting, the commitment to adequate funding, and the effectiveness of Union-level action and coordination. Accordingly, the Beating Cancer Plan leverages these learnings through a 'Health in All Policies' (HiAP) approach (Box 5) that is premised on a multisectoral approach and extensive stakeholder consultation. The Beating Cancer Plan is expected to draw €4 billion worth of funding from the EU4Health programme and other EU instruments and channel resources to Member States towards building national healthcare systems that are responsive to cancer care.²⁹³

The Commission's Communication on Europe's Beating Cancer Plan outlines substantive actions to mitigate the impact of the COVID-19 pandemic on cancer care and support structural improvements for a more sustainable cancer pathway.²⁹⁴ The proposed set of actions is expected to span across policy areas, from employment, education, social policy and equality through marketing, agriculture, energy, the environment and climate to transport, cohesion policy, and taxation.

As explicitly acknowledged in the Europe's Beating Cancer Plan, the European Parliament provided input through the work of the Special Committee on Beating Cancer (BECA), which had been in place from September 2020 to December 2021.²⁹⁵ Based on the report²⁹⁶ of the BECA committee, on 16 February 2022 the European Parliament adopted its final recommendations²⁹⁷ for a comprehensive EU strategy to fight cancer. The resolution focused on cancer prevention, equal access to combating cancer, equal access to cancer care across borders, and a European approach towards addressing medicinal shortages.

Box 5: Definition of the Health in All Policies (HiAP) approach

"Health in All Policies" means an approach to the development, implementation, and review of public policies, regardless of the sector, whereby the health implications of decisions are taken into account, and which seeks to achieve synergies and to avoid harmful health impacts being caused by such policies, in order to improve the health of the population and health equity.'

Source: [Regulation \(EU\) 2022/2371](#) on serious cross-border threats to health, Article 3(8)

7. The EU global health strategy announced in November 2022 represents the external dimension of the EHU and is a key plank of the EU's strategic autonomy.²⁹⁸ The strategy deepens the EU's leadership and affirms the responsibility for tackling the key global challenges and health inequalities in alignment with the UN Sustainable Goals (SDGs). Another objective of the strategy is to combat health threats. It promotes a sustainable meaningful partnership of equals drawing on the Global Gateway.²⁹⁹

²⁹² European Commission, Webpage [A Cancer Plan for Europe](#).

²⁹³ Ibid.

²⁹⁴ European Commission, Europe's Beating Cancer Plan, Communication [COM\(2021\) 44](#), 3 February 2021.

²⁹⁵ [Webpage](#) of the BECA special committee.

²⁹⁶ European Parliament, [Outcome, work and activities of the Special Committee on Beating Cancer](#), 16 February 2022.

²⁹⁷ European Parliament, [Resolution](#) of 16 February 2022 on strengthening Europe in the fight against cancer – towards a comprehensive and coordinated strategy (2020/2267(INI)).

²⁹⁸ European Commission, [Webpage](#) European Health Union.

²⁹⁹ European Commission, EU to improve global health security and deliver better health for all, [press release](#), 30 November 2022.

The strategy puts forward three key interrelated priorities in dealing with global challenges:

- deliver better health and well-being of people across the life course;
- strengthen health systems and advance universal health coverage;
- prevent and combat health threats, including pandemics, applying a One Health approach.

It seeks to regain the ground lost to reach the universal health-related targets in the 2030 SDGs. To do so, the strategy refocuses European action on achieving universal health coverage, strengthening primary health care, and tackling the root causes of ill health, like poverty and social inequalities. The strategy stresses the importance of addressing the drivers of ill health, such as climate change and environmental degradation, food security, conflict, and other humanitarian crises. Therefore, the strategy introduces a robust 'health-in-all-policies' (HiAP) approach to ensure that a wide variety of policies genuinely contribute to health goals. It also seeks to improve global health security, thereby protecting citizens from threats by stepping up prevention, preparedness and response, and early detection.

3.1.2. Joint Procurement Agreement (JPA) and medical countermeasures

Box 6: Joint procurement of critical medical countermeasures under Regulation 2022/2372³⁰⁰

With the aim of addressing the supply shortages that became apparent during the COVID-19 pandemic,³⁰¹ the 'Emergency Framework Regulation' (EU) 2022/2372 establishes a new framework of measures for ensuring the supply of crisis-relevant medical countermeasures, which can be activated in the event of a public health emergency. The regulation includes provisions for the procurement, purchase, and manufacturing of crisis-relevant medical countermeasures and raw materials, and a mechanism for monitoring shortages of crisis-relevant medical countermeasures to counteract shortages.

The regulation sets up an advisory Health Crisis Board, activated in the event of crisis and ceasing to operate immediately after. This board is composed of the Commission and one representative from each Member State and mandated with ensuring coordination and information exchange between the various EU actors and Member States. To monitor shortages, the Commission – advised by the Health Crisis Board – is tasked with maintaining, by means of implementing acts, a list of crisis-relevant medical countermeasures and raw materials. The Commission should also monitor the supply and demand of the latter, including production capacity, stockpiles, possible critical aspects, and the risk of disruption in the supply chains and purchasing agreements.

The Health Crisis Board advises the Commission on the appropriate mechanism to purchase crisis-relevant medical countermeasures and raw materials, through activation of existing contracts or the negotiation of new contracts. In that regard, the Commission can act as a central purchasing body for participating Member States, under the rules and procedures laid down in the EU's Financial Regulation, using available instruments, such as Council Regulation (EU) 2016/369 on the provision of emergency support within the Union and the joint procurement procedure referred to in Article 12 of Regulation (EU) 2022/2371 on serious cross-border health threats.

This Emergency Framework Regulation complements existing tools. Throughout 2020, in response to the COVID-19 crisis, the European Commission used the EU's Joint Procurement Agreement for medical countermeasures (JPA), enabled by Decision 1082/2013/EU. However, given that this instrument was designed as a preparedness instrument, it 'does not provide the flexibility and speed required to respond to the extreme urgency of the COVID-19 pandemic'.³⁰² The ensuing discussion will therefore focus on the JPA, both as predominantly the preparedness tool it was designed for and its role on the frontline of the EU's crisis response.

³⁰⁰ [Council Regulation \(EU\) 2022/2372](#) of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level.

³⁰¹ European Commission, Proposal for a Council regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level, [COM\(2021\) 577](#), 16 September 2021.

³⁰² European Court of Auditors, [Special report 19/2022](#): EU COVID-19 vaccine procurement – Sufficient doses secured after initial challenges, but performance of the process not sufficiently assessed, 12 September 2022.

Background

The Joint Procurement Agreement for medical countermeasures (JPA) is a voluntary political agreement that allows EU institutions, Member States, and participating third countries to jointly purchase medical countermeasures for serious cross-border health threats, including vaccines, antivirals and other treatments.

The EU JPA was born out of accelerated need for medical countermeasures after the H1N1 influenza pandemic in 2009 highlighted the vulnerabilities of public procurement of medical supplies,³⁰³ and in particular, the differences in the purchasing power of EU Member States to obtain pandemic vaccines and medications. Enabled by Article 5 of Decision 1082/2013/EU,³⁰⁴ the EU JPA came into force in 2014, with an initial pool of 14 signatories.³⁰⁵ To date, the number of signatories has risen to 37, including all EU and EEA countries, the UK and the countries of the Western Balkans.³⁰⁶ The remit of the agreement allows for crisis procurement of vaccines and antivirals and other medical countermeasures such as personal protective equipment (PPE), respiratory ventilators, and diagnostic tests, essential to counter serious cross-border health emergencies.

Objectives

The objective of the JPA is to secure more equitable access to specific medical countermeasures and improved security of supply, together with more balanced prices for the participating countries.³⁰⁷ The JPA determines the practical arrangements governing the mechanism for emergency procurement, the decision-making process with regard to the choice of the procedures, and it also organises the assessment of tenders and the award of contracts.

The JPA mechanism does not use EU funds to purchase in-demand medical supplies on behalf of the participating states. Instead, it offers them the choice to purchase the supplies from the concluded contracts, using their national budgets.³⁰⁸

Key initiatives

During the COVID-19 pandemic, the JPA 'has emerged as a core instrument to support a pan-European purchasing of PPE, ventilators and devices necessary for coronavirus testing'.³⁰⁹ The first COVID-19-related joint procurement calls were launched in March 2020.³¹⁰ Since then, the Commission has launched a number of joint procurement competitions for the purchase of PPE, ventilators, and intensive care unit (ICU) medicines.³¹¹ Successful tenders include procurement of

³⁰³ Nicoll A. and McKee M., 'Moderate pandemic, and not many dead: learning the right lessons in Europe from the 2009 pandemic', *European Journal of Public Health*, 20(5), 2020, pp. 486-488.

³⁰⁴ [Decision No 1082/2013/EU](#) of 22 October 2013 on serious cross-border threats to health.

³⁰⁵ These were: (1) Belgium, (2) Croatia, (3) Czechia, (4) Cyprus, (5) Estonia, (6) Greece, (7) Latvia, (8) Malta, (9) Netherlands, (10) Portugal, (11) Slovakia, (12) Slovenia, (13) Spain, and (14) UK. European Commission, [Webpage](#) Signing ceremonies for Joint Procurement Agreement.

³⁰⁶ European Commission, [Webpage](#) Signing ceremonies for Joint Procurement Agreement.

³⁰⁷ European Commission, [Webpage](#) Joint Procurement of medical countermeasures – Ensuring Proper Preparedness.

³⁰⁸ European Court of Auditors, [The EU's initial contribution to the public health response to COVID-19](#), Review no 1, 2021.

³⁰⁹ McEvoy E. and Ferri D., 'The Role of the Joint Procurement Agreement during the COVID-19 Pandemic: Assessing Its Usefulness and Discussing Its Potential to Support a European Health Union', *European Journal of Risk Regulation*, Vol. 11(4), 2020, pp. 852-853.

³¹⁰ European Court of Auditors, [The EU's initial contribution to the public health response to COVID-19](#), Review no 1, 2021.

³¹¹ European Commission, Coronavirus: Commission signs a joint procurement contract with Gilead for the supply of Remdesivir, [press release](#), 8 October 2020.

³¹² Ibid.

gloves and coveralls for €1.4 billion, eye and respiratory protection for €150 million, and ventilators for €750 million.³¹³

As outlined in Chapter 2.1.2., the EU's joint public procurement for COVID-19 vaccines followed a different pattern, under the EU vaccines strategy. The EU vaccines strategy was launched with the express purpose of accelerating the development, authorisation, manufacture, and distribution of vaccines across the Member States. It gave the European Commission the executive authority to sign Advance Purchase Agreements (APAs) with pharmaceutical companies on behalf of the Member States and coordinate the supply and distribution of vaccines. This involved a significant change in how the JPA had so far operated. Whereas previously the EU provided for collective purchasing under the JPA, the Commission now had no role in distribution.

Table 8: EU vaccine portfolio

Company	Type of vaccine	No of doses needed (per person)	No of doses (secured)	Status
Pfizer-BioNTech	mRNA	2 doses	2.4 billion	Approved
Moderna	mRNA	2 doses	460 million	Approved
AstraZeneca	Adenovirus	2 doses	400 million	Approved
Janssen Pharmaceuticals	Adenovirus	1 dose	400 million	Approved
Sanofi-GSK	Protein	2 doses	300 million	Approved ¹
HIPRA Human Health	Protein	1 dose	250 million	Under EMA rolling review ²
Novavax	Protein	2 doses	200 million	Approved
Valneva	inactivated virus vaccine		1.2 million	Approved ³

Source: European Commission, [EU's Vaccine Portfolio](#) (accessed: 8 January 2023), with updated information from: ⁽¹⁾ Sanofi-Pasteur: marketing authorisation issued on 10/11/2022. Source: EMA, [COVID-19 vaccines authorised](#) [stated as 'Under EMA rolling review' on [EU's Vaccine Portfolio](#)]; ⁽²⁾ HIPRA Human Health: start of rolling review 29/3/2022. Source: EMA, [COVID-19 vaccines under rolling review](#); ⁽³⁾ Valneva: marketing authorisation issued on 24/6/2022. Source: EMA, [COVID-19 vaccines authorised](#). [stated as 'In development' on [EU vaccine portfolio](#)].

3.1.3. Civil Protection, RescEU, and medical stockpiles

Background

Introduced in 2001, the European Civil Protection Mechanism (UCPM) has supported, coordinated and supplemented participating states in the field of civil protection for more than two decades. The UCPM supports prevention, preparedness and response activities, thus covering the whole disaster management cycle. It can be activated by any participating state affected by a natural or man-made disaster inside or outside the EU. Currently, the participating states include all EU Member States and eight other countries (Albania, Bosnia and Herzegovina, Iceland, North Macedonia, Norway, Montenegro, Serbia and Türkiye). The UCPM is managed by the Commission's Directorate-General for European Civil Protection and Humanitarian Aid Operations (DG ECHO).

³¹³ McEvoy E. and Ferri D., 'The Role of the Joint Procurement Agreement during the COVID-19 Pandemic: Assessing Its Usefulness and Discussing Its Potential to Support a European Health Union', *European Journal of Risk Regulation*, Vol. 11(4), 2020, pp. 851-863.

The remit of its actions is broad, covering both assets and expertise as well as material assistance.³¹⁴ Actions include search and rescue operations, forest firefighting, medical personnel deployment, medical equipment, water purification, emergency shelter, and repatriation of EU citizens.³¹⁵ In the consolidated version of Decision No 1313/2013/EU on the Union Civil Protection Mechanism, a disaster is defined as 'any situation which has or may have a severe impact on people, the environment, or property, including cultural heritage.'³¹⁶

Drawing on the experience of the early months of COVID-19 response, the Commission proposed targeted amendments to Decision No 1313/2013 to enhance the UCPM's capacity to react quickly and efficiently and build up stronger response and preparedness capacities in the face of major crises affecting a large number of countries simultaneously. These amendments, adopted in Regulation (EU) 2021/836,³¹⁷ strengthened the UCPM crisis and emergency support.

RescEU – a common European reserve of resources – is a strategic reserve established in 2019 by Decision EU 2019/420, which amended Decision No 1313/2013/EU on the Union Civil Protection Mechanism.³¹⁸ Thus, rescEU is fully integrated into the EU Civil Protection Mechanism. For its part, it contributes to a stronger collective response to disasters through a voluntary pool of national capacities providing mutual support to Europe and the rest of the world. RescEU is independent of – and different to – the joint procurement actions taken under the JPA mechanism (see Chapter 3.1.2.) It works as a last resort safety net that complements countries' own local and national capacities (i.e. the first responders of the participating states).

RescEU is funded by the EU and managed by the Commission in close cooperation with Member States. The rescEU reserve includes a fleet of firefighting planes and helicopters, medical evacuation planes, and stockpiles of medical items, mobile laboratories and field hospitals and vaccines; the latter are to ensure an effective response during different types of disasters, such as the health threat caused by the COVID-19 pandemic.³¹⁹

The Emergency Response Coordination Centre (ERCC) is the organisational hub of the UCPM and coordinates the operations of the rescEU mechanism. In addition, it monitors disasters around the globe, maps disaster risks and provides real-time information on them. It also coordinates disaster relief, and emergency assistance to all EU Members and participating states.³²⁰

The EU's role in civil protection stems from Article 196 TFEU, which constitutes the legal basis for civil protection within the EU. Furthermore, Article 214 TFEU authorises ad hoc humanitarian assistance, relief, and civil protection for people in third countries, in natural or man-made disasters. According to article 28 of Decision 1313/2013 on the UCPM, any country in the world, the United Nations and its agencies or other relevant international organisation, can call on the EU Civil Protection Mechanism for help. Beyond the COVID-19 assistance in Europe and worldwide, previous uses include the 2015 European migration crisis; the 2015 Mediterranean forest fires; 2018 forest

³¹⁴ European Council and Council of the European Union, [Webpage](#) EU Civil Protection.

³¹⁵ Schmertzling L., [EU civil protection capabilities](#), EPRS, European Parliament, July 2020; Glencros A., 'The EU to the rescEU? Assessing the geopolitics of the EU's medical stockpile', *European View*, Vol. 21(1), 2022, pp. 48-55.

³¹⁶ [Decision No 1313/2013/EU](#) of 17 December 2013 on a Union Civil Protection Mechanism (consolidated text), Art. 4.

³¹⁷ [Regulation \(EU\) 2021/836](#) of 20 May 2021 amending Decision No 1313/2013/EU on a Union Civil Protection Mechanism.

³¹⁸ [Decision \(EU\) 2019/420](#) of 13 March 2019 amending Decision No 1313/2013/EU on a Union Civil Protection Mechanism.

³¹⁹ Halleux V., [Union Civil Protection Mechanism 2021-2027](#), EPRS, European Parliament, April 2021; A., Glencros, [The EU to the rescEU? Assessing the geopolitics of the EU's medical stockpile](#), *European View*, Vol. 21(1), 2022, pp. 48-55.

³²⁰ Schmertzling L., [EU civil protection capabilities](#), EPRS Briefing, July 2020.

fires in Sweden; and floods in Belgium 2021. At present, the Russian war against Ukraine has led to the largest emergency operation in the history of the UCPM.³²¹

Objectives

Building on the principles of solidarity and shared responsibility, the targeted amendments adopted regarding Decision 1313/2013 on the UCPM in 2021 seek to build better crisis and emergency support for citizens within and beyond the EU. The general objective is to be better prepared, to react faster and more effectively to crises, especially those with a high socio-economic impact, such as the COVID-19 crisis. The objective of rescEU is to strengthen the EU's response to health emergencies through medical stockpiles in participating EU Member States, to allow for a quicker reaction to health crises. The principal role of rescEU is to strengthen European preparedness for disasters and manage emerging risks, and in that capacity, operate as the 'last resort' of civil protection.

Key initiatives

The legislative amendments that aimed to reinforce the European Civil Protection Mechanism to better tackle adverse effects of large-scale emergencies, entered into force in 2021. They enhanced the flexible system providing comprehensive cross-sectoral support to Member States and their citizens. The total budget allocated to the UCPM for 2021-2027 amounts to €3 319 billion, out of which €2 056 billion come from the EU recovery instrument, while the remaining €1 263 billion are funded by the multiannual financial framework 2021-2027.³²²

The rescEU strategic stockpiling of emergency medical equipment was introduced in the midst of the COVID-19 pandemic. In November 2022, the stockpile was hosted in Belgium, Denmark, Germany, Greece, Hungary, Romania, Slovenia, Sweden, and the Netherlands.³²³ The principal areas of COVID-19-related assistance requested under the UCPM comprised coordinating and co-financing the delivery of PPE and emergency medical equipment, repatriation flights for EU citizens, and transport of medical teams to countries in need.³²⁴ According to the European Commission, emergency assistance offered through the rescEU medical reserve include:

- Delivery of 1.3 million FFP2 and FFP3 protective facemasks to Italy (142 000), Spain (173 000), Croatia (65 000), Lithuania (20 000), Montenegro (140 000) and North Macedonia (255 000) and Serbia (510 000).³²⁵
- ERCC organised 408 consular repatriation flights to assist 100 313 citizens, including 90 060 EU citizens (figures for January-July 2020).³²⁶
- EU-supported delivery of 18 000 vaccine doses reached Kosovo in June 2021.³²⁷

3.1.4. Emergency Support Instrument, Coronavirus Response Investment Initiative and financial support

The European Commission provided financial support and critical health system assistance to Member States in their immediate response to the COVID-19 crisis and mitigation of its long-term

³²¹ European Commission, [Website](#) on European Civil Protection and Humanitarian Aid Operations (Accessed 6 January 2022); [Factsheet](#) on European Civil Protection and Humanitarian Aid Operations: European Civil Protection Pool, 2022.

³²² European Commission, [The EU's 2021-2027 long-term budget and NextGenerationEU: Facts and figures](#), 2021.

³²³ European Commission, [Factsheet](#) RescEU; [Factsheet on European Civil Protection and Humanitarian Aid Operations European Civil Protection Pool](#), 2022; DG ECHO [Annual Report 2021](#).

³²⁴ [Factsheet on European Civil Protection and Humanitarian Aid Operations European Civil Protection Pool](#), 2022.

³²⁵ European Commission, [Webpage](#) Crisis management and solidarity.

³²⁶ European Commission, [Overview of repatriation flights](#), 7 December 2020.

³²⁷ European Commission, COVID-19: EU helps deliver vaccines to Kosovo, [press release](#), 29 June 2021.

impact. This involved harnessing emergency funds from the Emergency Support Instrument (ESI) and a package of measures launched under the Coronavirus Response Investment Initiative (CRII) and the CRII+. In addition, the EU4Health programme was adopted with investment in a €5.3 billion budget (2021-2027) to contribute to resilient health systems and reinforce crisis preparedness in the EU.³²⁸

Box 7: EU4Health programme

The EU4Health programme, established by Regulation (EU) 2021/522, is designed to support the European Health Union and mitigate long-term health challenges by building stronger, more resilient and accessible health systems. It follows on from successive EU health spending programmes first established in 2003. Prior to COVID-19, the health programme was due to lose its dedicated funding stream in the EU budget, and to be merged with the European Social Fund at the end of the third EU health programme (2014-2020). However, the pandemic changed the situation, bringing the added value of common EU crisis preparedness capabilities to the fore of managing cross-border health threats.

EU4Health has a budget of €5.3 billion (2021-2027), which represents a significant increase compared with previous programmes. As a stand-alone dedicated funding programme, it focuses on long-term health challenges, paving the way to a European Health Union. It has four general objectives: i) improve and foster health; ii) protect people; iii) ensure access to medicines, medical devices, and crisis-relevant products; and iv) strengthen health systems. EU4Health provides funding to reinforce the EU's resilience to cross-border health threats. It also supports Europe's Beating Cancer plan and the pharmaceutical strategy for Europe. Moreover, it funds digitalisation of health systems, aims to reduce antimicrobial-resistant infections, and seeks to improve vaccination rates.

The EU4Health programme recognises the one health approach (i.e. the interconnection between human and animal health and more broadly the environment). For its part, it supports the implementation of the European Semester and the European Pillar of Social Rights in the area of health. In this context, EU4Health connects to the health-related United Nations Sustainable Development Goals (SDGs), namely SDG 3 'Ensure healthy lives and promote wellbeing for all at all ages'.

Sources: [Regulation \(EU\) 2021/522](#); [EPRS briefing](#) by Scholz N., 2021.

Background of ESI and CRII/CRII+

ESI: The Emergency Support Instrument (ESI) is an agile, needs-based instrument designed to respond flexibly to the evolving needs of Member States, as the EU moves from the immediate response phase of the pandemic to managed exit, recovery, and prevention phases. It is centrally operated by the European Commission and anchored in the principles of solidarity. It maximises EU added value by complementing and supplementing other EU instruments such as the JPA, rescEU, the CRII (see below), and national state efforts. The ESI was activated in April 2020 with a budget of €2.7 billion.³²⁹

From April 2020 to January 2022, the ESI provided financial support to Member States to secure COVID-19 vaccines, COVID-related therapeutics, and the transport of medical teams and equipment.³³⁰ This was the second activation of the ESI instrument since its creation in 2016.

CRII: The Coronavirus Response Investment Initiative (CRII) was set up by the European Commission in March 2020 by Regulation (EU) 2020/460³³¹ to provide emergency and flexible support to EU Member States. It consists of three main elements: €8 billion of immediate liquidity to accelerate up

³²⁸ European Commission, [Webpage](#) Public Health: EU4Health programme 2021-2027 – a vision for a healthier European Union.

³²⁹ European Commission, [Questions and Answers](#): Emergency Support Instrument, 23 June 2020.

³³⁰ European Commission, [Webpage](#) Emergency Support Instrument.

³³¹ [Regulation \(EU\) 2020/460](#) of 30 March 2020 on the Coronavirus Response Investment Initiative.

to €37 billion of European public investment, maximum flexibility in applying EU spending rules, and access to the EU Solidarity Fund.³³²

Objectives

ESI: The objective of the ESI is to help Member States respond to the COVID-19 pandemic by addressing needs in a strategic and coordinated manner at the European level. More specifically, it mitigates the immediate consequences of the pandemic and anticipates needs related to the recovery.

ESI Regulation (EU) 2020/521 presents a list of indicative actions that might be pursued under the provision.³³³ This includes the purchase and distribution of masks and ventilators to Member States, transport of medical equipment and personnel to border regions and evacuation of patients, and purchase of rapid antigen tests to strengthen testing capacity across Member States.

CRII / CRII+: The objective of the CRII and CRII+ is to provide additional financial assistance to Member States to tackle the coronavirus crisis. The funds for the CRII and CRII+ are delivered through the REACT-EU (Recovery Assistance for Cohesion and the Territories of Europe) package.³³⁴ REACT-EU is a large programme under the new NextGenerationEU amounting to €50.6 billion. The REACT-EU package extends crisis response and repair measures under the CRII and CRII+, to support investment projects into green, digital, and resilient recovery.³³⁵ REACT-EU was an addition to the 2014-2020 European Regional Development Fund and European Social Fund allocations and thus bridged the gap between emergency measures and long-term recovery plans.

In order to achieve these stated objectives, the CRII utilises the full array of funding options under the EU budget to provide EU Member States with targeted assistance to aid financial recovery – with maximum flexibility and minimal administrative burden. This involved the mobilisation of unspent EU cohesion policy funding and assisting Member States in channelling money towards where the need is most acute.³³⁶ EU cohesion policy contributes towards strengthening socio-economic and territorial cohesion in the European Union, with a view to correcting the imbalance between countries and regions.³³⁷ The priority sectors of the CRII scheme were: coronavirus-related health expenditure within Member States e.g. hospital equipment, respiratory ventilators, and PPE; working capital for small and medium-sized enterprises (SMEs), and support for national short-term employment schemes.³³⁸

The **CRII+** follows the first package of CRII measures, to allow for a sustained and prompt response to the continuing COVID-19 crisis.³³⁹ It is comprised of three elements: (1) flexibility in the use of structural funds, including a 100 % EU co-financing rate for cohesion policy programmes for 2020-2021, including a EU co-financing rate for cohesion policy programmes; (2) improved protection for the most deprived sections, with schemes for food aid and basic material assistance

³³² European Commission, [Questions and Answers](#): European coordinated response to corona, 13 March 2020.

³³³ [Council regulation \(EU\) 2020/521](#) of 14 April 2020 on activating the emergency support under Regulation (EU) 2016/369, and amending its provisions taking into account the COVID-19 outbreak.

³³⁴ European Commission, [Webpage](#) Cohesion policy action against coronavirus.

³³⁵ Ibid.

³³⁶ European Commission, [Questions and Answers](#): European coordinated response to corona, 13 March 2020.

³³⁷ European Commission, [Webpage](#) Cohesion Policy 2021-2027.

³³⁸ European Commission, [Questions and Answers](#): European coordinated response to corona, 13 March 2020.

³³⁹ European Commission, [Webpage](#) Coronavirus Response Investment Initiative Plus: New actions to mobilise essential investments and resources.

through electronic vouchers; and (3) continued assistance to vital sectors, to include the agriculture and marine fisheries sectors.³⁴⁰

Key initiatives

The ESI: From April 2020 to January 2022 the ESI provided financial support to Member States to secure COVID-19 vaccines, COVID-related therapeutics, and the transport of medical teams and equipment.³⁴¹ This was the second activation of the ESI instrument since its creation in 2016. A significant part of the ESI budget is used to secure COVID-19 vaccines through advance purchase agreements (APAs) with vaccine producers: this is part of the Commission's vaccines strategy. In addition, under its 'mobility package', the ESI provides support for the transport of essential goods, medical teams, and patients. In total, the EU allocated a total budget of €2.7 billion to the ESI in the context of the COVID-19 pandemic, of which €220 million was mobilised under the 'ESI Mobility Package'.³⁴²

The ESI was utilised for the procurement of PPE, medical equipment and vaccines, essential medical products, and medicines, including active pharmaceutical ingredients (APIs).³⁴³ Table 9 lists ESI key initiatives.

Table 9: Key initiatives under the ESI

ESI	Initiative	Amount of EUR
Treatments	Two contracts with pharmaceutical company Gilead for the purchase and distribution of Veklury (API: remdesivir).	€70 million, twice
	Clinical trials for repurposing API Raloxifene – to assess the safety of Raloxifene to prevent the replication of the COVID-19 virus in cells.	€1 million
Testing	Purchase of 20 million rapid antigen tests to be delivered to 24 Member States.	€100 million
	Scaling up COVID-19 testing capacity and support staff training for sampling collection and analysis.	€35.5 million
ESI Mobility Package	Support for the Member States for cargo operations (e.g. medical items, COVID-19 vaccination equipment, and therapeutics).	>€164 million
	The transport of medical teams and personnel within and into the EU, and the transfer of patients within the EU and from the EU to non-EU countries.	€9 million

Source: European Commission, [Webpage](#) Emergency Support Instrument.

³⁴⁰ European Commission, [Corona Response Investment Initiative](#).

³⁴¹ European Commission, [Webpage](#) Emergency Support Instrument.

³⁴² European Commission, [Factsheet](#) Emergency Support Instrument.

³⁴³ Active pharmaceutical ingredients (APIs) are defined as 'substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis'. EMA, [API – the new approach for third countries – what are the consequences – should we expect shortage of medicinal products in the country? Perspective from an acceding country](#), 2013.

This enabled more than 2 000 operations to transport medical equipment, as well as approximately 515 health workers and 135 patients.

CRII/CRII+: The principal impact of the CRII/CRII+ measures are in the health sector (to secure PPE, expand testing capacity, and support hospitals), the business sector (provide working capital to SMEs, facilitate digitalisation, redesign financial instruments), and social support towards employment retention schemes and vulnerable communities. According to the latest data, 25 EU Member States and the UK have requested 239 amendments to their cohesion policy programmes utilising the flexibilities offered by the CRII and CRII+. ³⁴⁴

Examples of thematic reprogramming under the CRII/CRII+ include: ³⁴⁵

- €8.3 billion in EU reallocations for health actions resulting in a net increase of €8 billion at the EU level;
- €12.5 billion in EU reallocations in business support resulting in a net increase of €4.2 billion at the EU level;
- €5.1 billion of direct support for people, including workers and vulnerable groups.

3.1.5. Team Europe and the EU's contributions to the global response to COVID-19

Box 8: EU global health strategy

The EU global health strategy, which provides a framework leading up to 2030, was adopted on 30 November 2022. ³⁴⁶ The strategy considers global health as an essential pillar of EU external policy. It identifies policy priorities, guiding principles and lines of action with the objective to shape global health in accordance with the universal health-related SDG targets. The EU's goal to promote health sovereignty for more resilience and open strategic autonomy as well as addressing the economic, social and environmental root causes of ill-health through a 'health in all policies' approach features prominently in the strategy. It focuses on global health security through strengthening health systems, tackling health inequalities and advancing universal health coverage – taking account of structural factors, such as supply chain issues, vaccine manufacturing and vaccine inequities highlighted during the COVID-19 pandemic. These will be discussed in the relevant sections of Pillar 4. The analysis in this pillar will focus on Team Europe's contributions to the global health response during the COVID-19 pandemic.

Background

The EU's global response to the COVID-19 pandemic is an important dimension of the EU's coordinated actions. ³⁴⁷ It adopts a 'Team Europe' approach, addressing the health crisis and humanitarian needs while also enhancing partner countries' health, water and sanitation systems as well as research and preparedness capacities. It also seeks to support vaccination and mitigate the wider socio-economic consequences of the pandemic, thus reducing the risk of destabilisation. The Team Europe approach combines resources from the EU, its Member States, and European financial institutions, especially the European Investment Bank (EIB) and the European Bank for Reconstruction and Development (EBRD). ³⁴⁸

³⁴⁴ European Commission, [Webpage](#) Cohesion policy action against corona.

³⁴⁵ European Commission, [Coronavirus Dashboard: EU cohesion policy response to the crisis](#). (Accessed 13 September 2022).

³⁴⁶ European Commission, EU Global Health Strategy: Better Health For All in a Changing World, Communication [COM\(2022\) 675](#), 30 November 2022.

³⁴⁷ European Commission, Commissioner Urpilainen: Team Europe with our partners against Covid-19, [press statement](#), 28 March 2020.

³⁴⁸ European Union, Global EU response to COVID-19 JOIN(2020)11, 8 April 2020.

The EU's global response to the COVID-19 pandemic includes contributions to global partnerships, such as the Access to COVID-19 Tools (ACT)-Accelerator, which is a global partnership between international organisations (WHO, PAHO, World Bank, UNICEF), private-public partnerships (e.g. CEPI, GAVI), governments, academics, civil society organisations, private businesses and philanthropists (e.g. the Bill and Melinda Gates Foundation, Wellcome).³⁴⁹ The ACT-Accelerator, launched in April 2020, supports development, production and equitable access to COVID-19 tests, treatments and vaccines.³⁵⁰

Through the Team Europe approach, the EU played a leading role in setting up the COVAX Facility, the vaccine pillar of the ACT-Accelerator. The COVAX Facility pools the resources of high-income economies and low- and middle income economies, together representing 90 % of the world's population, to foster vaccine development and ensure their fair distribution to all.³⁵¹ It makes a rational case for a collective benefit and builds on the WHO's strengths as a central and global player in health, while also involving UNICEF for the logistic dimension. COVAX has contributed to developing a scheme for a globally equitable distribution of COVID-19 vaccines, with an emphasis on early vaccination of key healthcare workers and vulnerable population groups. To ensure equitable distribution, COVAX commits to the 20 % rule, meaning that no economy can receive more vaccines through the COVAX Facility than what is needed to vaccinate 20 % of its population, before all economies reach the same threshold.³⁵²

Objectives

The EU's global response to COVID-19 offers a single framework of action in support of partners to fight the spread of the coronavirus and its adverse socio-economic effects. The Team Europe approach rests on four pillars: 1) Team Europe priorities: to offer emergency and humanitarian support; boost health, water and sanitation systems; enhance research capacities; and tackle adverse socio-economic effects of the pandemic; 2) Team Europe packages: to create coherent support packages for partner countries in need; 3) Team Europe for global preparedness: support for the Global Preparedness Monitoring Board; 4) Team Europe for global coordination and multilateralism: acting through and together with G7, G20 and the UN, to promote and lead a coordinated global response.³⁵³

The WHO has set an ambitious objective for countries to vaccinate 70 % of their population against COVID-19 by mid-2022, which was, however, not achieved. Similarly, COVAX's objective to vaccinate at least 30 % of every world economy's population by the end of 2021 was not met either. In addition, COVAX has committed to eight objectives to ensure equitable access to COVID-19 vaccines, updated in April 2022.³⁵⁴ During the two years following the first roll-out of vaccines in February 2021, COVAX has struggled to meet its vaccination goals. Difficulties in production and challenges in administration of vaccines in countries where the health infrastructure is weak present some of the challenges encountered by the COVAX Facility. Nevertheless, by mid-June 2022, over 1.5 billion doses had been delivered to 145 countries.³⁵⁵

³⁴⁹ The Pan-American Health Organization (PAHO); the Coalition for Epidemic Preparedness Innovations (CEPI); Global Alliance for Vaccines and Immunisation (GAVI).

³⁵⁰ WHO, [Webpage](#) ACT-Accelerator (Accessed on 8 February 2023); Pichon E., [Understanding COVAX: The EU's role in vaccinating the world against Covid-19](#), EPRS, European Parliament, March 2022.

³⁵¹ WHO, [Webpage](#) COVAX.

³⁵² Berkley S., [COVAX explained](#), Gavi, 2020.

³⁵³ European Union, Global EU response to COVID-19, Joint communication [JOIN\(2020\) 11](#), 8 April 2020; Bentzen N., [The EU's global response to coronavirus](#), EPRS, European Parliament, April 2020.

³⁵⁴ WHO, [Webpage](#) COVAX objectives (Accessed 8 February 2023).

³⁵⁵ [COVAX webpage on vaccine roll-out](#) (Accessed 8 February 2023).

Key initiatives

As the single European framework for the EU's external response to the COVID-19 crisis, Team Europe is a solidarity mechanism. The Team Europe approach had gathered a total of €53.7 billion by December 2021, of which close to 90 % was already disbursed by end of 2021.³⁵⁶ In April 2021, Commissioner for International partnership, Jutta Urpilainen, highlighted the key initiatives accomplished on all three fronts of the Team Europe approach a year after the outbreak of the pandemic. She also emphasised the impact of joint EU efforts recognised by multilateral stakeholders, such as WHO, GAVI and the global partnership of the ACT-Accelerator, in terms of European added value, policy coherence and partnerships.³⁵⁷

Team Europe packages are implemented, among others, in Europe's immediate neighbourhood: the Western Balkans, the Eastern Partnership countries, and the Southern Neighbourhood countries. In addition, the EU's contributions to global health are continuing through Team Europe and the COVAX Facility.

EU support to the Eastern Partnership countries

For Eastern Partnership countries, the EU has mobilised a support package of €2.5 billion to aid socio-economic recovery and meet emergency medical needs in Armenia, Azerbaijan, Belarus, Georgia, Moldova, and Ukraine.³⁵⁸ Examples of the EU response at the regional level include:

- The EU-WHO Solidarity for Health Initiative (€35.2 million) addressing the COVID-19 pandemic in the Eastern Partnership. To date, over 12 million pieces of PPE and 48 000 test kits have been delivered;³⁵⁹
- EU-WHO action (€40 million) to develop, support, and update national vaccine deployment plans.³⁶⁰

EU support to the Southern Neighbourhood

To assist the Southern Neighbourhood, the EU has reconfirmed its solidarity with regional partners and mobilised a support package of over €2.3 billion to respond to the immediate health crisis and support socio-economic recovery in the region in the medium to long term.³⁶¹ Examples of engagement in the region include:

- The EU Emergency Trust Fund for Africa (EUTF) with an assistance package of €120 million to protect migrants and refugees and stabilise local communities in North Africa;³⁶²
- The EU Regional Trust Fund in Response to the Syrian crisis has redirected funds within the health and water, sanitation and hygiene sectors (WASH) to mobilise €55 million for health and social protection for vulnerable communities and internally displaced people in Syria, Jordan, and Lebanon.³⁶³

³⁵⁶ European Commission, [Webpage](#) Team Europe (Accessed 8 February 2023); Infographic on [Team Europe external response to COVID-19](#).

³⁵⁷ [Letter from Commissioner for International Partnerships Jutta Urpilainen to the European Parliament](#), April 2021.

³⁵⁸ European Commission, [EU support to Eastern Partnership countries in tackling COVID-19](#), 2021.

³⁵⁹ European Union and World Health Organization, [Webpage](#) The Solidarity for Health Initiative.

³⁶⁰ European Commission, [EU support to Eastern Partnership countries in tackling COVID-19](#), 2021.

³⁶¹ European Commission, [Webpage](#) EU Emergency Trust Fund for Africa.

³⁶² Ibid.

³⁶³ European Commission, EU adopts €55 million support package for Syrian refugees and local communities in Jordan and Lebanon to mitigate coronavirus pandemic, [press release](#), 10 June 2020.

EU support to the Western Balkans

The EU's engagement with the COVID-19 crisis and recovery in the Western Balkans included a number of initiatives covering emerging and structural support. The EU has mobilised a support package of over €3.3 billion to address the health crisis and the socio-economic consequences of the COVID-19 pandemic.³⁶⁴ Examples of EU support in the region include:³⁶⁵

- €42 million for immediate support to the Western Balkans health sector for medical procurement of PPE, respiratory ventilators, testing kits, etc.;
- €88 million towards the health, research and water needs, including vaccination of vulnerable groups;
- €7 million in collaboration with the WHO to support the effective reception and administration of COVID-19 vaccines received through the COVAX Facility;
- €762 million towards socio-economic recovery from the health crisis, plus €750 million in macro-financial assistance to support Western Balkan governments with a balance of payments;
- In addition, the EU is providing €1.7 billion of preferential loans for public sector investments to help safeguard jobs for people working for SMEs in the region.

Team Europe's contributions to COVAX

On 18 September 2020, the European Commission confirmed its participation in the COVAX Facility for equitable access to affordable COVID-19 vaccines and made a contribution of €400 million. In 2021 EU Member State contributions amounted to a third of the total number of donated vaccine doses under the COVAX Facility.³⁶⁶ At present, Team Europe is one of the lead COVAX donors. Current Team Europe contributions to the COVAX scheme amount to €3.5 billion, of which €2.5 billion comes from EU member states and €1 billion from the EU's budget (€400 million in direct contributions plus €600 million in guarantees) (figures for February 2022).³⁶⁷

3.2. Effectiveness

The discussion on 'effectiveness' considers how successful the EU public health intervention was in achieving its stated objectives and, conversely, the extent to which the progress towards the objectives can be attributed to the policy intervention.³⁶⁸

Box 9: Effectiveness analysis

Effectiveness analysis considers the success of EU action in the achievement and progress towards objectives. This involves an evaluation of the progress made to date and the role of the EU action in delivering the observed changes. To this end, the effectiveness analysis here will identify the factors that drive or hinder progress towards an objective and if they are linked to the EU intervention.

The Better Regulation toolbox also identifies timing (alongside the reliability of available data) as a crucial variable in evaluation and fitness checks. At the 'early stage' of the intervention's lifecycle, it may not be possible to judge criteria in any depth. Stakeholder opinions may be the only indicator of whether needs have changed. This is pertinent to various aspects of the EU's COVID-19 response, e.g. several aspects of the EHU and the changes to the Regulation on Serious Cross border Health Threats are too new to allow for an in-depth assessment.

Source: European Commission, Better Regulation [toolbox, chapter 6](#).

³⁶⁴ European Commission, [Webpage](#) European Neighbourhood Policy and Enlargement Negotiations: EU response to the coronavirus pandemic.

³⁶⁵ European Commission, [EU Support to Western Balkans in tackling Covid-19](#), 2021.

³⁶⁶ De Bengy Puyvallée A. and Storeng K.T., '[COVAX, vaccine donations and the politics of global vaccine inequity](#)', *Global Health* 18(26), 2022, pp. 1-14.

³⁶⁷ Council of the European Union, [Infographic COVID-19: the EU's contribution to global vaccine solidarity](#).

³⁶⁸ European Commission, [Better Regulation Toolbox, Tool #47: Evaluation criteria and questions](#), 2021, pp. 403-404.

EQ [Evaluation Question] 1.1: To what extent does the EHU effectively use its resources to provide EU-level protection, prevention, preparedness, and response during the COVID-19 pandemic?

The EHU package is underwritten by the lessons from COVID-19. The EHU provides a legislative initiative, with attendant funding, to reinforce core EU health agencies (the ECDC and EMA), to revitalise cross-border healthcare, and strengthen European emergency preparedness and pharmaceutical policy.

Among the various initiatives that comprise the establishment of the EHU, the coordination of cross-border health threats through HERA, the expanded mandates of the ECDC and EMA, were regarded by stakeholders to be of most importance when it comes to evaluating the EU's public health response to COVID-19.

Regulation on Serious Cross-border Threats to Health

The new Regulation (EU) 2022/2371 on serious cross-border threats to health³⁶⁹ provides the legal basis to develop an EU-level health crisis and pandemic plan ('Union prevention, preparedness and response plan on health crises'), enhance risk assessments for health threats, enforce a coordinated response at EU level, and improve the mechanism for response to public health emergencies. The Regulation provides a far-reaching framework for disease prevention and health promotion for communicable diseases, building on a long-standing priority area and capacity built over prior health crises. The latter refers, for example, to the health-security framework to deal with cross-border health threats,³⁷⁰ the joint procurement of medical supplies (introduced during H1N1 2009),³⁷¹ and EU-level surveillance conducted by the ECDC.³⁷²

One clear area of the new regulation's effectiveness is that it allows for a faster and more coherent response at the EU level. As consulted stakeholders point out, it has the potential to allocate scarce resources better and make efficient use of capacities across Member States in emergency situations, and is responsive to the lessons of COVID-19. For instance, the COVID-19 pandemic revealed differences in national health system capacities with regard to healthcare staff and ICU capacity. At the height of the pandemic, Germany, France, Italy, and the Netherlands cooperated by transferring patients to Member States with available ICU care beds. An EU preparedness plan – such as the proposed Regulation – formalises such cooperation and ensures applicability more widely across all Member States rather than on an ad-hoc basis in certain Member States only.

HERA

HERA was established to provide better integration in health-crisis preparedness and response. Several stakeholders from EU institutions and Member States consulted were altogether positive in their assessment of the creation of HERA and stronger mandates for the ECDC and EMA. They viewed these developments as important building blocks towards building an EU-level plan for protection, preparation, prevention, and response, and delivering on a European Health Union.

Stakeholders from the Member States consulted for this study agreed that the establishment of HERA was an important starting point for becoming more strategic and better prepared in the event of future serious health threats.

It makes the EU more prepared and able to respond faster; evidence of this is clear in the monkey pox emergency. For that reason, it was important that the funds were used well. However, given its recent establishment (September 2021) at the same time, some of the stakeholders pointed out that it was still too premature to evaluate the effectiveness of HERA. Some interviewees were doubtful

³⁶⁹ [Regulation \(EU\) 2022/2371](#) of 23 November on serious cross-border threats to health.

³⁷⁰ Provided for in [Decision No 1082/2013/EU](#) of 22 October 2013 on serious cross-border threats to health.

³⁷¹ European Commission, [Webpage](#) Preparedness and response planning - Joint Procurement of medical supplies.

³⁷² [Regulation \(EC\) No 851/2004](#) of 21 April 2004 establishing a European Centre for Disease Prevention and Control.

about how effectively it would function in this crowded landscape of overlapping competences and responsibilities, considering the degree to which HERA's remit and responsibilities necessarily overlapped with existing institutions (Table 10).

Table 10: EU bodies with responsibilities for pandemic planning and preparedness

EU agency/institution	Current roles and responsibilities
DG SANTE	Provides a forum for coordination and sharing of best practices through the EU Health Security Committee (HSC) and independent scientific committees. Procures medical countermeasures and equipment through the EU Joint Procurement Agreement.
Directorate-General for Research and Innovation (DG RTD)	Allocates and coordinates EU investments in research and development for medical countermeasures and diagnostics.
ECDC	Provides surveillance of communicable diseases. Issues scientific advice on communicable disease epidemiology, prevention, and control. Provides public health training.
EMA	Assesses the safety and effectiveness of novel health technologies. Jointly coordinate clinical trials for potential medical countermeasures.
HERA	Stockpiling essential medical countermeasures and equipment. Horizon scanning of future health threats. Funding research and development. Supporting manufacturing capacity.

Source: M. Anderson, R. Forman and E. Mossialos, '[Navigating the role of the EU Health Emergency Preparedness and Response Authority \(HERA\) in Europe and beyond](#)', *The Lancet Regional Health*, 9, 100203, 1 October 2021.

In contrast, stakeholders expressed concern over the lack of clarity in the definition of a 'public health emergency' at the Union level. Besides the prioritisation of communicable disease prevention, the EHU also addresses non-communicable diseases, with a particular focus on cancer. The early diagnosis, prevention, and treatment of cancer is, of course, prioritised through Europe's Beating Cancer Plan – but EU-level coordination remains weak in addressing the social determinants of health (diet, physical activity, alcohol, tobacco).³⁷³

EQ 1.2: To what extent does the JPA effectively use its services to secure more equitable access to specific medical countermeasures and improved security of supply, together with more balanced prices for the participating EU countries?

The joint procurement of vaccines and essential countermeasures enabled by the JPA was the visible face of the EU-coordinated COVID-19 response. The effectiveness of the JPA is evident in terms of the diversified portfolio of COVID-19 vaccines, and the broad use of the JPA for crisis procurement. Under the EU vaccines strategy, the European Commission built a diversified portfolio of vaccines for EU citizens. Beginning in December 2020, the Commission gradually granted five

³⁷³ Bucher A., [Does Europe need a Health Union?](#), Bruegel, 2022.

conditional market authorisations for COVID-19 vaccines to Pfizer-BioNTech (21 December 2020), Moderna (6 January 2021), AstraZeneca (29 January 2021), Janssen (11 March 2021) and Novavax (20 December 2021).³⁷⁴

A second measure of the effectiveness of the JPA was the increased regional participation in the JPA, and the significant growth in its membership. The clear economic advantages of centralised cross-border procurement during health emergencies are appreciated by Member States. This is evident, for example, in the increased participation of countries in the JPA. The number of signatories in the JPA has risen to 37 countries and covers 537 million people, including all EU and EEA countries, the UK, plus Albania, Bosnia and Herzegovina, Kosovo, Montenegro, North Macedonia, and Serbia.³⁷⁵

Stakeholders consulted agreed that the JPA was fit for purpose as an instrument of crisis procurement – although concerns were raised about its operation and practice. The consulted stakeholders pointed out that the JPA helped streamline procurement and facilitated equal access for all participating Member States, but concerns were raised regarding the extent to which the JPA retains value outside of a crisis, such as the COVID-19 pandemic. In this regard, there was some expectation that the JPA could retain its efficiency and utility by extending procurement to new products, such as orphan medicines. But in some sense, the great strength of JPA during the COVID-19 pandemic is also its most undermining weakness. Since COVID-19, JPA has gained popularity among Member States, but as interviewed stakeholders pointed out, considering the complexities of national health systems and medical needs, EU-level procurement is more likely to complement, not replace, procurement at the national level.

Unintended consequences of the JPA

Despite the clear economic advantages of centralised cross-border procurement, Joint Procurement for COVID-19 vaccines was marked by a raft of problems. The vaccination process across the EU was initially slow, and the Commission faced criticism over the initial slow pace of vaccine delivery³⁷⁶ and lack of due process in contracts with vaccine manufacturers. As one stakeholder pointed out, the focus was more on getting the right prices than on timely or expedient delivery. Following criticisms from Member States, the Commission took AstraZeneca to court over unmet delivery promises and announced export controls for vaccines produced within the EU. This was a point reiterated by the stakeholders interviewed, who pointed both to the slow pace of delivery under JPA, as well as the lack of choice.

The ECA special report on EU COVID-19 vaccine procurement concludes there are lessons to be learnt.³⁷⁷ Though successful by some of the metrics, e.g. 80% of the adult population vaccinated by the end of 2021 and the diversified portfolio of COVID-19 vaccine, auditors concluded the Commission's contracts did not include specific provisions to address supply disruptions. On consideration, the Commission had limited leverage to overcome supply challenges, and when confronted with severe supply shortfalls in early 2021, it became clear that most contracts did not include specific provisions to address supply disruptions. Indeed, the auditors are unsure of the extent to which the Commission had analysed the production and supply chain challenges of vaccine production until after signing most of the contracts. A task force set up to support manufacturing and supply chains helped resolve bottlenecks, but the size of its impact on the ramp-

³⁷⁴ EMA, [Webpage](#) COVID-19 vaccines: authorised.

³⁷⁵ European Commission, [Webpage](#) Signing ceremonies for Joint Procurement Agreement.

³⁷⁶ Hyde R., '[Von der Leyen admits to COVID-19 vaccine failures](#)', *The Lancet*, Vol. 397, Issue 10275, 20–26 February 2021, pp. 655–656.

³⁷⁷ European Court of Auditors, [Special report 19/2022](#): EU COVID-19 vaccine procurement – Sufficient doses secured after initial challenges, but performance of the process not sufficiently assessed, 12 September 2022.

up of vaccine production remains unclear. That said, the contracts signed in 2021 had stronger provisions on delivery schedules and production locations than those signed in 2020. However, the ECA audit concludes the Commission is yet to scrutinise and benchmark its procurement process and test its pandemic procurement system through stress tests or simulations.

An academic assessment³⁷⁸ of the JPA has raised additional issues concerning the quality of crisis procurement. Beyond the pace of the rollout of the JPA, it noted the issue of the quality of medical supplies and the tendering process. In Spain, for example, 17% of the COVID-19 tests purchased from a Chinese manufacturer did not test accurately for COVID-19.³⁷⁹ The Dutch Ministry of Health recalled 600,000 face masks due to poor quality.³⁸⁰ Other countries reported difficulties in procuring the desired number of tests and critical medical supplies, including swabs. The NGO Transparency International warned of the risks of increased corruption in the medical market, with evidence of undue discretion in some of the contracts awarded in Sweden, the UK, Italy, Germany, and Slovenia for example.³⁸¹

Interviewed stakeholders at the EU and Member State level suggested that the EU's limited competences in the domain of health are a mediating factor. Contracts were negotiated by the European Commission on behalf of each Member State and not directly for the EU. Unlike the US Operation Warp Speed (a USD 18 billion private-public partnership for vaccine development and delivery), the Commission did not possess the financial authority to back vaccine development and the associated supply chain.³⁸²

The distinction between emergency and non-emergency is another important factor for consideration. The joint procurement exercise was undoubtedly successful in the specific context of the pandemic and COVID-19 vaccine procurement. Health Technology Assessments (HTAs) were suspended for crisis procurement of COVID-19 vaccines. But this is a unique situation. HTAs are essential for all other pharmaceuticals procured under the JPA, and Regulation (EU) 2021/2282³⁸³ on health technology assessment (HTAR) which entered into force in January 2022 becomes applicable as of January 2025.³⁸⁴

EQ 1.3: To what extent did rescEU effectively use its resources to strengthen the EU response to health emergencies, through medical stockpiles in participating EU Member States, to allow for a quicker reaction to health crises?

Consulted stakeholders agreed that rescEU met its stated objectives to strengthen the EU response to health emergencies through medical stockpiles in participating EU Member States, to allow for a quicker reaction to health crises. Its great success, stakeholders stated, was the ability to intervene when Member States were in need. As one interviewee pointed out, from 2018 to the current day (interview conducted in mid-October 2022), there has been a 570% increase in activations of the rescEU mechanism. That said, there was a limited room in the legislation for the Commission to procure some items directly rather than working with Member States.

As a result of the COVID-19 experience, consulted stakeholders confirm that the EU is looking ahead of COVID-19 and stockpiling different kinds of countermeasures. The UCPM fits into this scheme precisely because it derives effectiveness from a cross-sectorial focus: so far that its scope of operations ranges from natural disasters to health emergencies.

³⁷⁸ Halloran D., 'Procurement during a Public Health Crisis: the Role of the European Union', *Irish Studies in International Affairs*, 32(1), 2021, pp. 67-81.

³⁷⁹ Ibid.

³⁸⁰ Ibid.

³⁸¹ Ibid.

³⁸² Kirkegaard J.F., 'The European Union's troubled COVID-19 vaccine rollout', *PIIE*, 2021.

³⁸³ [Regulation \(EU\) 2021/2282](#) of 15 December 2021 on health technology assessment.

³⁸⁴ European Commission, [Webpage](#) New regulation on health technology assessment.

Moreover, the lessons from COVID-19 have yielded an accumulated body of knowledge regarding what is needed in times of crisis and the organisational capacity necessary to coordinate quickly from one sector to the other. Even so, the consulted stakeholders argued that a shortage of capacities to deal with all sorts of emergencies still remains. One suggestion from a stakeholder was that it was prudent to develop the existing infrastructure, e.g. in the form of a European civil protection agency or force that complements the capacities of Member States and does joint procurements. This would go a long way towards facing the real challenge, which is in maintaining the capacities in stockpiling out of crisis and prioritising the rescEU stockpile in the longer term.

EQ 1.4: To what extent does the ESI and CRII/CRII+ help Member States respond to the coronavirus pandemic by addressing needs in a strategic and coordinated manner at European level?

The Coronavirus Response Investment Initiative (CRII) and the Emergency Support Instrument (ESI) together comprised €3.5 billion out of the €4.5 billion (i.e. 3% of the EU budget) specifically allocated to public health measures (figures for June 2020). Stakeholders interviewed made no mention of the financial instruments, suggesting limited familiarity with these tools.

EQ 1.5: To what extent does the Team Europe's contribution to global health contribute to its stated objectives?

The EU's contributions to the global health response to the COVID-19 pandemic were governed by two objectives: first, to strengthen global health security and to mitigate vaccine shortages in LMIC countries; second, to bolster the EU's enlargement policies in its immediate neighbourhood.

The recently released EU Global Health strategy admits to a 'massive unfinished agenda' – to the detriment of progress towards the SDGs. This view is consistent with the opinion expressed by consulted stakeholders. A section of academic opinion has even suggested that the pandemic is a contributor to Europe's declining influence in the world.³⁸⁵ However in this present analysis (in Pillar 4), the reversal in the SDGs was multifactorial and borne out of structural factors, and is therefore not solely linked to the EU's role in global health.

Team Europe's COVID-19 response towards the Enlargement countries

Team Europe's COVID-19 response towards Enlargement countries comprised a set of interconnected initiatives – namely, financial assistance of €3 billion to the Western Balkans for emergency needs, recovery, reconstruction,³⁸⁶ and inclusion in the joint procurement scheme for PPE and the 'green lane' border crossing arrangements.³⁸⁷ These initiatives notwithstanding, policy analysts warn that the cumulative effects of the pandemic have impaired the EU's soft power in the Western Balkans.³⁸⁸

In part, the EU's COVID-19 response has been considered weakened by the challenges highlighted in the Commission's 2021 progress reports. Corina Stratulat of the European Policy Centre Brussels points out that the reasons are historical. Since 2004 the European Commission has refined its enlargement strategy to strengthen democratic systems and economies in the Western Balkans. But policy experts such as Stratulat point out the results are still underwhelming.³⁸⁹ This year's country reports again call attention to persistent and serious problems with the rule of law, the

³⁸⁵ Kahn S., [The COVID-19 pandemic, what lessons for the European Union?](#) Foundation Robert Schuman, *European Issues*, 2021.

³⁸⁶ European Commission, DG NEAR, [Webpage](#) EU response to the coronavirus pandemic.

³⁸⁷ Cameron A. and Leigh M., [Has COVID-19 dented the EU's credibility in the Balkans?](#), Bruegel blog, 2020.

³⁸⁸ Ibid.

³⁸⁹ Stratulat C., [EU enlargement to the Western Balkans – Three observations](#), Commentary, European Policy Centre, 8 November 2021.

independence of the judiciary, media freedom, and the fight against organised crime and corruption throughout the region.³⁹⁰

Interviewed stakeholders were overall positive in their assessment of the EU's COVID-19 response towards the Enlargement countries, viewing it as an expression and extension of the European solidarity principle that underpinned the COVID-19 response to EU Member States.

Team Europe's COVID-19 response to global health

The United Nation's *Sustainable Development Goals (SDGs) Report 2022* warns that 'multiple, cascading, and intersecting crises' predominated by COVID-19, climate change and conflict have reversed years of progress in poverty alleviation, improved health and education, and provision of basic services.³⁹¹ While recognising the EU's major contribution to global objectives through the Team Europe approach, the EU Global Health strategy (November 2022) acknowledges the 'massive unfinished agenda' in global health.³⁹²

Global access to COVID-19 vaccines has been unequal – and particularly so on the African continent. As of December 2022, 20.5% of the population in low income countries (LICs) have been fully vaccinated, compared to 74.5% in high-income countries (HICs).³⁹³ Africa continues to be the continent with the lowest vaccination rate. As of October 2022, only 24% of its population had completed the primary vaccination series;³⁹⁴ and COVID-19 vaccine rate in Africa stood at 40% in November 2022.³⁹⁵

This highlights basic inequalities in access to COVID-19 vaccines and the structural factors, including suboptimal production capacities and dependencies, amongst other challenges that forestalled timely and equitable distribution of COVID-19 vaccines worldwide.

3.3. Coherence

The section on 'coherence' considers how well different interventions and policy instruments work together at the EU, national, and international levels.³⁹⁶ Accordingly, the analysis will either highlight the synergies that improved overall performance or alternately point towards possible points of tension, e.g. objectives which are potentially contradictory, or inefficient approaches.

³⁹⁰ Ibid.

³⁹¹ UN, [The Sustainable Development Goals Report 2022](#).

³⁹² Our World in Data, [Share of people who completed the initial COVID-19 vaccination protocol](#), 2022 (Accessed 10 December 2022).

³⁹³ WHO African Region, [COVID-19 vaccination roll-out stagnates in Africa](#), 20 October 2022.

³⁹⁴ Ibid.

³⁹⁵ Statista, [Number of administered coronavirus \(COVID-19\) vaccine doses per 100 people in Africa as of November 3, 2022, by country](#). [The WHO Coronavirus \(COVID-19\) Dashboard](#), accessed 13 February 2023, demonstrates the great variation in vaccination rates between African countries. The total doses administered per 100 population ranges from below 20 to over 100.

³⁹⁶ European Commission (2021), [Better Regulation Toolbox, Tool #47: Evaluation criteria and questions](#), pp. 408-409. (Accessed 29 November 2022).

Box 10: Evaluation of coherence

The evaluation of coherence looks at how well different interventions, EU/international policies or national/regional/local policy elements work together. It may highlight areas of synergy which improve performance or point to tensions, e.g. objectives that are contradictory/overlapping/ causing inefficiencies.

'Internal' coherence looks at how various components of the EU intervention operate together to achieve its objectives. 'External' coherence considers similar checks in relation to other ('external') interventions at different levels: for example, between EU interventions within the same policy field. At its widest, external coherence looks at compliance with national policies or international agreements/declarations, in particular UN sustainable development goals (SDGs) and EU interventions in developing countries.

Source: European Commission, [Better Regulation toolbox, chapter 6](#).

EQ 2.1: To what extent did EU's internal coordination and coherence of COVID-19 response contribute to achieving external coherence and coordination of EU's activities with its partners?

The EU's public health response to the COVID-19 pandemic operated in a complex environment involving various stakeholders and partner organisations from EU Member States, EU institutions and agencies, and international institutions such as the COVAX facility. Internal coordination and coherence are essential to achieving external coherence and coordination of the Centre's activities within its interactions with its partners.

ESI aims to enhance existing EU programmes and instruments, including rescEU and the Joint Procurement Procedure, and to complement ongoing efforts at the national level. ESI provides fast and targeted actions to support Member States in extraordinary circumstances.

The stakeholders consulted for this study stated there was good coordination and organisation within the EU institutions and organisations and avoidance of repetition of work. Stakeholders referred to 'daily collaborations' with other DGs to ensure policies and actions were consistent. As one stakeholder pointed out, where an overlap was detected, coordination was sought.

The present study found no evidence to suggest a lack of internal coordination and coherence between the various EU agencies and institutions – although how well HERA would function without duplication of roles and responsibilities was raised in the consultations conducted (for HERA, see EQ 1.1).

EQ 2.2: To what extent are the activities of the EU COVID-19 response coordinated and complementary to those of the Member States?

Coordination between the EU and Member States in health matters is enabled through Article 168 TFEU, which firmly designates health systems as a national competence of the Member States. Since 2020, the European Parliament³⁹⁷ and civil society have called for a greater role of the EU in health. In a Eurobarometer survey (April 2021), 38% of Europeans reported healthcare as the number one task of the EU institutions – ahead of economic recovery, fighting climate change or reducing unemployment. This sentiment finds echoes in the CoFoE proposals, which are reviewed in detail in Pillar 5. However, Member States representatives consulted expressed a preference for a model of cooperation based on knowledge sharing, resource pooling, and crisis procurement.

In contrast, EU pharmaceutical legislation shapes health systems in the Member States. A European pharmaceutical strategy is also a pillar of the EHU (outlined in section 3.1.1). Medical products, including medical devices, represent approximately 20% of health spending in the EU and EU regulation of markets for pharmaceuticals has created a central market authorisation system. The European Commission's pharmaceutical strategy is an EU common response to internal market issues but also to global competition pressure in the sector.

³⁹⁷ European Parliament, [Resolution](#) of 10 July 2020 on the EU's public health strategy post-COVID-19 (2020/2691(RSP)).

In effect then, the sharing of health competences between the EU and the Member States translates into a range of complexities when it comes to evaluating EU-level COVID-19 response. Stakeholders consulted were in two minds of the value of coordination offered by the EU. On the one hand, some Member States stated EU support was of value in emergency procurement, though there was a lack of choice in the selection of key items such as diagnostic kits – and the supplies received were, at times, in contradiction of local health advisories. On the other hand, smaller countries with weaker capacities expressed satisfaction with the support received from the EU.

On consideration, a coordinated EU response to COVID-19 would require improved levels of coordination between the EU agencies and Member States, alongside greater parity across health system capacities and health outcomes. The disparities in health systems and health outcomes across the Member States have prompted questions over the scope and effectiveness of the EHU – and specifically: how far the EHU can deliver on the promises of health equity and ensure solidarity at the European level. Political will for structural reforms and sufficient funding will be critical to ensure the EHU delivers on its stated objectives.³⁹⁸

EQ 2.3: To what extent are the activities of the EU COVID-19 response coordinated and complementary to global priorities and international partners?

In the initial phase of the pandemic, the EU and its Member States came under criticism for their failure to contribute more fully to global vaccine solidarity efforts. In part, the problem was procedural.

In effect, an EU Member State has one of three options for national vaccine procurement: a national strategy for vaccine procurement, including APAs, EU collaboration through the vaccines strategy, or COVAX. This pits COVAX against the EU model. While EU Member States can donate to COVAX, they cannot participate in both schemes.³⁹⁹ EU Member States responded by choosing the EU collaboration to meet domestic medical needs while donating to COVAX as a contribution to global health.⁴⁰⁰ (see also EQ 1.3, section 5.5.).

3.4. EU added value

The section on 'EU added value' reflects on changes that can be reasonably attributed to EU intervention beyond what can be reasonably expected of or attributed to national actions by the Member States.⁴⁰¹

Box 11: The EU added value

EU added value looks for changes that are due to the EU intervention, over and above what could reasonably have been expected from national actions by the Member States. It presents the arguments on causality and draws conclusions, based on available evidence, about the performance of the EU intervention.

The timing of the EU intervention is an important variable in the judgement of EU added value (as with effectiveness analysis). In the 'early years' of the intervention, EU added value may be difficult to judge. In these cases, the Better Regulation guidelines advise confirming the validity of the (theoretical) EU-added value.

Source: European Commission, [Better Regulation toolbox, chapter 6](#).

³⁹⁸ Purnhagen K.P. et al., '[More competences than you knew? The web of health competence for European Union action in response to the COVID-19 outbreak](#)', *European Journal of Risk Regulation*, Vol. 11(2), 2020, pp. 297-306.

³⁹⁹ Greer S.L., '[National, European, and global solidarity: COVID-19, public health and vaccines](#)', *Eurohealth*, 26(2), 2020, pp. 104-108.

⁴⁰⁰ Reuters, '[Exclusive: WHO sweetens terms to join struggling global COVAX vaccine facility – documents](#)', 2020.

⁴⁰¹ European Commission (2021), [Better Regulation Toolbox, Tool #47: Evaluation criteria and questions](#), pp. 409-411. (Accessed 29 November 2022).

EQ 3: What was the added value of the EU's COVID-19 response?

In addition to the strain on health systems, COVID-19 severely disrupted services at the internal and global levels. The EU's COVID response added value by allowing for a faster and more coordinated response at the EU level. In particular, stakeholders consulted pointed to the vaccine strategy with joint procurement of vaccines, crisis procurement through the rescEU stockpile, the ease of mobility provided by the EU digital certificate, and the imposition of green lanes (to maintain open borders and avoid shortages) were exceptional solidarity measures (of these four, the joint procurement mechanism and rescEU form part of this study, and their added-value will be addressed in more detail).

Many stakeholders consulted for this study shared a positive assessment of the EU's COVID-19 response on account of the fact that a coordinated response to the COVID-19 pandemic would have been difficult to achieve by Member States acting alone. In particular, the EU agencies, instruments, and strategies that were emphasised by stakeholders were joint procurement, the rescEU stockpiling, and the surveillance and scientific advice provided by the ECDC.

In particular, stakeholders from smaller countries with weaker capacities found exceptional added value in the advisory issued by the ECDC. Having said that, our analysis and evaluation of these instruments shows that the results are far from uniform.

At the same time, stakeholders called for a layered approach where mitigation measures must take into account the local circumstances despite the view that cross-border health threats are best addressed at the Union level. A similar view is to be found in the citizens-led CoFoE proposals, where the foundations for public health, including prevention and preparedness, are founded in a localised, community-based approach (see discussion in section 5.2). In the same vein, consulted stakeholders pointed out it will be important to ensure close collaboration and synergies between the various DGs. This will be essential towards establishing a system where Europe is better-equipped to face emergencies.

JPA

The analysis of the added value of the JPA is complex. Joint procurement actions under the JPA strengthen the purchase power of Member States, allowing participating Member States to improve their purchasing power for scarce resources, and derive benefits from risk-sharing and economies of scale.⁴⁰² This is especially valuable in crisis procurement.

However, patients' primary concerns are affordability of and access to medicines. That said, if viewed from the perspective of patients, the principal question is about affordability and access to medicines best suited to their condition. Related to this is the matter of vaccine delivery and uptakes and the wide divergence in vaccine coverage rates which is a function of healthcare systems, cultural attitudes, and resources – all of which vary greatly across the Member States.

Would it have been more efficient to leave vaccine procurement to national authorities? On the short term, the slow pace of vaccine rollout in the initial months undermined the benefits of shared European procurement. In the longer-term, though, the benefits of the collective approach became more evident. By mid-August 2021, the EU had overtaken the US in vaccine delivery, with 61.9% of the EU population vaccinated with the first dose (and 53.5% with the second dose), compared to US figures of 59.6% and 50.6%, respectively. Also, overcoming the initial criticisms over lack of leadership, the European Commission has concluded additional deals for 1.8 billion doses through 2023 with Pfizer-BioNTech, and a joint procurement contract with Spanish company HIPRA Human Health for 250 million doses of their protein COVID-19 vaccine. That said, some stakeholders pointed

⁴⁰² Halloran D., '[Procurement during a Public Health Crisis: the Role of the European Union](#)', *Irish Studies in International Affairs*, 32(1), pp. 67-81, 2021.

out the fact that the Member States could procure countermeasures alone, undermining the solidarity principle.

RescEU

Since its activation in March 2020, the UCPM has provided essential emergency assistance to EU Member States and beyond. The clear success of the rescEU mission is evident both in the range of services provided (i.e. repatriation consular assistance, mobile medical teams, PPE deliveries) and in the geographical spread of its actions: throughout the EU, to its enlargement countries in the Western Balkans, and further afield. As a 'last resort' mechanism, rescEU provides emergency assistance – not structural support by way of health system strengthening, for example.

However, the optimal operation of the UCPM (since March 2020) can mask its actual operation in crises. When comparing early requests and receipts of emergency assistance by Italy, France, and Spain (the early sites of COVID-19 infection in Europe), it is evident that European solidarity was expressed in two ways: bilateral assistance between EU Member States (without recourse to the EU-level) or coordinated by the North Atlantic Treaty Organization (NATO). Italy registered the first cases in Lombardy in late February 2020, and its first requests for activation of the UCPM in late February 2020 went unheeded.⁴⁰³ The earliest emergency assistance to Italy arrived bilaterally from EU countries (i.e. France and Germany) and non-EU countries (China, Russia, Cuba, and Venezuela); and from the NATO civil protection mechanism (Euro-Atlantic Disaster Response Coordination Centre, NATO-EADRCC). Spain similarly received its early emergency assistance from Czechia, Türkiye, and Germany (all coordinated by the NATO-EADRCC).⁴⁰⁴ France, on the other hand, requested assistance from the UCPM to facilitate the repatriation of citizens. Emergency assistance was also received from bilateral partners (Germany, Luxembourg, Switzerland, and Austria) for the transfer of critically ill patients to ICUs abroad.⁴⁰⁵

Global dimensions

As previous sections outline, the primary ground for the EU's COVID response was coordinated at the level of the EU. Stakeholder consultations converged on the common point that the EU's COVID-19 response, taken with European solidarity in mind, did not extend timely assistance to the global pandemic.

3.5. Main findings

Effectiveness of the EU response

- The new Regulation on Serious Cross-border Threats to Health allows for a faster and more coherent response at EU level, and has the potential to better allocate scarce resources and make efficient use of capacities across Member States in emergency situations.
- Some stakeholders expressed their concern over the lack of clarity in the definition of a 'public health emergency' at the EU level.
- The creation of HERA and stronger mandates for the ECDC and EMA are viewed as important building blocks towards developing an EU-level plan for protection, preparation, prevention, and response and delivering a European Health Union.
- The effectiveness of JPA is evident in terms of the diversified array of COVID-19 vaccines, the broad use of the JPA for crisis procurement, the increased regional participation in the JPA, and the significant growth in its membership.

⁴⁰³ Beaucillon C., '[International and European emergency assistance to EU Member States in the COVID-19 crisis: why European solidarity is not dead and what we need to make it both happen and last](#)', *European papers*, Vol. 5(1), 2020, pp. 387-401.

⁴⁰⁴ Ibid.

⁴⁰⁵ Ibid.

- Stakeholders identified several issues in regard to the JPA, such as an initially slow pace of delivery, and a lack of choice of vaccine suppliers. Some of them expressed concerns regarding the quality and compliance with rules of crisis procurement.
- Considering the complexities of national health systems and medical needs, EU level procurement is more likely to complement, not replace, procurement at the national level.
- Concerns were raised as to the extent to which the JPA retains value outside of a crisis. In this regard, there is some expectation that the JPA could retain its efficiency and utility by extending procurement to new products.
- Stakeholders agreed that rescEU strengthened the EU response to health emergencies through medical stockpiles in participating EU Member States and allowed for quicker reaction to health crises. The reason for its success is the ability to intervene when Member States are in need.
- Stakeholders pointed out that a shortage of capacities to deal with all sorts of emergencies still remains.

Coherence of the EU response

- The study found no evidence to suggest a lack of internal coordination and coherence between the various EU agencies and institutions.
- There are doubts about the potential duplication of competences and responsibilities of the EU's health DGs and agencies with HERA's creation.
- The EU's limited competences in the health domain and the present health system disparities across Member States have been considered as impediments to further coordinated efforts in the area of tackling health threats .
- EU Member States responded by choosing EU collaboration to meet domestic medical needs, while donating to COVAX as a contribution to global health.

Added value of the EU response

- Many stakeholders, in particular, those from smaller Member States, shared a positive assessment of the EU's COVID-19 response: a coordinated response to the COVID-19 pandemic would have been difficult to achieve by the Member States acting alone.
- Whereas cross-border health threats are best addressed at the EU level, stakeholders called for mitigation measures to take into account local circumstances.
- Centralised procurement actions under the JPA strengthen the buying power of Member States. However, some stakeholders cautioned that the fact that the Member States could procure countermeasures alone might undermine the solidarity principle.

The Union Civil Protection Mechanism (UCPM) has provided essential emergency assistance to EU Member States and beyond.

4. EU prevention and response capacity (Pillar 4)

The COVID-19 pandemic caused widespread disruption to national health systems within the EU, as well as affecting economies worldwide. As of December 2022, there have been 642,379,243 confirmed cases worldwide, with 6.6 million confirmed deaths officially reported;⁴⁰⁶ estimates of the actual death toll suggest it could exceed 20 million fatalities worldwide.⁴⁰⁷ In the EU, COVID-19 has led to the death of more than 1.1 million people – a figure which is likely underestimating the actual COVID-19 death toll in the EU.⁴⁰⁸

Despite its global nature, the COVID-19 pandemic did not affect everyone equally, with the world's most vulnerable populations bearing the brunt of the crisis. The United Nation's Sustainable Goals Development Report 2022 warned that a 'cascading and intersecting crisis' of COVID-19, climate change, and conflict has reversed more than four years of progress against poverty – and decades of improvement in global health – and putting the 2030 Sustainable Goals in 'grave danger'.⁴⁰⁹ As of December 2022, 12 billion COVID-19 vaccine doses have been administered worldwide;⁴¹⁰ but only 20.5% of the population in low income countries (LICs) have been fully vaccinated, compared to 74.5% in high-income countries (HICs).⁴¹¹ The COVID-19 pandemic also masked a concurrent 'shadow pandemic'⁴¹² of domestic violence, mental ill-health, educational deprivation and social isolation brought on by lockdowns and persistent disruptions to elective and chronic care.

The immediacy of the COVID-19 pandemic serves as a preview to the existential threat of future pandemics, likely to be caused by zoonoses. Zoonoses are diseases or infections naturally transmitted from animals to humans. The WHO estimates that 60% of emerging infectious diseases (EIDs) reported globally are zoonotic.⁴¹³ COVID-19 is one of several high-impact infectious diseases or designated Public Health Emergencies of International Concern (PHEIC) that emerged from wildlife, linked to the human relationship with nature: this is an interdependence that is theorised and institutionalised as the 'One Health' approach. Since the revision of the International Health Regulations (IHR) in 2007, the WHO has declared seven such PHEICs: the influenza H1N1 pandemic in 2009, polio in 2014, the Ebola epidemic in West Africa in 2014, the Zika virus epidemic in 2016, the Ebola epidemic in the Democratic Republic of Congo in 2020, COVID-19 also in 2020, and monkey pox in 2022.⁴¹⁴ The lessons from the COVID-19 pandemic and the internal organisation of EU health policies through the EHU (described in Pillar 3) create the opportunity for a leading role for the EU in global health policy.^{415 416}

Global vulnerabilities and significant unmet medical needs mandate an enhanced level of preparedness at the EU-level anchored in robust forms of international cooperation and a broader

⁴⁰⁶ The Economist, [The pandemic's true death toll](#), 25 October 2022.

⁴⁰⁷ WHO, [Coronavirus \(COVID-19\) Dashboard](#) (Accessed 12 December 2022).

⁴⁰⁸ WHO and ECDC, Joint ECDC-WHO Regional Office for Europe, [Weekly COVID-19 Surveillance Bulletin](#) (Accessed 12 December 2022).

⁴⁰⁹ UN, [The Sustainable Development Goals Report 2022](#).

⁴¹⁰ WHO, [Coronavirus \(COVID-19\) Dashboard](#) (Accessed 12 December 2022).

⁴¹¹ Our World in Data, [Share of people who completed the initial COVID-19 vaccination protocol](#) (Accessed 10 December 2022).

⁴¹² UN, [Ending Shadow Pandemic in COVID-19 World](#), 2022.

⁴¹³ WHO, Eastern Mediterranean Office, [Zoonotic disease: emerging public health threats in the region](#).

⁴¹⁴ Medialdea Carrera R., [The importance of cross-border pandemic preparedness](#), *Eurohealth*, 26, 34, 2020.

⁴¹⁵ Kickbusch I. and De Ruijter A. [How a European health union can strengthen global health](#), *The Lancet Regional Health Europe*, 1, 100025, 2021.

⁴¹⁶ Kickbusch I., [If you want a stronger EU: Build a European Health Union](#), *Eurohealth*, Vol. 26(3), 2020, pp. 32-33.

public health approach.⁴¹⁷ This would involve a long-term preventive plan that is predicated on resilient health systems, investments into One Health, and reinforced global health security.^{418 419} Achieving this goal will revolve around the ability of the EU, its Member States, and international partners to act more effectively in addressing the social and environment determinants of ill-health⁴²⁰ and to do so in alignment with Sustainable Development Goals (SDGs).^{421 422}

As previously outlined in Pillar 3, Regulation (EU) 2022/2371 on serious cross-border threats to health⁴²³ provides the legal basis to develop an EU-level health crisis and pandemic plan and enhance risk assessments for health threats, with provisions on the exchange of information, early warning and risk management. This chapter begins with an overview of the EU's prevention and preparedness framework (section 4.1), followed by descriptions of the extended mandates of the ECDC and EMA (section 4.2), as well as the activities of HERA (section 4.3). After that, the next sections will focus on the EU Global Health strategy (section 4.4), the One Health approach (section 4.5), and finally the WHO pandemic treaty (section 4.6).

4.1. The EU's prevention and preparedness framework

The EU agencies ECDC and EMA play a central role in the EU's prevention and preparedness framework against future cross-border health threats. This section will examine the ECDC's and EMA's governance throughout the COVID-19 pandemic, with an outline of their founding mandates.

4.1.1. The ECDC's governance during the COVID-19 pandemic

The ECDC's founding mandate

The ECDC is the core EU agency responsible for strengthening the EU's response capacity to current and emerging infectious diseases. According to its founding regulation,⁴²⁴ the agency's priority is centred around the interdependent mandates to 'protect and improve human health by prevention of human disease ... [and] counter potential threats to health with a view to ensuring a high level of protection of health of European citizens'.

The ECDC was founded in 2004 to monitor health threats, following the 2002 SARS outbreak. The agency's primary mandate was to increase the EU's surveillance capacity. In the wake of the 2009 H1N1 outbreak, the agency expanded its remit to include a vaccine strategy.

⁴¹⁷ Renda A. and Castro R., '[Towards stronger EU governance of health threats after the COVID-19 pandemic](#),' *European Journal of Risk Regulation*, 11(2), 2020, pp. 273–282.

⁴¹⁸ Mauer N. et al., '[Towards a European Health Union: new instruments for stronger and more resilient health systems](#),' *Eurohealth*, 28 (1), 57–61, 2022.

⁴¹⁹ Sipido K.R. et al., '[Overcoming fragmentation of health research in Europe: Lessons from COVID-19](#),' *The Lancet*, 395, 1970–1971, 2020.

⁴²⁰ De Ruijter A., '[What do we actually mean by a European Health Union?](#),' *Eurohealth*, 26 (3), 2020, pp. 30–31.

⁴²¹ Bazzan G., '[Exploring Integration Trajectories for a European Health Union](#),' *European Journal of Risk Regulation*, Vol. 11(4), 2020, pp. 736–746.

⁴²² Vervoort D. and Van Daalen K.R., '[The European Union, economies and public health: not one without the other](#),' *Public Health*, Vol. 194, 2021, pp. 1–3.

⁴²³ [Regulation \(EU\) 2022/2371](#) of 23 November 2022 on serious cross-border threats to health.

⁴²⁴ [Regulation \(EC\) No 851/2004](#) of 21 April 2004 establishing a European Centre for Disease Prevention and Control, paras. 7–9.

The agency is responsible for epidemiological surveillance, epidemic intelligence, risk assessments of cross-border health threats and providing evidence,⁴²⁵ e-based advice and technical assistance to adjacent European agencies, national governments, and the public.⁴²⁶

The Early Warning and Response System (EWRS) is also housed with the ECDC. As a restricted-access online portal that connects public health agencies across Europe, it allows for the facilitation of sharing surveillance data in real-time.⁴²⁷ Currently, the ECDC collects, analyses, and communicates data on 50 infectious disease topics, including COVID-19, monkey pox, influenza, and tuberculosis, as well as vaccination and viral and bacterial resistance against medication.⁴²⁸

The ECDC's response to COVID-19

In 2020, responding to COVID-19 was the ECDC's predominant activity, demanding most of the agency's time and resources. Principally, the agency's COVID-19 response activities covered four areas of action: (1) data output and technical reports; (2) scientific guidance for policymakers; (3) information for practitioners and the public; and (4) responses to impromptu requests by EU institutions and Member States.⁴²⁹

- **Data and surveillance output:** The ECDC collated and published surveillance outputs and epidemiological overviews in various formats. These included: Rapid Risk Assessments (RRA's), Weekly Threat reports, hospital and ICU admission and occupancy rates, the geographic distribution of cases worldwide, surveillance summaries and situational dashboards per country. During the COVID-19 pandemic, the creation of RRAs was prioritised. The agency issued 19 RRAs to support the European Commission and Member States in their preparedness and response capacities, with timely health situation assessments and suggested response measures. The dimensions covered include the transmissibility and severity of Variants of Concern (VoCs),⁴³⁰ response options on vaccination rollouts and Non-Pharmaceutical Interventions (NPIs),⁴³¹ and viral transmission in healthcare settings⁴³².
- **Scientific guidance:** The ECDC issued scientific guidance to public health agencies, health professionals and Ministries of Health, with expert guidance and recommendations on crisis response. Topics covered include strategies for COVID-19 viral testing,⁴³³ advice on social distancing,⁴³⁴ and contact tracing⁴³⁵.
- **Information to health care professionals and the general public:** The ECDC issued videos, infographics and posters, targeting a broad audience.

⁴²⁵ ECDC, [Consolidated Annual Activity Report 2020](#), 2021.

⁴²⁶ [Regulation \(EC\) No 851/2004](#) of 21 April 2004 establishing a European Centre for Disease Prevention and Control, paras. 7-9.

⁴²⁷ ECDC, [Early Warning and Response System of the European Union \(EWRS\)](#), 2018.

⁴²⁸ ECDC, [Webpage](#) About ECDC.

⁴²⁹ ECDC, [Strategic and performance analysis of ECDC response to the COVID pandemic](#), November 2020.

⁴³⁰ ECDC, [Threat Assessment Brief: Implications of the emergence and spread of the SARS-CoV-2 B.1.1.529 variant of concern \(Omicron\) for the EU/EEA](#), *Risk Assessment*, 2021.

⁴³¹ ECDC, [Assessing SARS-CoV-2 circulation, variants of concern, non-pharmaceutical interventions and vaccine rollout in the EU/EEA](#), *Rapid Risk Assessment*, 2021.

⁴³² ECDC, [COVID-19 outbreaks in long-term care facilities in the EU/EEA in the context of current vaccination coverage](#), *Rapid Risk Assessment*, 2021.

⁴³³ ECDC, [COVID-19 testing strategies and objectives](#), 2020.

⁴³⁴ ECDC, [Considerations relating to social distancing measures in response to COVID-19: Guidance](#), 2020.

⁴³⁵ ECDC, [Contact tracing: Public health management of persons, including healthcare workers, having had contact with COVID-19 cases in the European Union: Technical report](#), 2020.

- **Responses to *impromptu* requests for information from external stakeholders.** The ECDC staff addressed niche questions from European agencies, Ministries of Health (MoHs), and media representatives. Frequent requests for additional information involved: additional comments on RRAs, detailed case-based reporting on cases from China, and sharing RRAs on the EWRS platform.⁴³⁶

Analysis of the ECDC's COVID-19 response

At the beginning of the pandemic, the ECDC failed to detect the seriousness of the threat and the lack of preparedness within the Member States. Still in January 2020, the agency assessed the epidemiological risk in Europe as low and argued that the EU was well prepared; in February, the agency considered the EU's laboratory and testing capacities to be sufficient and the EU's containment strategy a success. A sanitary alarm was raised only by March 2020.⁴³⁷

This failure was linked to the Member States' lack of timely data sharing.⁴³⁸ *Ex-post* performance analysis of the agency has since also highlighted structural flaws in its organisational core.⁴³⁹ Principally, there were four overlapping issues: the lack of adequate funding and resources, the lack of requisite discretion and decision-making, the agency's relatively limited geographical scope, and legislative barriers which hinder data sharing.

First, the ECDC's initial capacities were severely undermined by a lack of funding and personnel.⁴⁴⁰ At the start of the pandemic, the agency had an operating budget of €59 million (figures for 2020) and employed 280 full-time staff.⁴⁴¹ However, the agency's budget and staffing were significantly increased in the years since. In 2021 the agency's core budget was increased to €168.1 million, employing 351 staff members.⁴⁴²

Second, the agency lacked regulatory decision-making powers in its core functions of risk assessment and epidemiological surveillance. The ECDC collects data related to COVID-19 through the EWRS and the European Surveillance System (TESSy). Member States use the EWRS to report laboratory-confirmed cases of COVID-19 every 24 hours and provide more detailed epidemiological information through TESSy on a weekly basis. The agency relies on data provided by the Member States in both cases – data which reportedly was partial and incomplete during the COVID-19 crisis.⁴⁴³ Moreover, though responsible for risk assessment, the agency lacks discretion over risk management; that discretion lies firmly with the Member States.

Third, the agency's relatively limited geographical scope further limits its surveillance activities. The ECDC's mandate is restricted to the EU/EEA region. As such, it does not include Switzerland, Ukraine,

⁴³⁶ ECDC, [Strategic and performance analysis of ECDC response to the COVID pandemic](#), 2020.

⁴³⁷ Beaussier A. and Cabane L., '[Strengthening the EU's Response Capacity to Health Emergencies: Insights from EU Crisis Management Mechanisms](#)', *European Journal of Risk Regulation*, Vol. 11(4), 2020, pp. 808-820.

⁴³⁸ Nabbe M. and Brand H., '[European Union's Concern about Health for All. Concepts, Definition, and Scenarios](#)' *Healthcare*, Vol. 9(21), 1741, 2021.

⁴³⁹ ECDC, [Strategic and performance analysis of ECDC response to the COVID pandemic](#), 2020.

⁴⁴⁰ Beaussier A. and Cabane L., '[Strengthening the EU's Response Capacity to Health Emergencies: Insights from EU Crisis Management Mechanisms](#)', *European Journal of Risk Regulation*, Vol. 11(4), 2020, pp. 808-820.

⁴⁴¹ Renda A. and Castro R., '[Towards stronger EU governance of health threats after the COVID-19 pandemic](#)', *European Journal of Risk Regulation*, 11(2), 2020, pp. 273–282.

⁴⁴² Anderson A. and Mossialos E., '[Time to Strengthen Capacity in Infectious Disease Control at the European Level](#)', *International Journal of Infectious Diseases*, Vol. 99, 2020, pp. 263–265.

⁴⁴³ ECDC, [Strategic and performance analysis of ECDC response to the COVID pandemic](#), 2020, p. 14.

⁴⁴⁴ ECDC, [Consolidated annual activity report](#), 2021.

⁴⁴⁵ Beaussier A. and Cabane L., '[Strengthening the EU's Response Capacity to Health Emergencies: Insights from EU Crisis Management Mechanisms](#)', *European Journal of Risk Regulation*, Vol. 11(4), 2020, pp. 808-820.

Belarus, and the Western Balkans region, i.e. countries that share multiple borders with the EU.⁴⁴⁶ This is a significant barrier against mounting a comprehensive European response to infectious disease and collaborations with intergovernmental agencies, such as the WHO, at the European level. For instance, the WHO Regional Office for Europe conducts surveillance of infectious diseases for 53 countries, thus covering a much vaster geographical area (including Norway, Switzerland, Türkiye, and Ukraine).⁴⁴⁷ In comparison, the remit of the ECDC only extends to 29 countries: the EU27, and 2 EEA countries (Iceland and Norway).⁴⁴⁸

Fourth, legislative barriers over data sharing currently limit the ECDC's scope of action.⁴⁴⁹ For example, the GDPR affects the sharing of anonymised patient information. This will have consequences for the participation of non-EU countries in the agency's disease surveillance activities, also partly due to differences between EU and non-EU countries when it comes to security measures. Similarly, improved compliance with data reporting on the part of Member States may require legislation. An interviewed stakeholder found that the ECDC's surveillance efforts are hampered by the gaps, variations, and delays in data reporting by the Member States. Non-compliance by Member States – and their failure to meet reporting – would also hinder the agency's ability to provide timely guidelines.

4.1.2. EMA governance during the COVID-19 pandemic

EMA's founding mandate

EMA fosters the evaluation and supervision of medicines to benefit human health. It conducts scientific evaluations of medicines for human and veterinary use to protect public and animal health. It was founded in 1995 and is based within the EU Medicines Regulatory Network (EMRN) – a partnership between the European Commission and medicines regulatory authorities within the EEA countries and EMA.⁴⁵⁰

EMA's response to COVID-19

EMA established dedicated task forces to deal with the scientific, regulatory, and operational challenges posed by the COVID-19 pandemic.⁴⁵¹ The aim was to safeguard the Agency's core activities related to the evaluation and supervision of medicines during the pandemic and to earmark dedicated resources dealing with COVID-19.

This involved:

- The establishment of an Emergency Task Force (ETF) to provide scientific advice to pharmaceutical developers and review scientific data on COVID-19 vaccines and therapeutics. In addition, the ETF also offered scientific support towards facilitating clinical

⁴⁴⁶ Anderson M., Mckee M. and Mossialos E., '[Editorial: Covid-19 exposes weaknesses in European response to outbreaks](#)', *British Medical Journal*, 368, 2020.

⁴⁴⁷ These are: the EU27 plus (1) Albania, (2) Andorra, (3) Armenia, (4) Azerbaijan, (5) Belarus, (6) Bosnia and Herzegovina, (7) Georgia, (8) Iceland, (9) Israel, (10) Kazakhstan, (11) Kyrgyzstan, (12) Monaco, (13) Montenegro, (14) North Macedonia, (15) Norway, (16) Republic of Moldova, (17) Russian Federation, (18) San Marino, (19) Serbia, (20) Switzerland, (21) Tajikistan, (22) Türkiye, (23) Turkmenistan, (24) Ukraine, (25) United Kingdom, and (26) Uzbekistan. WHO/Europe, [An Introduction to WHO in the European region](#), p. 43.

⁴⁴⁸ ECDC, [Webpage](#) What we do.

⁴⁴⁹ Anderson A. and Mossialos E., '[Time to Strengthen Capacity in Infectious Disease Control at the European Level](#)', *International Journal of Infectious Diseases*, Vol. 99, 2020, pp. 263–265.

⁴⁵⁰ EMA, [Webpage](#) About us: History of EMA.

⁴⁵¹ EMA, [Webpage](#) EMA's governance during Covid-19 pandemic.

trials and provided scientific recommendations on the most promising medicines before their authorisation.⁴⁵²

- An EMA COVID-19 Steering Group to provide strategic supervision over the evolving scientific and regulatory challenges posed by COVID-19. Its principal responsibilities are monitoring the agency's COVID-19 response and ensuring continuity with the agency's business plan.⁴⁵³
- The EMA Health Threats Plan prescribes how the agency works during a health crisis. This involves the work of its staff and scientific committees, as well as the agency's external communication with EU Member States, international partners, and other stakeholders. The plan also covers operational aspects such as rapid scientific advice for products under development and fast-track approval of vaccines and antivirals.⁴⁵⁴
- The EMRN Business Continuity Plan, with a specific focus on the authorisation of COVID-19 medicine and addressing medical shortages in ICUs.⁴⁵⁵
- Continuing collaborations with the EU and international partners through the OPEN Initiative. The OPEN initiative promotes the co-sharing of scientific expertise between the WHO, EMA, and selected medicines regulators outside the EU. Currently, the initiative extends to Australia, Canada, Japan, and Switzerland.⁴⁵⁶

Analysis of EMA's response to COVID-19

The COVID-19 pandemic placed an intense and sustained demand on EU medical regulators' resources, including EMA, with multiple medicinal products subject to fast-track evaluation and safety monitoring.⁴⁵⁷

The COVID-19 pandemic accelerated the pace and extent of research on COVID-19-related vaccines and medicine development. As a result, EMA faced specific challenges, including the need to adapt to emerging scientific data and communicate uncertainty in real-time. Additionally, EMA's scientific committees and their experts from EU Member States were tasked with evaluating products and carrying out pharmacovigilance activities in other therapeutic areas, including unmet medical needs. Moreover, parallel to the scientific work, there was an unprecedented need to communicate rapidly evolving scientific knowledge and extensive data generated, including genuine concerns from the public, while also counteracting misinformation by providing authoritative reference data and reports.⁴⁵⁸

As with the ECDC, the unprecedented demand for medicine and medical countermeasures during the COVID-19 pandemic tested EMA's resources and necessitated resorting to ad hoc measures. Additionally, the agency did not have access to sufficient health data to formulate recommendations that could be coordinated across the EU. Vaccine developers also pointed to the lack of harmonisation on procedures relating to clinical trials, in consequence of which each trial needed to be separately authorised in each individual Member State.

⁴⁵² EMA, [Webpage](#) Emergency Task Force (ETF).

⁴⁵³ EMA, [Webpage](#) EMA's governance during COVID-19 pandemic - EMA COVID-19 Steering Group.

⁴⁵⁴ EMA, [Webpage](#) Public health threats - Health Threats Plan.

⁴⁵⁵ EMA, [European Medicines Regulatory Network COVID-19, Business Continuity Plan](#), 10 September 2020.

⁴⁵⁶ EMA, [Questions and Answers on the Pilot Project Open](#), 3 February 2021.

⁴⁵⁷ EMA, Additional measures to allow experts to focus on COVID-19 activities, [press release](#), 11 May 2021.

⁴⁵⁸ Cavaleri M. et al., '[Shaping EU Medicines Regulation in the post COVID-19 era](#)', *The Lancet Regional Health – Europe*, Vol. 9(100192), 2021.

EMA was found to lack preparedness to cope with public health emergencies.⁴⁵⁹ Preparedness in this context required tools and methods for monitoring, reporting and data collection. A key priority would be to gather data on key medicines and medical devices and address shortages in health emergencies.

Stakeholders consulted for this study pointed out the importance of ensuring the availability of critical medicines and supplies for future health crises. The importance of addressing medical shortages has also been raised by professional membership-based organisations, such as the Pharmaceutical Group of the European Union (PGEU), which represent community pharmacists in Europe. PGEU emphasises the importance of increased transparency and timely communication, which are critical in the response phase of a health crisis.⁴⁶⁰ Specifically, PGEU underscores the criticality of ensuring a transparent and timely mechanism to communicate shortages of medicines and medical devices – and coordinated actions to prevent or manage such shortages in future health emergencies.

4.2. Expanded mandates of the ECDC and EMA under the EHU

The expanded mandates of the ECDC and EMA provide a key plank for the EU's prevention and preparedness to future health threats, and form a crucial building block for the EHU as outlined in Pillar 3. This section will describe the changes in responsibility of both agencies.

4.2.1. A stronger mandate for the ECDC

On 23 November 2022, the Council and the European Parliament adopted Regulation (EU) 2022/2370⁴⁶¹ that updates and expands the ECDC's mandate in order to strengthen the agency's work in disease surveillance, early warning, preparedness and response.⁴⁶² This expanded mandate involves the following initiatives:⁴⁶³

- **Assistance with preparedness and response planning.** The establishment of an EU Health Task Force to assist local responses to the outbreak of disease and provide expertise to EU Member States and the Commission in the development, examination and updating of preparedness plans. The ECDC is also tasked with the development of digital platforms for epidemiological surveillance.
- **EU-level health crisis and pandemic plan.** Regulation (EU) 2022/2371 on serious cross-border threats to health⁴⁶⁴ provides the legal basis to develop an EU-level health crisis and pandemic plan and enhance risk assessments for health threats, with provisions on the exchange of information, early warning and risk management. At the same time, the Member States' national plans will be harmonised by the Commission with this 'Union prevention, preparedness and response plan'.
- **Closer coordination with the WHO and more robust data protection provisions.** Under the revised mandate, the ECDC will pursue closer coordination with international agencies, such as the WHO, to better align with and coordinate recommendations and actions. At the same time,

⁴⁵⁹ European Commission, Proposal for a regulation on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices, Communication [COM\(2020\) 725](#), 11 November 2020.

⁴⁶⁰ Pharmaceutical Group of European Union, [Position Paper on Health Emergency Preparedness and Response Authority \(HERA\)](#), 2022.

⁴⁶¹ [Regulation \(EU\) 2022/2370](#) of 23 November 2022 amending Regulation (EC) No 851/2004 establishing a European Centre for Disease Prevention and Control.

⁴⁶² Council of the EU, Stronger European Centre for Disease Prevention and Control: Council and European Parliament reach provisional agreement, [press release](#), 29 November 2021.

⁴⁶³ European Commission, [Questions and Answers](#): Building a European Health Union: stronger crisis preparedness and response for Europe, 11 November 2020.

⁴⁶⁴ [Regulation \(EU\) 2022/2371](#) of 23 November 2022 on serious cross-border threats to health.

EU health agencies will adopt stronger data protection provisions, with limitations on the use and communication of personal data.

Stakeholders from the Member States and EU agencies were positive in their assessment of the enhanced mandate of the ECDC. However, a common concern was how this was to be operationalised in practice. Although the ECDC is entrusted with disease surveillance and risk assessment, the agency's recommendations are non-binding. Moreover, while the agency is officially tasked with risk assessment, risk management remains a national competence. This discrepancy was generally highlighted by interviewed stakeholders from across EU agencies and institutions.

4.2.2. A stronger mandate for EMA

Regulation (EU) 2022/123 on a reinforced role for EMA in crisis preparedness and management has been applicable since 1 March 2022 (except for the provisions on shortages of critical medical devices which will apply as of 2 February 2023).⁴⁶⁵ This regulation formalises the structures and processes EMA established during the COVID-19 pandemic and entrusts new tasks and remits to the agency.

As part of this extended mandate, EMA will monitor events which have the potential to contribute to a health-related crisis. This includes monitoring medical shortages, and reporting on critical medicines shortages. The agency will also coordinate Member States' responses on shortages of critical medical devices and *in vitro* (or companion) diagnostics in crisis situations.^{466 467}

In addition, EMA is tasked with coordinating EU-level responses to public health emergencies. This involves the following responsibilities:⁴⁶⁸

- Reinforcing the COVID-19 EMA Pandemic Task Force (COVID-ETF) through providing evidence-based advice on medicines with the potential to avert a public health emergency, and supporting EMA committees on authorisation and safe monitoring of medicine.
- Coordinating independent vaccine effectiveness and safety monitoring studies using relevant data compiled by public authorities.
- Establishing a pan-European network of real-world data (DARWIN-EU), to leverage and provide EMA committees with Real-World Evidence (RWE) from healthcare databases across the EU.

4.3. HERA and health preparedness in the EU

The COVID-19 pandemic occasioned introspection about – as well as investments into – the state of health preparedness in the EU. Since 2020 the EU has improved its health security architecture by adopting new legislation and investing in infrastructure, bolstering preparedness, and reinforcing emergency mechanisms.

HERA is key to the EU's reinforced health security architecture. The COVID-19 pandemic also exposed the interdependence in the health field, with research, transport, industrial policy, and the internal market, for example. Consequently, resilience was underscored as a cross-cutting strategic cornerstone for all EU policies.⁴⁶⁹

⁴⁶⁵ EMA, A stronger role for EMA, [press release](#), 31 January 2022.

⁴⁶⁶ [Regulation \(EU\) 2017/745](#) of 5 April 2017 on medical devices.

⁴⁶⁷ [Regulation \(EU\) 2017/746](#) of 5 April 2017 on *in vitro* diagnostic medical devices.

⁴⁶⁸ EMA, website [Data Analysis and Real World Interrogation Network \(DARWIN-EU\)](#).

⁴⁶⁹ European Commission, 2020 Strategic Foresight Report, Communication [COM\(2020\) 493](#), 9 September 2020.

Health preparedness in the EU is a crucial pillar of action for HERA. It will be grounded in four interweaving strands and the early lessons from the COVID-19 pandemic. The 2022 State of the Health Preparedness Report outlines these to be: (1) threat assessment and intelligence gathering; (2) advanced research and development of countermeasures; (3) access to medical countermeasures – resilient supply chains and production capacities; and (4) international coordination and global activities.⁴⁷⁰

These capacities strengthen protection against ongoing and emerging health threats from pathogens with high pandemic potential, chemical, biological, radiological and nuclear (CBRN) threats, and rising threats from antimicrobial resistance (AMR) or other unknown threats.

- **Threat assessment and intelligence gathering.** Threat assessment and intelligence gathering involve two aspects: the prioritisation and the detection of threats. The European Commission identified three health threats that require coordination of measures at the EU level in the context of medical countermeasures for the former aspect. The three threat categories of life-threatening or seriously harmful hazards to health are (1) pathogens with high pandemic potential; (2) chemical, biological, radiological and nuclear (CBRN); and (3) AMR.⁴⁷¹ The identification and prioritisation of threat categories were undertaken with a view to ensuring a systemic, long-term approach to preparedness towards ensuring an assured provision of the most relevant medical countermeasures. The list is prepared iteratively, with threats identified and prioritised in collaboration with relevant stakeholders, including Member States and global partners, and adopted an “all hazards approach”.⁴⁷² The latter aspect involves considering several criteria, including mode of transmission, risk of spreading to the community, and the availability of treatment.
- The pandemic also demonstrated the usefulness of interconnected and cross-sectoral intelligence-gathering systems for facilitating evidence-based decision-making. Accordingly, the Medical Countermeasures Intelligence Platform (HERA's MCMI platform) was established to strengthen the link between health threat detection and the availability of relevant medical countermeasures to address health threats.⁴⁷³ The MCMI platform complements existing epidemic intelligence resources by combining intelligence on health threats with medical countermeasures. Towards this, the platform intends to collect information on the production and stockpiling of crisis-relevant raw materials, equipment and infrastructure from manufacturers and Member States.⁴⁷⁴
- **Advanced research and development of countermeasures.** The pandemic has also made clear that there was insufficient investment in medical countermeasures that pose a high risk for investors with regard to market uptake. From 2023, the Commission will be providing €100 million to top up Invest EU efforts in de-risking private investment (“HERA INVEST”) which should stimulate innovation in medical countermeasures for which currently there are insufficient market incentives. This financing instrument takes into account the experience gained in previous and existing programmes, such as the Innovative Medicines Initiative (IMI1 and IMI2), the European Innovation Council (EIC) and the European Institute of Innovation and Technology (EIT).
- The Commission will continue to develop and fund large-scale multi-centre clinical trials, such as European pandemic clinical trial platforms (e.g. EU-RESPONSE and VACCELERATE), with an established trial infrastructure and coordination mechanism for research preparedness. Moreover, in the coming years, the European regulatory environment for

⁴⁷⁰ HERA, [Workplan 2022](#).

⁴⁷¹ European Commission, Health Union: HERA delivers list of top-3 health threats to prepare against, [press release](#), 12 July 2022.

⁴⁷² HERA, [Workplan 2022](#).

⁴⁷³ European Commission, European Health Emergency preparedness and Response Authority (HERA): Getting ready for future health emergencies, [press release](#), 16 September 2021.

⁴⁷⁴ HERA, [Workplan 2023](#).

clinical trials will facilitate, streamline, speed up, and increase transparency for multinational clinical trials as well as for possible new COVID-19 therapeutics and vaccines. In addition, it will ensure that the EU offers an attractive and favourable environment for carrying out clinical research on a large scale, with high standards of public transparency and safety for clinical trial participants.

- **Access to medical countermeasures – resilient supply chains and production capacities.** The pandemic exposed the EU's dependence on external supplies of key medical countermeasures, including vials, syringes, PPE, and other products essential for the production of therapeutics, vaccines, and diagnostics. The Pharmaceutical Strategy for Europe highlights the need to strengthen the security of medicines supply across the EU and avoid shortages.

The EHU will provide the EU with strong tools to identify supply chain issues during a crisis. For instance, through its extended mandate, EMA will gather information on sites manufacturing active pharmaceutical ingredients, crisis-relevant medicinal products, and relevant medical devices and identify risks of shortages and supply chain bottlenecks. On 24 October 2022, the Council adopted the new EU Emergency Framework Regulation (EU) 2022/2372⁴⁷⁵ to facilitate timely purchase and access to medicines, vaccines and raw materials and activate emergency funding to monitor production facilities during a health crisis.⁴⁷⁶ Under this regulation, the Commission may monitor upstream issues in the supply chains of raw materials and other components necessary for manufacturing crisis-relevant medical countermeasures (see also Box 6).

In addition, the Commission's proposal for a Single Market Emergency Instrument (SMEI) also aims at preserving the free movement of goods, services and persons, and the availability of essential goods and services in the event of future emergencies.⁴⁷⁷ Moreover, to cater to the rapidly increasing demand for certain raw materials, a legislative initiative on critical raw materials was announced for the first quarter of 2023.

The Commission coordinates supply chain surveillance via the Task Force for Industrial Scale-up of COVID-19 vaccines (TFIS) to help scale up the production of COVID-19 vaccines.⁴⁷⁸ Globally, the Joint EU-US COVID-19 Manufacturing and Supply Chain Taskforce coordinated EU and United States action to prevent and mitigate disruptions in manufacturing processes and supply chain shortages.⁴⁷⁹

International coordination and global activities. COVID-19 exposed structural shortcomings in the EU's health security architecture and in global health security. A Team Europe approach was also essential in vaccine donations. As of November 2022, the EU and its Member States, through a Team Europe approach, have shared almost 500 million doses of COVID-19 vaccines with partner countries via COVAX and bilaterally, including through the UCPM.⁴⁸⁰ The EU has also reaffirmed and extended its commitments to global health security through the EU Global Health strategy. An

⁴⁷⁵ [Council Regulation \(EU\) 2022/2372](#) of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level.

⁴⁷⁶ Council of the EU, Council adopts law on the emergency framework regarding medical countermeasures, [press release](#), 24 October 2022.

⁴⁷⁷ European Commission, Proposal for a regulation establishing a Single Market emergency instrument and repealing Council Regulation No (EC) 2679/98, Communication [COM\(2022\) 459](#), 19 September 2022.

⁴⁷⁸ European Commission, [Webpage](#) Task Force for Industrial Scale-up of COVID-19 vaccines.

⁴⁷⁹ European Commission, United States–European Commission Joint Statement: Launch of the joint COVID-19 Manufacturing and Supply Chain Taskforce, [press statement](#), 22 September 2021.

⁴⁸⁰ HERA, [Workplan 2022](#).

important element of this is the effort to build partnerships to improve coordination and collaboration to ensure the availability and access to medical countermeasures at the global level.

As part of this effort, on 9 June 2022, the Commission and the relevant US authorities signed an administrative arrangement on preparedness and response to public health threats.⁴⁸¹ The arrangement will step up the sharing of information and knowledge and technical cooperation on epidemic and supply chain information. It will help to identify promising solutions for research innovation and the production of medical countermeasures, and will also coordinate support to third countries.⁴⁸² Similar partnerships are being negotiated with South Korea, Japan and the WHO.⁴⁸³

These actions should be read in conjunction with the new EU global health strategy, which builds on a holistic approach to global health. It covers different aspects of the work involved in strengthening health systems, service delivery, financing, the health workforce, medical products, vaccines, technologies, and digital health information systems. In this context, the Commission is strongly engaged in the ongoing negotiations for the establishment of a WHO convention on pandemic prevention, preparedness, and response ('Pandemic Treaty') and a revision of the International Health Regulations.

4.4. EU global health strategy

The COVID-19 pandemic revealed alarming inequalities and structural vulnerabilities. The United Nations' Sustainable Goals Development Report 2022 warns that a 'cascading and intersecting crisis' of COVID-19, climate change, and conflict has reversed more than four years of progress against poverty – and decades of progress in global health – and puts the 2030 Sustainable Goals in 'grave danger'.⁴⁸⁴ The uneven pace of COVID-19 vaccine rollouts is another marker of these inequalities and vulnerabilities. The COVID-19 vaccine rate in Africa stood at 40% (figures for November 2022):⁴⁸⁵ and only 20.5% of the population in low-income countries (LICs) were fully vaccinated, compared to 74.5% in high-income countries (HICs).⁴⁸⁶

Citizens' health and well-being, health systems, and health threats form the core priorities of the New EU global health strategy the European Commission released on 30 November 2022.⁴⁸⁷ The global strategy is an upgrade of the Commission's 2010 Communication on Global Health⁴⁸⁸ and is positioned within a changing geopolitical environment that is responsive to the 'rising' and 'evolving' health challenges of the present day. It is the external dimension of the EHU and is positioned within the Global Gateway and intended to build partnerships with partner countries based 'on joint responsibilities and co-ownership'.⁴⁸⁹ The Global Gateway is a new European strategy set out by the European Commission and the EU High Representative to boost 'smart, clean and secure links' in the digital, energy, and transport sectors and strengthen health, education and

⁴⁸¹ European Commission, European Commission and United States sign cooperation arrangement on preparedness and response to public health threats, [press release](#), 9 June 2022.

⁴⁸² HERA, [Workplan 2022](#).

⁴⁸³ European Commission, State of Health preparedness report, Communication [COM\(2022\) 669](#), 30 November 2022.

⁴⁸⁴ UN, [The Sustainable Development Goals Report 2022](#).

⁴⁸⁵ Statista, [Number of administered coronavirus \(COVID-19\) vaccine doses per 100 people in Africa as of November 3, 2022, by country](#).

⁴⁸⁶ Our World in Data, [Share of people fully vaccinated by country](#) (Accessed 10 December 2022).

⁴⁸⁷ European Commission, EU Global Health Strategy: Better Health For All in a Changing World, Communication [COM\(2022\) 675](#), 30 November 2022.

⁴⁸⁸ European Commission, The EU role in Global Health, Communication [COM \(2010\) 128](#), 31 March 2010.

⁴⁸⁹ European Commission, EU Global Health Strategy: Better Health For All in a Changing World, Communication [COM\(2022\) 675](#), 30 November 2022.

research systems worldwide. It will draw up to €300 billion of investments from the Team Europe Initiative (2021-2027) for priority areas in digital, climate and energy, transport, health, education and research.⁴⁹⁰

Developments in global health since 2010

Developments in global health since 2010 provide a relevant historical context for the new EU Global Health strategy. The European Commission's 2010 Communication on the EU Role in Global Health and the subsequent Council of the European Union's Conclusions set out a rights-based approach to the EU's role in global health.⁴⁹¹ In the decade of the 2010s, the EU's policies on global health were at the time shaped by the Millennium Development Goals (MDGs) and the 2008 WHO Report on Social Determinants in Health. Towards the former, the Commission Communication referred to the MDGs on child mortality, maternal mortality, and HIV/AIDS. Moreover, improved health was intrinsically connected with social justice. For instance, the WHO report outlined the necessary changes in existing power structures (political, economic, social, and gender-based) to affect improved health outcomes.⁴⁹² The Council of the EU's Conclusions⁴⁹³ defined the EU's role in global health as centred around the need to improve health, reduce inequalities, and increase protection against global health threats. The Conclusions identified persistent social and economic power structures (e.g. gender) as a crucial determinant of health and touches upon the role of the EU action in the fields of trade, migration, environment, and climate.

In the meantime, global developments since 2010 have altered the geopolitical environment for concerted global health action and introduced a new set of priorities and challenges. These include for example, the adoption of the SDG agenda by the UN in 2015, an increased awareness of the rising challenges of AMR, and the COVID-19 pandemic. Indeed, in light of these while acknowledging the impressive achievements of the Team Europe Initiative to facilitate the COVID-19 crisis, the EU strategy admits to a 'massive unfinished agenda in global health'.⁴⁹⁴

To begin with, the EU strategy refers to a set of binding challenges that demand attention and intervention. A first set of developments stemming from the rising challenges of AMR and mental health (the latter exacerbated by the effects of COVID-19 lockdowns) have introduced a set of health priorities that cut across geographic divisions. The evolving challenges of health and care systems, including workforce imbalances and resource shortages, also demand prioritisation – to be achieved by utilising the full potential offered alongside research and digitalisation.⁴⁹⁵

A second set of developments stem from the 2030 Agenda for Sustainable Development (adopted by the UN in 2015),⁴⁹⁶ which provides a framework for international cooperation on health. The 17 SDGs provide a global partnership for developed and developing countries, as well as a framework and strategies to improve health and education, together with poverty reduction, addressing climate change, and environmental challenges. The scope of global action is also expanded by the role of powerful actors such as the Bill and Melinda Gates Foundation, that have not only mobilised new sources of funding but also raise questions about global equity and accountability.⁴⁹⁷

⁴⁹⁰ European Commission, [Webpage](#) Global Gateway.

⁴⁹¹ European Commission, The EU role in Global Health, Communication [COM \(2010\) 128](#), 31 March 2010.

⁴⁹² WHO, Commission on Social Determinants of Health, [Closing the gap in a generation: health equity through action on the social determinants of health: Final report of the commission on social determinants of health](#), 2008.

⁴⁹³ Council of the European Union, [Council Conclusions on the EU role in Global Health](#), 10 May 2010.

⁴⁹⁴ European Commission, EU Global Health Strategy: Better Health For All in a Changing World, Communication [COM\(2022\) 675](#), 30 November 2022.

⁴⁹⁵ Ibid.

⁴⁹⁶ UN, [Sustainable Development Goals](#), 2022.

⁴⁹⁷ Bill and Melinda Gates Foundation, [Our work](#).

Additionally, experience gained during the COVID-19 pandemic have created an important political opportunity to take a leading role in the geopolitics of global health and work with international partners towards the SDGs.

Three priorities

The EU Global Health strategy offers an agenda leading up to 2030. It sets out three interrelated policy priorities, provides for twenty guiding principles to shape global health, and creates a new monitoring framework to assess the effectiveness and impact of EU policies and funding. The priorities are: (1) to deliver better health and well-being of people across their lifespan; (2) to strengthen health systems and advance universal health coverage; and (3) to prevent and combat health threats, including pandemics, applying a One Health approach.

The strategy is fitted within the EU's wider strategic agenda and promotes a sustainable meaningful partnership of equals drawing on the Global Gateway.⁴⁹⁸ Table 11 lists the 20 key projects put forward in the EU global health strategy and their indicative timeframe.⁴⁹⁹

Table 11: Global health projects

#	Global health projects	Indicative timeframe
Global projects		
1	Set up a coordination system with EU Member States to ensure a powerful EU voice and leadership in global health in a Team Europe approach. Support by EU4Health envisaged.	Second half of 2023
2	Expand the existing European Antimicrobial Resistance Surveillance Network into an integrated surveillance mechanism covering all pathogens. Supported by EU4Health.	2023-2024
3	Leverage the potential of health data worldwide. Supported by EU4Health.	2023-2024
4	Foster mutually beneficial mobility arrangements with partners , including by supporting partner countries in training, recruiting, putting into action and retaining healthcare workers and ensuring their professional development through education as well as vocational training programmes for auxiliary staff. Supported by the Neighbourhood, Development and International Cooperation Instrument – Global Europe (NDICI-Global Europe) and EU4Health.	2023-2025
5	Follow up, monitoring, and evaluation of the implementation of the EU global health strategy , in principle publishing a report every two years, supporting continuous dialogue and involvement of key stakeholders. Support by EU4Health envisaged.	2023
6	Support the United Nations Population Fund's Supplies Partnership on reproductive health commodities, helping to end unmet needs for family planning and preventable maternal mortality. Supported by the NDICI- Global Europe (€45 million pledged).	2023-2027
7	Support the Global Fund against AIDS, tuberculosis and malaria , and health system strengthening. Supported by the NDICI-Global Europe (€715 million pledged).	2023-2025

⁴⁹⁸ European Commission, EU Global Health Strategy: Better Health For All in a Changing World, Communication [COM\(2022\) 675](#), 30 November 2022.

⁴⁹⁹ Idem, Annex I.

#	Global health projects	Indicative timeframe
8	Support the Universal Health Coverage Partnership administered by the WHO to advance universal health coverage and strengthen health systems in partner countries. Supported by the NDICI-Global Europe and the Emergency Support Instrument (€125 million programmed).	2023-2027
9	Support Gavi, the Vaccine Alliance to ensure the expanded uptake of vaccines against childhood illnesses and increasingly to support adult health (for example, by administering the human papillomavirus vaccine). Supported by the NDICI-Global Europe (€300 million pledged).	2023-2025
10	Support the Pandemic Fund. Supported by the NDICI-Global Europe (€427 million pledged).	2023-2027
11	Support the roll-out of COVID-19 vaccines in selected most under-vaccinated countries. Supported by the NDICI-Global Europe and the Emergency Support Instrument (€375 million pledged).	2023
12	Support research and development of vaccines against emerging infectious diseases , including through the Coalition for Epidemics Preparedness Innovations (CEPI) . Supported by Horizon Europe.	2021-2024
Regional projects		
13	Team Europe initiative on Manufacturing and Access to Vaccines, Medicines and Health Technologies in Africa to strengthen pharmaceutical systems and, together with health industries, the regional manufacturing capacity. EU contribution supported by NDICI-GE and other instruments	2021-2027
14	Team Europe initiative to improve sexual and reproductive health and rights in sub-Saharan Africa, particularly among adolescent girls and young women. EU contribution supported by NDICI-GE.	2022-2027
15	Team Europe initiative on sustainable health security using a One Health approach in Africa to strengthen systems and capacities for sustainable, risk-informed prevention, preparedness, and response to infectious threats and antimicrobial resistance. EU contribution supported by NDICI-GE.	2022
16	Team Europe initiative for Africa-based public health capacity through support to public health institutes in Africa, at national and regional levels and through partnerships between African Union and EU public health institutes. EU contribution supported by NDICI-GE.	2023
17	Team Europe initiative on digital health for health system strengthening and universal health coverage to support strong and digitally enabled health systems in Africa. EU contribution supported by NDICI-GE.	2023
18	Support the Global Health EDCTP3 Joint Undertaking through a Team Europe approach and Team Africa coming to drive forward new solutions to reduce the burden of infectious diseases in sub-Saharan Africa, also addressing the rising threat of antimicrobial resistance and climate-crisis-related infectious disease challenges. Supported by Horizon Europe (€800 million programmed).	2021-2027
19	EU-Latin America and Caribbean Partnership on manufacturing vaccines, medicines and health technologies and strengthening health systems. EU contribution supported by NDICI-GE.	2022

#	Global health projects	Indicative timeframe
Bilateral projects		
20	Health system support and health system strengthening in partner countries to improve equitable access to essential care. List of countries where health is prioritised in the NDICI-GE multiannual indicative programmes: Egypt, Tunisia, Libya, Morocco, Democratic Republic of the Congo, Central African Republic, Burundi, Kenya, South Sudan, Sudan, Uganda, Madagascar, Ethiopia, Zambia, Zimbabwe, Nigeria, Mauritania, Guinea, Guinea-Bissau, Mali, Tajikistan, Laos, Afghanistan, Iran, Cuba, Palestine, Lebanon.	

Source: European Commission, [EU global health strategy](#), 2022, Annex I.

4.5. One Health approach

'One Health' considers the causal connection between the health of humans, animals, plants, and their shared environment (Box 4). It is a transdisciplinary and cross-sectoral approach,⁵⁰⁰ that allows for a deeper sustainable intervention, and multifactorial understanding of the social and environmental determinants of health. In so doing, it enables a more comprehensive and effective preventive approach, drawing on coordination across disciplines and sectors.⁵⁰¹

The WHO considers 'One Health' as both an impact logic and a policy outcome and defines it as 'an approach to designing and implementing programmes, policies, legislation, and research in which multiple sectors communicate and work together to achieve better public health outcomes'.⁵⁰²

One Health and emerging infectious disease outbreaks

One Health approaches have gained currency for their value in addressing emerging infectious disease (EID) threats. The majority of EIDs typically originate in wild animal reservoirs and habitats that experience marked anthropogenic pressures, such as demographic growth, intensive agriculture and changed land use patterns, or natural resource extraction.⁵⁰³

The One Health approach has affinities with comparable public health approaches, e.g. the EU's Health-in-all-Policies (HiAP) approach in so far as they break down disciplinary silos. It differs in that the One Health approach emphasises how competing interests, e.g. agricultural productivity, environmental health, animal health and the health of populations must be balanced over a long period. This ambition, and ambiguity, in One Health is a point of interest for policy and decision makers.

At a global level, there is broad support for the concept of One Health. Long-running interagency working groups and national multisectoral coordination mechanisms include Bangladesh's One Health Secretariat⁵⁰⁴ and Liberia's One Health Coordination Platform.⁵⁰⁵ Nearly 50 countries have signed the Global Health Security Agenda (GHSA), which was launched in 2014 to bring countries

⁵⁰⁰ Kelly T.R. et al., '[Implementing One Health approaches to confront emerging and re-emerging zoonotic disease threats: Lessons from PREDICT](#)', *One Health Outlook*, Vol. 2(1), 2020.

⁵⁰¹ Karesh W.B. et al., '[Ecology of zoonoses: natural and unnatural histories](#)', *The Lancet*, 2012; 380:1936–1945.

⁵⁰² WHO, [Webpage](#) One Health.

⁵⁰³ Karesh W.B. et al., '[Ecology of zoonoses: natural and unnatural histories](#)', *The Lancet*, 2012; 380:1936–1945.

⁵⁰⁴ Institute of Epidemiology, Disease Control and Research, [National Bulletin of Public Health \(NBPH\)](#): One Health Bangladesh.

⁵⁰⁵ Ministry of Health Liberia (2018), [One Health Coordination Platform](#).

together to promote One Health approaches and strengthen capacities to prevent, detect, and respond to disease threats.⁵⁰⁶

Despite this broad support, there are significant challenges to the implementation of One Health approaches. As consulted stakeholders pointed out, the complexity and intersectoral ambition of One Health is precisely what makes it so difficult to implement. This is an argument that is borne out by global experience. For instance, most countries lack formal mechanisms for the coordination and integration of activities across the health, agricultural, and environmental sectors, which are traditionally organised in separate ministries or government agencies with differing mandates on activities and spending.⁵⁰⁷ As a result, practical applications of One Health approaches have largely been ad-hoc, resulting in delayed or incomplete prevention and control measures.

The lessons of the COVID-19 pandemic – and the renewed support in the One Health approach as a key lever in prevention – is likely to occasion additional case studies and formal assessments demonstrating that social, health, and economic benefits are needed to garner broader high-level support by decision makers. A growing body of research, including studies revealing the financial benefits of One Health investments in addressing emerging zoonoses, is building the evidence base for One Health. For example, the World Bank's report *Putting Pandemics Behind Us* (2022) found that One Health provides a solid foundation for global health security and improved development outcomes at much lower societal and economic costs.⁵⁰⁸

One Health action to AMR

The 'One Health Action to AMR' is a collaborative and integrated approach to optimise health for people, animals, and the environment. The drivers of antimicrobial resistance (AMR) include antimicrobial use and abuse in human, animal and environmental sectors, and the spread of resistant bacteria and resistant determinants between these sectors.⁵⁰⁹ Accordingly, the One Health approach bolsters global health security and prevention by working at the human-animal-environment interface to address shared health threats such as zoonotic diseases, antimicrobial resistance, and food security.⁵¹⁰

AMR presents a significant social and economic burden. The economic burden of AMR is high, due to direct costs of treatment and productivity losses, making it a major global health security concern. The ECDC estimates that in the EU/EEA, AMR is responsible for 35,000 deaths annually and amounts to €1.5 billion in healthcare costs and productivity losses;⁵¹¹ the OECD estimation for AMR deaths in EU/EEA countries is 33,000.⁵¹² If left unaddressed, the cost of AMR could amount to USD 100 trillion by 2050 and lead to 10 million deaths worldwide.⁵¹³ The World Bank estimates that by 2050 drug-resistant infections will cause global economic damage at par with the 2008 financial crisis.⁵¹⁴

⁵⁰⁶ Global Health Security Agenda, 2019.

⁵⁰⁷ Lee K. and Brumme Z.L., '[Operationalizing the One Health approach: the global governance challenges](#)', *Health Policy and Planning*, Vol. 28, 2013, pp. 778–785.

⁵⁰⁸ World Bank, [Putting Pandemics Behind Us: Investing in One Health to Reduce Risks of Emerging Infectious Diseases](#), 2022.

⁵⁰⁹ McEwen S. and Collignon P., '[Antimicrobial Resistance: a One Health Perspective](#)', *Microbiology Spectrum*, Vol. 6(2), 2018, pp. 1–26.

⁵¹⁰ Sinclair R., '[Importance of a One Health approach in advancing global health security and the Sustainable Development Goals](#)', *Reviews in Science and Technology*, Vol 38(1), 2019, pp. 145–154.

⁵¹¹ ECDC, 35 000 annual deaths from antimicrobial resistance in the EU/EEA, [press release](#), 17 November 2022.

⁵¹² OECD and ECDC, [Antimicrobial Resistance: Tackling the Burden in the European Union](#), 2019.

⁵¹³ J. O'Neill, [Tackling drug-resistant infections globally: Final report and recommendations](#), 2016.

⁵¹⁴ World Bank, [Drug Resistant Infections: A threat to our economic future](#), 2017.

The development of novel antimicrobials or alternatives is a prime example of unmet medical need, given the lack of therapeutic options to address antimicrobial resistance (AMR). AMR decreases the capability to treat infectious diseases and threatens the ability to perform routine surgery. As underlined in the EU One Health Action Plan on AMR, it is a multifactorial problem of global concern, with serious health and economic ramifications. An important challenge is the excessive and inappropriate use of antimicrobials in animal and human healthcare, leading to the development of resistance.⁵¹⁵

The European Commission's 'One Health Action Plan against Antimicrobial Resistance (AMR)' sets out an integrated approach to tackling antimicrobial use and abuse in human, animal, and environmental sectors, and especially the spread of resistant bacteria between these sectors.⁵¹⁶ The Action Plan against AMR is a health priority area where different aspects of EU health policy converge. For instance, the EHU, HERA, and the pharmaceutical strategy all refer to the threat of AMR. Previous initiatives in tackling AMR include the Joint Programming Initiative on AMR (JPIAMR) and funding towards AMR research through the New Drugs for Bad Bugs Programme (ND4BBP).⁵¹⁷

Stakeholders interviewed were unsure how One Health could be operationalised. One interviewee stated that though One Health is mentioned extensively in EU documents, he expressed doubts about how to operationalise it. A point raised in the stakeholder consultations was that whilst the emphasis is currently on surveillance, prevention is also important. This is because such a combined emphasis will need to bring together sectors that sometimes have conflicting goals.

4.6. WHO pandemic treaty

The WHO pandemic treaty is a proposed international pandemic instrument establishing principles and priorities to strengthen pandemic prevention, preparedness and response. It is conceived as a legally binding instrument that is currently being developed by an intergovernmental negotiating body.⁵¹⁸ On behalf of the EU, the Council authorised the opening of the negotiation process on the agreement in March 2022, with a decision providing a negotiation mandate to the Commission in accordance with Article 218 TFEU.^{519 520}

On 25 November 2022, the conceptual zero draft of the treaty was made publicly available.⁵²¹ It is informed by the lessons from the COVID-19 pandemic and other disease outbreaks, driven by the need to ensure communities, governments, and all sectors are better prepared and protected to respond to future pandemics.

The treaty proposes to amend the shortcomings in the global response to the health crisis, particularly the failure of current international health and intellectual property (IP) laws to deliver timely and equitable access to essential medical countermeasures for the world's most vulnerable

⁵¹⁵ OECD and ECDC, [Antimicrobial Resistance: Tackling the Burden in the European Union](#), 2019.

⁵¹⁶ European Commission, [A European One Health Action Plan against Antimicrobial Resistance \(AMR\)](#), 2017.

⁵¹⁷ Kostyanov T. et al., 'The Innovative Medicines Initiative's New Drugs for Bad Bugs programme: European public-private partnerships for the development of new strategies to tackle antibiotic resistance', *Journal of Antimicrobial Chemotherapy*, Vol. 71(2), 2016, pp. 290-295.

⁵¹⁸ Hannon E. et al., 'Why we still need a pandemic treaty?', *The Lancet Global Health*, Vol. 10(9), 2022, pp. e1232-e1233.

⁵¹⁹ Council of the EU, Council gives green light to start negotiations on international pandemic treaty, [press release](#), 3 March 2022.

⁵²⁰ [Council Decision \(EU\) 2022/451](#) of 3 March 2022 authorising the opening of negotiations on behalf of the European Union for an international agreement on pandemic prevention, preparedness and response, as well as complementary amendments to the International Health Regulations (2005). The negotiation mandate is set out in the annex to this same Council decision, [document ST 6133/22 ADD 1](#).

⁵²¹ WHO, [Conceptual zero draft for the consideration of the Intergovernmental Negotiating Body at its third meeting](#), 2022.

populations. In addition, the treaty aims to increase pandemic preparedness by building and sustaining resilient supply chains and logistic networks for pandemic response products.⁵²²

Another set of challenges stemmed from the logistics of monitoring and surveillance. At present, the International Health Regulations (IHR) form the current global framework – and legally binding agreement – for 196 countries in preparing and responding to health emergencies.⁵²³ The IHR (first adopted in 1969, last revised in 2005)⁵²⁴ lays out the reporting obligations to the WHO and disease control measures, as well as the requirements for signatory countries to improve their capacities in legislation, coordination, and surveillance to better detect and respond to national health emergencies.⁵²⁵

However, as the COVID-19 pandemic made clear, the IHR has little influence to ensure that national governments comply with their responsibilities and supplying accurate and timely reports to the IHR.⁵²⁶ ⁵²⁷ The IHR primarily addresses capacities at the national level and does not have global oversight.

Box 12: The WHO pandemic treaty

The new treaty will represent the global commitment of the international community to help prevent disease outbreaks. It will establish principles, targets and priorities for pandemic prevention, preparedness, response and recovery of health systems. Its aims are to:

- achieve equity in pandemic prevention, preparedness response and recovery of health systems globally through equitable access and distribution of pandemic countermeasures;
- build resilient capacities in pandemic prevention, preparedness, response and recovery of health systems through strengthening health systems and workforce, and efficient monitoring;
- improve coordination, collaboration and cooperation in pandemic prevention, preparedness response and recovery of health systems;
- ensure sustainable and predictable financing mechanisms while enhancing transparency and accountability; support global coordination through a stronger and more accountable WHO.

Source: WHO, '[Conceptual zero draft for the consideration of the Intergovernmental Negotiating Body at its third meeting](#)', 2022.

The new WHO pandemic treaty is expected to be concluded in 2024.⁵²⁸ The treaty focuses on⁵²⁹ early detection and prevention of pandemics; resilience to future pandemics; response to future pandemics, by ensuring universal and equitable access to medical solutions, e.g. vaccines, medicine, and diagnostics; a stronger international health framework with the WHO as the coordinating authority on global health matters; and the 'One Health' approach.

Drawing on the lessons from the COVID-19 pandemic, the WHO pandemic treaty is expected to include the following areas of action:⁵³⁰

⁵²² Ibid.

⁵²³ WHO, [Webpage](#) International Health Regulations (IHR).

⁵²⁴ Ibid.

⁵²⁵ Ibid.

⁵²⁶ Wenham C., Reisdorf R. and Asthana S., '[Pandemic treaty: a chance to level up on equity](#)', *British Medical Journal*, 377: o1279, 2022.

⁵²⁷ Vinuales J. et al., '[A global pandemic treaty should aim for deep prevention](#)', *The Lancet*, 397(10287), 2021, pp. 1791-1792.

⁵²⁸ European Council, '[An International treaty on pandemic prevention and preparedness](#)', 2022

⁵²⁹ WHO, [Conceptual zero draft for the consideration of the Intergovernmental Negotiating Body at its third meeting](#), 2022.

⁵³⁰ Ibid.

- Global preparedness, response and recovery arrangements to help anticipate and prevent future pandemics, address them more effectively when they do arise and recover more steadily;
- Sustained, predictable funding for health emergency preparedness and response, including from domestic budgets to support preparedness measures and help ensure that the world is prepared and can respond to the emergence of dangerous pathogens;
- Governance and oversight mechanisms to increase trust, ensure accountability and foster transparency.

Stakeholders interviewed for this study point out that going forward all countries should be able to have the right monitoring capacity to monitor outbreaks of diseases. This should be combined with transparency and the willingness to share results from monitoring as soon as possible. Much of this is already set in the IHR, but they could be written down in legal arrangements. Smaller countries with weaker capacities for surveillance and monitoring should be assisted in this regard. Preparedness should also rely on fairer and more equitable access to medical countermeasures within the EU, and on timely delivery to global populations.

Consulted stakeholders agreed that supporting the treaty and strengthening cooperation with the WHO includes exchange of information and supporting less developed countries if needed. Prevention and preparedness are important; acting in times of crisis means that it is already too late. There was also the suggestion for the EU to operationalise the principle in which all agree that the pandemic should be treated as a global issue and that cooperation means sharing knowledge transfer of technology during an emergency and not putting obstacles in the way of supplying medical countermeasures.

4.7. Main findings

EU's prevention and preparedness framework

- At the beginning of the pandemic, the ECDC was slow to detect the seriousness of the threat and the lack of preparedness within the Member States, due to a lack of appropriate funding and resources, as well as the need for more requisite discretion and decision-making. These issues were solved by 2021 when the agency's core budget increased to €168.1 million and greater resources allowing for 351 staff members;
- Even though the ECDC is responsible for risk assessment, the agency lacks discretion over risk management which lies firmly with the Member States. Furthermore, the agency's geographical scope limits its surveillance activities, while legislative barriers over data sharing presently limit the ECDC's scope of action;
- Stakeholders from the Member States and EU agencies were positive in their assessment of the strengthened mandate of the ECDC. Although the ECDC is entrusted with disease surveillance and risk assessment, the agency's recommendations are non-binding. Stakeholders pointed out that the ECDC is officially tasked with risk assessment, whilst risk management remains a national competence.
- The COVID-19 pandemic placed an intense and sustained demand on the resources of EU medical regulators, including EMA, with multiple medicinal products subject to fast-track evaluation and safety monitoring.
- During the COVID-19 pandemic, EMA faced specific challenges of its own, including the need to adapt to emerging scientific data and to communicate uncertainty in real-time;
- EMA was found to be lacking in preparedness for coping with public health emergencies. Preparedness in this context necessitated tools and methods for monitoring, reporting, and data collection. Stakeholders consulted emphasised the importance of ensuring a ready supply of critical medicines for future health crises. Therefore, a key priority would be to gather data on essential medicines and medical devices and address shortages in health emergencies.

Expanded mandates of the ECDC and EMA under the EHU

- Stakeholders emphasise how critical it is to ensure a transparent and timely mechanism to communicate shortages of medicines and medical devices – as well as coordinated actions to prevent or manage such shortages in future health emergencies;
- As part of the extended mandate, EMA will monitor events that have the potential to contribute to a health-related crisis. This includes monitoring medical shortages and reporting on shortages of critical medicines. The agency will also coordinate the responses of EU Member States on shortages of essential medical devices and companion diagnostics during crises.

HERA and health preparedness in the EU

- HERA's key pillar of action is health preparedness in the EU. This is grounded in four interweaving strands and early lessons from the COVID-19 pandemic. These strands are: (1) threat assessment and intelligence gathering; (2) advanced research and development of countermeasures; (3) access to medical countermeasures and resilient supply chains and production capacities; (4) international coordination and global activities;
- The pandemic exposed the EU's dependence on external suppliers of key medical countermeasures, including vials, syringes, PPE, and other products essential for the production of therapeutics, vaccines, and diagnostics.

EU Global health strategy

- The EU Global Health strategy offers an agenda leading up to 2030. It sets out the following three interrelated policy priorities: (1) deliver better health and well-being of people across their lifespan; (2) strengthen health systems and advance universal health coverage; and (3) prevent and combat health threats, including pandemics, applying a One Health approach.

One Health approach

- The lessons of the COVID-19 pandemic are likely to occasion additional case studies and formal assessments demonstrating that social, health, and economic benefits from such approaches are necessary to garner broader high-level support by decision-makers;
- AMR presents a significant social and economic burden. In the EU/EEA, AMR is responsible for 35,000 deaths annually, and leading to €1.5 billion in healthcare costs and productivity losses;
- The European Commission's 'One Health Action Plan against Antimicrobial Resistance (AMR)' sets out an integrated approach to tackling antimicrobial use and abuse in human, animal, and environmental sectors, especially the spread of resistant bacteria between these sectors;
- Among stakeholders interviewed, there is uncertainty about how One Health could be operationalised. The current emphasis is on surveillance, but prevention is also important. The approach will also need to bring together sectors that sometimes have conflicting goals as well.

WHO pandemic treaty

- The planned WHO pandemic treaty focuses on early detection and prevention of pandemics; resilience to future pandemics; response to future pandemics by ensuring universal and equitable access to medical solutions, e.g. vaccines, medicine, and diagnostics; a more robust international health framework with the WHO as the coordinating authority on global health matters, and the 'One Health' approach;
- On behalf of the EU, the Council started the negotiation process on the pandemic treaty in March 2022, giving the Commission a negotiation mandate. Regarding this treaty, stakeholders interviewed for this study say that going forward, all countries should have the

right capacity to monitor outbreaks of diseases. Additionally, stakeholders agreed that supporting the treaty and strengthening the WHO cooperation includes exchanging information and supporting less developed countries if needed.

5. Considerations regarding EU competences in public health (Pillar 5)

As Europe transitions from a period of immediate response phase to the COVID-19 pandemic to managed prevention and recovery, the question has inevitably turned to: how well is Europe equipped to deal with future serious cross-border health threats? Do the existing competences adequately enable the EU to effectively coordinate public health action? This chapter illustrates the status quo of the EU's competences in public health (section 5.1), followed by discussions at the CoFoE on public health (section 5.2). The chapter concludes with reflections on the pros and cons of potential Treaty changes (section 5.3).

5.1. EU competences in public health: status quo

5.1.1. Public health in the EU Treaties

The EU's competences are consolidated in the Treaty on European Union (TEU) and the Treaty on the Functioning of the European Union (TFEU). Whereas the TEU's Articles 2 and 9 set out the principles of *inter alia* equality, democracy and respect for human rights, the TFEU states specific competences in the area of public health. As laid down in Article 4 TFEU, one of the principle areas where the EU and its Member States share competence is 'common safety concerns in public health matters'. Specifically, the EU has the competence to support, coordinate or supplement the actions of Member States in the protection and improvement of human health.⁵³¹ Moreover, the EU needs to take into account the protection of human health when defining and implementing policies and activities.⁵³²

The EU's legal base to adopt public health law and policies are Article 168 TFEU (protection of public health), Article 114 TFEU (single market) and Article 153 TFEU (social policy). In the context of the COVID-19 pandemic, the TFEU's Articles 122 and 222 (solidarity) and 196 (civil protection) have also been relevant. Other articles have also been used as legal base in the area of health law, such as Article 16 TFEU on data protection and Article 179 TFEU on strengthening the EU's research and technological bases.

Article 168 TFEU covers a broad spectrum of public health aspects (e.g. research, health information, education, monitoring, early warning and combating serious cross-border health threats) (Box 13). Article 168(4) TFEU provides competence for binding legislation on the quality and safety standards for substances of human origin, blood and blood derivatives.⁵³³ Other than that, it gives the EU limited power in public health: the EU shall 'encourage cooperation' (and if necessary, lend support to Member States)⁵³⁴, and 'may also adopt incentive measures'⁵³⁵ (i.e. finance) which naturally depends on budgets made available. Competence in healthcare is attributed to Member States, and not to the EU.⁵³⁶ Tools provided under Article 168 TFEU include the power for the Council to adopt

⁵³¹ Art. 6 TFEU.

⁵³² Art. 9 TFEU.

⁵³³ Art. 168(4) TFEU.

⁵³⁴ Art. 168(2) TFEU.

⁵³⁵ Art. 168(5) TFEU.

⁵³⁶ Art. 168(7) TFEU.

recommendations.⁵³⁷ Even though Council recommendations are non-binding, they have been used to establish impacts in health (e.g. cancer screening⁵³⁸ and smoke-free environments⁵³⁹).⁵⁴⁰

Box 13: Article 168 TFEU

1. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.

Union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health.

The Union shall complement the Member States' action in reducing drugs-related health damage, including information and prevention.

2. The Union shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action. It shall in particular encourage cooperation between the Member States to improve the complementarity of their health services in cross-border areas.

Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination, in particular initiatives aiming at the establishment of guidelines and indicators, the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation. The European Parliament shall be kept fully informed.

3. The Union and the Member States shall foster cooperation with third countries and the competent international organisations in the sphere of public health.

4. By way of derogation from Article 2(5) and Article 6(a) and in accordance with Article 4(2)(k) the European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this Article through adopting in order to meet common safety concerns:

(a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures;

(b) measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health;

(c) measures setting high standards of quality and safety for medicinal products and devices for medical use.

5. The European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, may also adopt incentive measures designed to protect and improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health, and measures which have as their direct objective the protection of public health regarding tobacco and the abuse of alcohol, excluding any harmonisation of the laws and regulations of the Member States.

6. The Council, on a proposal from the Commission, may also adopt recommendations for the purposes set out in this Article.

7. Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them. The measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood.

⁵³⁷ Art. 168(6) TFEU.

⁵³⁸ [Council recommendation 2003/878/EC](#) of 2 December 2003 on cancer screening.

⁵³⁹ [Council recommendation 2009/C 296/02](#) of 30 November 2009 on smoke-free environments.

⁵⁴⁰ Greer S.L. et al., [Everything you wanted to know about EU health policy but were afraid to ask](#), European Observatory on Health Systems and Policies, 2022.

Historically, most impact in the area of public health has been made not on the sole basis of Article 168 TFEU, but rather by using other Treaty bases such as the internal market and fiscal governance.⁵⁴¹ Classic examples of such law surround tobacco control and include Council Directive 2011/64/EU on the structure and rates of excise duty applied to manufactured tobacco (the Tobacco Tax Directive) which has Article 113 TFEU as its legal base.⁵⁴² Article 113 TFEU sets out that the Council can 'adopt provisions for the harmonisation of legislation concerning turnover taxes, excise duties and other forms of indirect taxation to the extent that such harmonisation is necessary to ensure the establishment and the functioning of the internal market and to avoid distortion of competition'.⁵⁴³ Another classic example in health law is data protection (Article 16 TFEU). This article is the basis for the European Health Data Space (EHDS), which builds on the GDPR, putting in place additional safeguards (see section 3.1.1).

Discussions around potential Treaty change

Whereas at the beginning of the pandemic, a lot of discussion focused on health systems responses, effectiveness of contact tracing, the healthcare workforce and solidarity, the pandemic had stirred the discussion about the EU's competences in public health. The term 'European Health Union' was introduced in spring 2020⁵⁴⁴ and explored much more later that year⁵⁴⁵, followed by its mentioning in the 2020 State of the Union address by Commission President Von der Leyen. She stated: 'For me, it is crystal clear – we need to build a stronger European Health Union'.⁵⁴⁶ At that time, the European Health Union (EHU) included increased funding for the then new EU4Health programme, a stronger EMA and ECDC, and building a European BARDA (i.e. an agency for biomedical advanced research and development to support response and preparedness for cross-border threats – this later takes the form of the HERA 'incubator'). Most notably, Von der Leyen urges discussing 'the question of health competences', which she deems a 'noble and urgent task for the Conference on the Future of Europe'.⁵⁴⁷

In the past years, the Commission stated that a stronger EHU would bring more resilient health systems.⁵⁴⁸ Specifically, the analysis of documents communicating the Commission's position in light of the COVID-19 pandemic shows that the Commission needs Member States' commitment to move towards a common approach, with EU-wide health policies, more robust systems, and a focus on the collective power of the EU.⁵⁴⁹ The analysis of policy documents, speeches, press releases and other relevant documents by the Commission shows, however, that the role and therewith the power of the EU remained unspecified.⁵⁵⁰

The option of changing the Treaties has been discussed in the context of a 'bold, strong, future European Health Union', as envisioned by the European Commission. The pandemic has shown that it is difficult to uphold the division between healthcare policy (which is a Member State

⁵⁴¹ Ibid.

⁵⁴² [Council Directive 2011/64/EU](#) on the structure and rates of excise duty applied to manufactured tobacco.

⁵⁴³ Article 113 TFEU.

⁵⁴⁴ Andriukaitis VP, 'The European Health Union is an initiative with potential to shape European politics for decades to come', *Eurohealth*, Vol. 26(3), 2020, pp. 29-30.

⁵⁴⁵ For example, the *Eurohealth* issue of September 2020 focuses on the European Health Union. 'Dancing with elephants: New partnerships for health, democracy, business', *Eurohealth*, 26(3), 2020, pp. 29-33.

⁵⁴⁶ European Commission, [State of the Union Address by President von der Leyen at the European Parliament Plenary](#), 16 September 2020.

⁵⁴⁷ Ibid.

⁵⁴⁸ Orhan R., Paric M. and Czabanowska K., 'Lessons Learnt from the EU Response to NCDs: A Content Analysis on Building Resilient Post-COVID Health Systems', *Healthcare*, Vol. 9(12), 2021, pp. 1659ff.

⁵⁴⁹ Ibid.

⁵⁵⁰ Ibid.

competence) and public health (which is a shared competence).⁵⁵¹ The proposal to an EHU is focused on communicable diseases by strengthening the procurement of medical countermeasures, improving the coordination of health communication, and strengthening the executive power of the Health Security Committee (HSC).⁵⁵² However, as scholars such as Ilona Kickbusch and Aniek de Ruijter pointed out, for an EHU 'a much more encompassing approach will be needed'.⁵⁵³ This has resulted in the European Health Union campaign, a civil society initiative which was launched in late 2020.

This campaign calls on political leaders in the framework of the CoFoE⁵⁵⁴ and sets out a vision of the EHU. Initiators of the EHU campaign include Vytenis Andriukaitis (WHO Special Envoy for the European region and former European Commissioner for Health and Food Safety), Clemens Martin Auer (former Special Envoy of Health for the Austrian Ministry of Health and former Vice-Chair of the WHO's Executive Board), Violeta Bulc (former European Commissioner for Transport and former Deputy Prime Minister of Slovenia), and Klaus Hänsch (former President of the European Parliament). The current number of signatures is 1346,⁵⁵⁵ including many scholars, research institutes, NGOs, and individuals from Ministries of Health (i.e. from Malta, Croatia, Austria and the regional administration of Lisbon), national public health institutes (e.g. Italy, Finland and Austria), and several signatures from individuals working at the European Commission. The campaign is ongoing.

The EHU is defined as complementing national policies, 'directed towards protecting, improving and promoting human health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health'.⁵⁵⁶ To this end, the campaign calls for a Treaty change and even proposes specific textual changes. For example, it proposes to Article 168 TFEU the addition of adopting legislation under the ordinary legislative procedure and incentive measures to protect and improve human health (Box 14).

Box 14: The European Health Union campaign's proposed amendment to Article 168 TFEU

The European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives of the European Health Union through adopting measures for the approximation of law, regulation or administrative action in Member States, and incentive measures, designed to protect and improve human health.

Source: European Health Union, [Position paper: Treaty change for a European Health Union](#) (2021)

Strengthening the role of the EU internally is regarded to be needed to ensure a stronger role externally (i.e. in global health).⁵⁵⁷ This strengthening can take the form of giving the EU competences in very concrete areas of health policy, yet preserving the principle of subsidiarity.⁵⁵⁸ Member States also spoke of an EU health policy that is much more ambitious, along the possibility

⁵⁵¹ Kickbusch I. and De Ruijter A., '[How a European health union can strengthen global health](#)', *The Lancet Regional Health Europe* 1(100025), 2021.

⁵⁵² De Ruijter A., '[What do we actually mean by a European Health Union?](#)', *Eurohealth* 26(3), 2020, pp. 30-31.

⁵⁵³ Kickbusch I. and De Ruijter A., '[How a European health union can strengthen global health](#)', *The Lancet Regional Health Europe* 1(100025), 2021.

⁵⁵⁴ The CoFoE is a citizens-led series of discussions on the future of Europe. See section 6.2 for more information.

⁵⁵⁵ Reference date: 6 December 2022. Source: European Health Union, [Position paper: Treaty change for a European Health Union](#), 2021.

⁵⁵⁶ European Health Union, [Position paper: Treaty change for a European Health Union](#), 2021.

⁵⁵⁷ Kickbusch I. and De Ruijter A., '[How a European health union can strengthen global health](#)', *The Lancet Regional Health Europe* 1(100025), 2021.

⁵⁵⁸ Andriukaitis V., '[The European Health Union is an initiative with potential to shape European politics for decades to come](#)', *Eurohealth*, Vol. 26(3), 2020, pp. 29-30.

of Treaty changes.⁵⁵⁹ Without making any Treaty changes, however, a shift towards increased EU competences has been observed. A clear example of this is the newly adopted Regulation on Serious Cross-border Threats to Health.⁵⁶⁰ This regulation moves this area from largely intergovernmental to supranational (i.e. EU) governance by setting out a more clear and focused role for EU institutions.⁵⁶¹

Regardless this shift, more ambition is needed in EU health policy according to Anne Bucher, former Director-General of DG SANTE. She states that health inequalities in and between Member States are still a large issue and monitoring these could be a role for the EU.⁵⁶² Another area where EU action could be of added value is upgrading the research-knowledge nexus such that the implementation of HiAP is supported. Following health outcomes at the EU level, for example, could help assess EU policies' health impacts and identify any gaps in EU regulation.⁵⁶³

5.1.2. EU response to COVID-19 pandemic – Action in other policy areas and interlinkages with health policy

In the response to the COVID-19 pandemic, the European Commission, the European Parliament, the Council and other EU institutions have adopted and published numerous regulations, decisions, communications, reports and conclusions.⁵⁶⁴ Considering the pandemic's impact on whole societies, beyond health and healthcare, these documents are formulated not only in the area of public health but also have a bearing on adjacent sectors. The latter includes: agriculture, budget; competition; consumers; digital single market; economic and monetary affairs; employment and social policy; enterprise; external relations; external trade; food safety; human rights; internal market; justice, freedom and security; maritime affairs and fisheries; regional policy; research and innovation; taxation; and transport.⁵⁶⁵

On the one hand, some of these policies focus on responding to short-term issues, such as the EU Digital COVID Certificate⁵⁶⁶, the implementation of the Green Lanes⁵⁶⁷, and the relief from import duties and VAT exemption on certain goods needed to combat the effects of the COVID-19 outbreak⁵⁶⁸. Some of the policies from other areas relate to health more explicitly. For example,

⁵⁵⁹ Brooks E. et al., '[EU health policy in the aftermath of COVID-19: neofunctionalism and crisis-driven integration](#)', *Journal of European Public Policy*, 2022.

⁵⁶⁰ [Regulation \(EU\) 2022/2371](#) of 23 November 2022 on serious cross-border threats to health.

⁵⁶¹ Ibid.

⁵⁶² Bucher A., '[Does Europe need a Health Union?](#)', Bruegel, 2022.

⁵⁶³ Ibid.

⁵⁶⁴ Reference date: 7 December 2022. Source: EUR-Lex, [COVID-19](#).

⁵⁶⁵ The selection of key documents related to the EU response to the COVID-19 pandemic is available on Eur-Lex. Source: EUR-Lex, '[COVID-19](#)'.

⁵⁶⁶ [Regulation \(EU\) 2022/1034](#) of 29 June 2022 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic; [Regulation \(EU\) 2022/1035](#) of 29 June 2022 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) with regard to third-country nationals legally staying or residing in the territories of Member States during the COVID-19 pandemic.

⁵⁶⁷ European Commission, Implementation of the Green Lanes under the Guidelines for border management measures to protect health and ensure the availability of goods and essential services, Communication [2020/C 96 I/01](#), 24 March 2020.

⁵⁶⁸ [Commission Decision \(EU\) 2020/1101](#) of 23 July 2020 on relief from import duties and VAT exemption on importation granted for goods needed to combat the effects of the COVID-19 outbreak during 2020; [Commission Decision \(EU\) 2021/2313](#) of 22 December 2021 on relief from import duties and VAT exemption on importation granted for goods needed to combat the effects of the COVID-19 outbreak during 2022.

Commission guidelines 2020/C 119/01 focus on the protection of health of persons on board of ships, including third country nationals stranded in the EU due to closed borders.⁵⁶⁹

On the other hand, some of the policies show that there has been a vision for the mid-term and long-term future in the midst of the pandemic. Notable is the place of health in other policy areas, and vice versa. One example is the Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system which was launched in mid-2020. The Farm to Fork Strategy is a key component of the EU Green Deal and 'addresses comprehensively the challenges of sustainable food systems and recognises the inextricable links between healthy people, healthy societies and a healthy planet'.⁵⁷⁰ Specifically, it is seen as 'a new comprehensive approach to how Europeans value food sustainability'.⁵⁷¹ The Strategy makes mention of both the Common Agricultural Policy (under responsibility of DG AGRI), the Common Fisheries Policy (under responsibility of DG MARE), and has a clear climate focus (DG CLIMA). Yet, the Farm to Fork Strategy itself is under the responsibility of DG SANTE. The interlinkages between these policy areas is illustrated by the part about the COVID-19 pandemic in the strategy:

*'The COVID-19 pandemic has underlined the importance of a robust and resilient food system that functions in all circumstances, and is capable of ensuring access to a sufficient supply of affordable food for citizens. It has also made us acutely aware of the interrelations between our health, ecosystems, supply chains, consumption patterns and planetary boundaries. It is clear that we need to do much more to keep ourselves and the planet healthy. The current pandemic is just one example. The increasing recurrence of droughts, floods, forest fires and new pests are a constant reminder that our food system is under threat and must become more sustainable and resilient.'*⁵⁷²

More 'traditionally' linked to health is the focus on diets and food security. Cancer and other diet-related diseases, but also healthcare costs, are mentioned in the strategy:

*'It is clear that the transition will not happen without a shift in people's diets. Yet, in the EU, 33 million people cannot afford a quality meal every second day and food assistance is essential for part of the population in many Member States. The challenge of food insecurity and affordability risks growing during an economic downturn so it is essential to take action to change consumption patterns and curb food waste. While about 20% of the food produced is wasted, obesity is also rising. Over half of the adult population are now overweight, contributing to a high prevalence of diet-related diseases (including various types of cancer) and related healthcare costs. Overall, European diets are not in line with national dietary recommendations, and the 'food environment' does not ensure that the healthy option is always the easiest one. If European diets were in line with dietary recommendations, the environmental footprint of food systems would be significantly reduced.'*⁵⁷³

In turn, health is included in other EU policies as well. In some cases, rebuilding healthcare systems is mentioned. The EU does not carry the competence of harmonising healthcare systems, but can influence them with incentive measures (i.e. budget). For example, Council Regulation (EU) 2020/2094 establishing a European Union Recovery Instrument mentions the following in its preambles:

'(7) The support under the instrument established by this Regulation (the 'Instrument') should in particular focus on measures to restore labour markets and social protection as well as health care

⁵⁶⁹ European Commission, Guidelines on protection of health, repatriation and travel arrangements for seafarers, passengers and other persons on board ships, Communication [2020/C 119/01](#), 14 April 2020.

⁵⁷⁰ European Commission, A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system, Communication [COM\(2020\) 381](#), 20 May 2020.

⁵⁷¹ Ibid.

⁵⁷² Ibid, p. 2.

⁵⁷³ Ibid p. 3.

*systems, to reinvigorate potential for sustainable growth and employment in order to strengthen cohesion among Member States and support their transition towards a green and digital economy, [...], for capacity building at Union level to enhance future crisis preparedness, for maintaining efforts to ensure a just transition to a climate-neutral economy, ...*⁵⁷⁴

5.2. Conference on the Future of Europe: Public health

The Conference on the Future of Europe (CoFoE) was a citizens-led series of discussions on the future of Europe. The CoFoE was the joint proposal of the European Commission and the European Parliament and lasted a year (April 2021 to May 2022). It culminated in a final report, submitted to the Presidents of the European Parliament, the European Commission, and the Council of the EU.

The CoFoE deliberations are distinctive in two aspects. First, the CoFoE proposals demonstrate a preference for stronger EU action across the themes and topics of deliberation. Second, the CoFoE proposals communicate a vision of a Europe that addresses generational challenges and delivers on matters most intimately connected to the everyday lives, e.g. affordable and equitable access to healthcare and wholesome foods, job security and housing. The CoFoE adopted 49 proposals, with 329 measures containing recommendations for future EU action. The topics of discussion were grouped around nine working groups, one of them being health.⁵⁷⁵

5.2.1. CoFoE recommendations related to public health policies

The CoFoE addressed health in conjunction with climate change, environmental issues and the new health challenges facing the EU.⁵⁷⁶ Specifically, the CoFoE final report contains four proposals, each with a clearly defined objective, and relevant measures. These were: (1) healthy food and healthy lifestyle; (2) Reinforcing the healthcare system; (3) A broader understanding of health; and (4) Equal access to health for all (see also Table 12).

The CoFoE's proposals on health provide a focal point where both long-term EU strategies and investments (into health promotion and affordable, universal healthcare access) and the recent lessons from COVID-19 (e.g. health system resilience) coalesce. The proposals are also undergirded in a broad-based understanding of health, and 'One Health' – signalling both an eye to the future, whilst also providing an illustration of how an abstract concept may translate to a policy reality.

The lessons from COVID-19 pervade throughout the CoFoE proposed measures, acting as cross-cutting themes across all four proposals in the health domain. This is evident in the emphasis on the proposal calling for reinforced health systems, to be based on resilience and affordable healthcare access, adequate research funding, accelerated digitisation of the health space and improved working conditions for healthcare professionals. The proposals also call for a health system that is geared towards achieving strategic autonomy at the EU level and secure medical supply chains: this is to be based on ensuring independence from third countries for medicines (active ingredients) and medical devices (including raw materials). In this regard, the proposals foresee an important role for European agencies more generally, and HERA in particular, in ensuring that essential and priority medicinal products and treatments (such as, biotechnology solutions) are available at the EU level. Drawing on the experience of COVID-19, European agencies are also expected to organise and coordinate strategic stockpiling throughout the EU. In order to achieve the requisite coordinated, long-term action at Union level, the CoFoE proposals called for health and healthcare to be included as 'a shared competence between the EU and EU Member States, by Article 4 TFUE'.⁵⁷⁷

⁵⁷⁴ [Council Regulation \(EU\) 2020/2094](#) of 14 December 2020 establishing a European Union Recovery Instrument to support the recovery in the aftermath of the COVID-19 crisis, preamble 7.

⁵⁷⁵ Ibid, p. 5.

⁵⁷⁶ Ibid, pp. 43-51.

⁵⁷⁷ Ibid, p. 50.

The CoFoE proposals on health are shaped by the lessons from COVID-19 in further ways. Whereas the measures described above are geared towards structural reform of the health system – another package of measures and expectations in the health domain concern the responsibilities, expectations and medical needs of citizens and communities. Here too, the lessons from COVID-19 are evident in so far as the priority given to the raised awareness and early diagnosis of mental health, attention to women's health, and the set of measures directed to alleviating health poverty in Europe (through encouragement of free dental care of children, for example).

Table 12: CoFoE (2021-2022): Proposals on health, with objectives and measures

Proposal	Objectives	Measures
CoFoE Proposal 7: Healthy Food and Healthy Lifestyle	Ensure that all Europeans have access to the building blocks of a healthy lifestyle: by health communication and promotion of healthy and affordable foods and access to healthy lifestyle .	(1) Setting minimum standards for food quality, including food traceability and limiting the use of antibiotics and other animal medicinal products; (2) Health education and promotion of healthy lifestyle, through taxation of non-healthy processed food; establishment of a European-wide evaluation system for processed food based on scientific expertise, and a label covering the use of hormonal substances and endocrine disruptors in food production. (3) Encouraging dialogue with the food chain actors from production to sales for corporate social responsibility regarding healthy food; (4) Supporting at EU level the provision of healthy, varied and affordable food in establishments servicing the public, such as school canteens, hospitals, or nursing homes, including through dedicated funding; (5) Investing in research on the impact of the use of antibiotics and the effects of hormonal substances and endocrine disruptors in human health.
CoFoE Proposal 8: Reinforcing the healthcare system	Reinforce the resilience and quality of healthcare systems	(1) The creation of a European health data space to facilitate exchange of health data, ease access to individual medical records through an EU individual electronic health passport, in compliance with data protection rules; (2). Adequate working conditions, through strong collective bargaining, in terms of wages and working arrangements, and harmonisation of training and certification standards for health professionals; networking and exchange programmes; ensure talent retention for young professionals; (3) Ensuring strategic autonomy at EU level to avoid dependency on third countries for medicines and medical devices; consider organising coordinated strategic stockpiling throughout the EU; (4) Develop, fund and coordinate health research and innovation programmes, including for European Reference Networks as they constitute the basis of the development of networks of medical care for highly specialised and complex treatments;

Proposal	Objectives	Measures
		(5) Investing in the health systems, in particular public and non-for profit, infrastructure and digital health and ensuring that healthcare providers respect the principles of full accessibility, affordability and quality of services – to ensure that resources are not drained by profit-oriented health operators with little to no regard for the general interest; (6) Issue strong recommendations to the Member States to invest in effective, accessible, affordable, high-quality and resilient health systems, notably in the context of the European Semester. The impact of the war in Ukraine on public health demonstrates the need to further develop resilient health systems and solidarity mechanisms.
CoFoE Proposal 9: A broader understanding of Health.	Adopt a holistic approach to health in line with the “One Health Approach” .	(1) Improve understanding of and raise awareness of mental health issues, from an early childhood and early diagnostics, building on good practices developed throughout the EU, which should be made readily accessible through the Public Health Best Practice Portal; organise best practices exchange events co-organised by EU institutions and relevant stakeholders, and develop an EU Action Plan on mental health providing a long term Mental Health Strategy, including on research and also tackle the issue of availability of professionals; (2) Develop at EU level a standard educational programme on healthy lifestyles, covering also sexual education, healthy lifestyle and environmental protection, and disability rights; (3) Develop first aid courses including a practical component – that would be made available to all citizens free of charge and consider regular courses as standard practice for students and in workplaces. There should also be a minimum number of defibrillators available in public places in all Member States; (4) Expanding the health week initiative to be coordinated across the EU; (5) Recognise hormonal contraception products and female sanitary products, as regular medical treatment in terms of taxation. Ensure access to reproductive treatments for all individuals suffering fertility problems.

Proposal	Objectives	Measures
CoFoE Proposal 10: Provide equal access to health for all.	Establish a “right to health”, by guaranteeing all Europeans have equal and universal access to affordable, preventive, curative and quality health care.	(1) Establish common minimum healthcare standards at EU level, covering prevention, accessibility and proximity of care, and provide support to achieve these standards; (2) Recognising the need to take full account of the principle of subsidiarity and the key role of local, regional and national players in health matter, ensure ability to act at EU level when the right to health is addressed. Allow faster and stronger decision-making on key subjects and improve the effectiveness of European governance towards the development of the European Health Union (such as, in the event of a pandemic or for rare diseases); (3) Enhance the European Health Union using the full potential of the current framework and include health and healthcare among the shared competences between the EU and the EU Member States by amending Article 4 TFUE; (4) Ensure anyone can access existing treatments within the EU, facilitate cross-border cooperation, on rare diseases, cancer, cardiovascular diseases and highly specialised treatments, such as organ transplants and the treatments of severe burns. A European network for transplants and organ donations should be put in place for the benefit of all European patients in need of a transplant; (5) Ensure affordability of care, through stronger investment in healthcare, in particular dental care to everyone within 15 to 20 years; (6) Ensure that treatments and medicines across the EU are of equal quality and of fair local cost, including through tackling existing fragmentation of the Internal Market; (7) Fight health poverty by encouraging free of charge dental care for children, low-income groups and other vulnerable groups, such as the disabled, in tandem with a consideration of the impact of poor-quality housing on health; (8) Consider the international dimension to health and recognise that medicines should be universally available, including in poorer countries.

Source: Conference on the Future of Europe, [Report on the Final Outcome](#), 2022, pp. 49-52.

5.2.2. EU action already taken in the area of CoFoE and public health

The EU has adopted many policies and legislation in the past years that relate to the CoFoE proposals and their objectives and measures (Table 12). This section elaborates on some of those initiatives listed in Table 12, linking them to each CoFoE proposal.

CoFoE proposal 7: Healthy Food and Healthy Lifestyle

The objective of this proposal is to ensure that all Europeans have access to the building blocks of a healthy lifestyle by health communication and promotion of healthy and affordable foods and access to healthy lifestyle. Central to addressing this ask is the Farm to Fork Strategy (see section 5.1.2). Limiting the use of antibiotics (measures 1 and 5) is coherent with the EU's action on AMR (see section 4.5). Another proposed measure is on food labelling, which the Commission intends to address with the revision of the Food Information to Consumers (FIC) Regulation and the sustainability labelling framework. The revised FIC Regulation will introduce mandatory front-of-pack nutrition labelling, set nutrient profiling criteria, extend the mandatory origin of certain products, and revise the rules on date marking.⁵⁷⁸ Additionally, the revised FIC Regulation will introduce a mandatory indication of the list of ingredients and the nutrition declaration on alcoholic beverage labels, linking this revision to ambitions of the Europe's Beating Cancer Plan (see section 3.1.1)⁵⁷⁹. Considering the CoFoE recommendations, there are still gaps in the EU's framework to healthy food and healthy lifestyle. For example, taxation of non-healthy processed food has not been harmonised across the EU yet.

CoFoE proposal 8: Reinforcing the healthcare system

The objective of this proposal is to reinforce the resilience and quality of healthcare systems. This includes the European Health Data Space to facilitate the exchange of health data (section 3.1.1). The measures on the harmonisation of training and organising coordinated strategic stockpiling are addressed by the recently adopted Regulation on Serious Cross-border Threats to Health (section 5.3.1).⁵⁸⁰ Furthermore, the CoFoE calls for the EU to invest in health systems and to issue strong recommendations to Member States “to invest in effective, accessible, affordable, high-quality and resilient health systems”. Considering the limited competence the EU has regarding healthcare systems (i.e. none), this is an interesting point. Nonetheless, this is also covered by the Regulation on Serious Cross-border Threats to Health. In particular, the Regulation reinforces a network that aims to contribute to the assessment of national health systems' capacity to diagnose, prevent and treat communicable diseases. Also, it sets out that the EU needs to support Member States in strengthening the resilience, responsiveness and readiness of healthcare systems in addressing future challenges including pandemics (section 5.3.1).

CoFoE proposal 9: A broader understanding of health

The objective of this proposal is to adopt a holistic approach to health in line with the One Health approach. Other than the measure on a standard educational programme on healthy lifestyles including environmental protection, the CoFoE's conclusions in proposal 9 focus on a broad range of public health subjects such as mental health, first aid courses for the public, the expansion of the health week initiative, and the recognition of certain sexual and reproductive health products to be considered as regular medical treatment (in terms of taxation). Regarding mental health, as a response to the CoFoE's conclusions, the Commission has announced a new initiative in the State of

⁵⁷⁸ European Commission, [Webpage](#) Proposal for a revision of the Regulation on Food Information to Consumers (FIC).

⁵⁷⁹ European Commission, Europe's Beating Cancer Plan, Communication [COM\(2021\) 44](#), 3 February 2021.

⁵⁸⁰ [Regulation \(EU\) 2022/2371](#) of 23 November 2022 on serious cross-border threats to health.

the European Union speech in September 2022.⁵⁸¹ This was further introduced as “an approach to boost mental health awareness across Europe, step up prevention, health promotion, improving access to mental healthcare services” by Commissioner Kyriakides.⁵⁸²

CoFoE proposal 10: Provide equal access to health for all

The objective of this proposal is to establish a 'right to health', by guaranteeing all Europeans have equal and universal access to affordable, preventive, curative and quality healthcare. This is the most radical proposal, in the sense that it calls for Treaty changes. In particular, the CoFoE concludes here that healthcare needs to be included as one of the shared competences between the EU and Member States (measure 3). However, action in healthcare is a clear competence of Member States (Article 168(7) TFEU, see section 5.1.1). The call for affordable care (measure 4) therefore also lies outside the competences of the EU, although the EU can support Member States via incentive measures (i.e. make budget available).⁵⁸³ Also, the EU supports Member States with the Pharmaceutical Strategy, which aims to ensure patients have access to high quality and affordable medicines (see section 3.1.1). The last CoFoE conclusion of proposal 10 is on considering the international dimension to health and recognising that medicines should be universally available. This is being addressed in the recently adopted EU global health strategy which aims to advance universal health coverage (see section 4.4).

5.2.3. Positions of EU institutions and individual Member States

The European Commission, the European Parliament, and the Council of the EU issued a joint declaration with a promise to follow-up on the CoFoE and examine the recommendations, each in alignment with their internal procedures and within their competences.⁵⁸⁴ Specifically, the Presidents of the three institutions promised 'to commit to listen to Europeans and to follow up on the recommendations made by Conference, in full respect of our competences and the subsidiarity and proportionality principles enshrined in the European Treaties'.

5.2.4. European Parliament

On 3 May 2022, the European Parliament held a plenary debate⁵⁸⁵ on the follow-up on the Conference on the Future of Europe and adopted a resolution calling for a Convention in accordance with Article 48 TEU.⁵⁸⁶ The Conference on the Future of Europe received due acknowledgement in Parliament, with a vast majority of Members of the European Parliament heralding the event as an 'unprecedented exercise in participatory democracy' – and that its outcome mandated due consideration.⁵⁸⁷

A cross-section of Members was in agreement that EU citizens needed to be engaged more fully in a stronger democratic representation at the EU level. Another reading of the CoFoE pointed out that

⁵⁸¹ European Commission, [2022 State of the union Address by President Von der Leyen](#), 14 September 2022.

⁵⁸² European Commission, Video [Keynote Speech](#) by Commissioner Stella Kyriakides at the High-Level Conference on Mental Health, organised by the Czech Presidency, 14 November 2022.

⁵⁸³ Art. 168(5) TFEU.

⁵⁸⁴ [Joint declaration on the Conference on the Future of Europe. Engaging with citizens for democracy – building a more resilient Europe](#), 2022.

⁵⁸⁵ European Parliament, [Debate](#) on the follow up of the Conference on the Future of Europe, 3 May 2022.

⁵⁸⁶ European Parliament, [Resolution](#) of 4 May 2022 on the follow-up to the conclusions of the Conference on the Future of Europe (2022/2648(RSP)).

⁵⁸⁷ European Parliament, Treaty review necessary to implement Conference proposals, Parliament declares, [press release](#), 4 May 2022.

citizen-driven proposals called for 'profound changes' – that included European elections,⁵⁸⁸ and new EU powers in areas of health, energy, migration and defence.⁵⁸⁹ At the same time, the Conference drew in criticism from a section of Members, who were unconvinced the proposals were representative of public opinion and criticised the process.

On 9 June 2022 the European Parliament adopted a resolution calling for a convention on Treaty change.⁵⁹⁰ The resolution made two observations: (1) that in addition to legislative proposals the opening of a process of institutional reforms is needed in order to implement the recommendations and meet democratic expectations of this citizens' participation process; and (2) that new policies and Treaty amendments are necessary in the interests of EU citizens and an essential means to reshape the EU, its capacity to act, and its democratic legitimacy and accountability.

Furthermore, the resolution points out that following recent crises, 'the Treaties need to be amended urgently to make sure the Union has the competence to take more effective action during future crises.' It submits to the Council a number of concrete proposals for amendments to the Treaties, one of them being to 'adapt the competences conferred on the Union in the Treaties, especially in the areas of health and cross-border health threats'. The resolution also proposes a reform of voting procedures, to enable majority voting replacing the unanimity requirement in relevant areas such as the adoption of sanctions and in emergencies.

5.2.5. Council of the European Union

In the follow-up to the CoFoE, the Council issued two technical assessments, that assessed the CoFoE proposals and related specific measures on grounds of their feasibility. As part of the assessment, the list of proposals and measures were mapped in relation to existing and ongoing EU initiatives, and on the legal basis for the implementation of the measures.^{591 592}

- A principal finding of the technical assessment is that a significant number of the proposals and related measures sought by the CoFoE were in the process of being addressed or are already addressed by the EU institutions. These are related to the areas of digital transformation, climate change and health for example.
- The preliminary assessment also highlighted proposals and related measures that could be further addressed by the EU institutions – but that the majority of these cases were possible within the current Treaty framework. In this regard, some of the proposals falling under this category (e.g. data protection) could be implemented by amending the EU legislative framework and reinforcing some of its provisions. Proposals falling under this category also included areas where existent tools and instruments needed to be harnessed to enable EU-level action.
- A third category of proposals would require new EU legislation, based on the current Treaty framework. Proposals falling under this category included upcoming initiatives such as a Media Freedom Act, initiatives for a Circular Economy Package, and topics in health.

⁵⁸⁸ European Parliament, MEPs begin revising rules on EU elections, calling for pan-European constituency, [press release](#), 3 May 2022.

⁵⁸⁹ European Parliament, Treaty review necessary to implement Conference proposals, Parliament declares, [press release](#), 4 May 2022.

⁵⁹⁰ European Parliament, [Resolution](#) of 9 June 2022 on the call for a convention on the revision of the Treaties, (2022/2705(RSP)).

⁵⁹¹ Council of the European Union, [Conference on the Future of Europe - Proposals and related specific measures contained in the report on the final outcome of the Conference on the Future of Europe: Preliminary technical assessment](#), 2022.

⁵⁹² Ibid.

The first technical assessment concluded that of the 49 CoFoE proposals, the majority were in alignment with ongoing EU initiatives or could be implemented within current legal basis. Very few required institutional reforms.

This is also the case for the CoFoE proposals and subsequent assessment relating to health. Upon examination the Council's technical assessment concluded that the majority of the CoFoE's proposals for health were being addressed by existing and ongoing EU initiatives aimed at better protecting citizen's health and at better responding to health crises.⁵⁹³ However, this convergence was lacking in specific CoFoE measures that asked for making healthcare (and education) a shared EU competence.⁵⁹⁴

5.2.6. European Commission

At the closing ceremony of the CoFoE, Commission President Ursula von der Leyen stated that European citizens had expressed their views on the direction they wished Europe to take. 'It is now up to us to take the most direct way there, either by using the full limits of what we can do within the Treaties... by changing the Treaties if need be.'⁵⁹⁵

The first analysis of the Commission's review of the CoFoE appeared in the Communication of 17 June 2022, containing a detailed follow-up on the CoFoE recommendations, and the next steps.⁵⁹⁶ The Communication divided the CoFoE proposals in four categories:

- Proposals that directly correspond to the Commission's initiatives e.g. the European Climate law, Digital Services act, the establishment of the HERA;
- Proposals addressing areas where the EU institutions have begun work e.g. the New Pact on Migration and Asylum;
- Planned actions that take into account reflections of the CoFoE, e.g. the Media Freedom Act and the European Innovation Agenda;
- New initiatives or areas of action that fall into the Commission's competences e.g. focus on mental health issues, nutrition and food security, and improved on eco-footprint.

In its analysis, the European Commission took a cautious view of Treaty changes, pointing out that 'Treaty change should not be an end in itself' and 'the vast majority of measures' would be actionable under the current provisions.⁵⁹⁷ Second, the Communication referred to the as yet 'untapped potential' within the existing Treaties which could be harnessed to respond to the Conference's proposals. This could be done using the 'passerelle clauses'⁵⁹⁸ in the Treaties to move to qualified majority voting in certain policy fields. The latter was explicitly called for by President von der Leyen in her Political Guidelines⁵⁹⁹ and her 2022 State of the Union address,⁶⁰⁰ in areas such as energy,

⁵⁹³ Council of the European Union, [Conference on the Future of Europe - Proposals and related specific measures contained in the report on the final outcome of the Conference on the Future of Europe: Preliminary technical assessment](#), p. 4, 2022.

⁵⁹⁴ Ibid., p. 7.

⁵⁹⁵ European Commission, [Speech by President von der Leyen at the closing event of the Conference on the Future of Europe](#), 9 May 2022.

⁵⁹⁶ European Commission, Conference on the Future of Europe: Putting Vision into Concrete Action, Communication [COM \(2022\) 404](#), 17 June 2022.

⁵⁹⁷ Ibid.

⁵⁹⁸ Silvia Kotanidis, [Passerelle clauses in the EU Treaties: Opportunities for more flexible supranational decision-making](#), EPRS, European Parliament, December 2020.

⁵⁹⁹ European Commission, [Political guidelines for the next European Commission 2019-2024](#), 2020.

⁶⁰⁰ European Commission, [2022 State of the Union Address by President Von der Leyen](#), 14 September 2022.

taxation, and for important aspects of the Common Foreign and Security Policy (sanctions and human rights).

However, in matters of health and defence, the ideas of the CoFoE were truly innovative and required the EU to venture into new and uncharted avenues. And some proposals, within these, explicitly called for Treaty change. In this regard, the Commission welcomed the European Parliament's willingness to use its powers under the Lisbon Treaty, and affirmed its own willingness to 'fully play its institutional role in the procedure set out in Article 48 of the Treaty on European Union', and in particular to give its opinion in response to a consultation by the European Council.⁶⁰¹

In her 2022 State of the Union address, President Von der Leyen gave her backing for a constitutional convention on Treaty reform, stating: 'As we are serious about a larger union, we also have to be serious about reform. So as this Parliament has called for, I believe the moment has arrived for a European Convention'.⁶⁰² Beyond this, the speech offered few details of what the Treaty change process should focus on.

5.2.7. Views of EU Member States

Opinions among Member States vary on the necessity for a Treaty convention. Supporters of Treaty changes say this will make the EU more transparent and accountable when responding to crises such as the COVID-19 pandemic. On the other hand, the majority of Member States voiced scepticism towards Treaty change. This section outlines the positions expressed by the Member States, through a discussion of the Non-papers issued by Member States.

Scepticism towards Treaty change

Non-paper by 13 countries (Bulgaria, Croatia, Czechia, Denmark, Estonia, Finland, Latvia, Lithuania, Malta, Poland, Romania, Slovenia, Sweden)

A Non-paper issued by 13 national governments on 9 May 2022 questioned the timing of a Treaty convention.⁶⁰³ The countries in question were: Bulgaria, Croatia, Czechia, Denmark, Estonia, Finland, Latvia, Lithuania, Malta, Poland, Romania, Slovenia, and Sweden. The joint statement noted that while the CoFoE proposals demonstrate a genuine interest in engaging with the policies that affect the daily lives of EU citizens, the signatories 'would not support any unconsidered and premature attempts to launch a process towards Treaty change'. They further argued that the EU's handling of the recent crises – including Russia's aggression on Ukraine and the COVID-19 – was adequate evidence of 'how much the EU can deliver within the current Treaty framework'.

Support of Treaty change

Non-paper by 6 countries (Belgium, Germany, Italy, Luxembourg, the Netherlands, Spain)

On 13 May 2022, six Member States issued a joint statement extending support to the proposals of the CoFoE.⁶⁰⁴ The signatories declared that they would 'remain in principle open to necessary treaty changes'. The statement suggested an interinstitutional process to 'coordinate consensus-building' in the Council, the European Parliament, and Commission.

⁶⁰¹ European Commission, Conference on the Future of Europe: Putting Vision into Concrete Action, Communication [COM \(2022\) 404](#), 17 June 2022.

⁶⁰² European Commission, [2022 State of the Union Address by President Von der Leyen](#), 14 September 2022.

⁶⁰³ [Non-paper by Bulgaria, Croatia, Czechia, Denmark, Estonia, Finland, Latvia, Lithuania, Malta, Poland, Romania, Slovenia, and Sweden on the outcome of and follow-up to the Conference on the Future of Europe.](#) (9 May 2022).

⁶⁰⁴ [Non-paper submitted by Germany, Belgium, Italy, Luxembourg, the Netherlands, and Spain on implementing the proposals of the Plenary of the "Conference on the Future of Europe"](#) (13 May 2022).

A position paper by the Young European Federalists supported Treaty change as a necessary legal requisite to achieve a more integrated European Health Union.⁶⁰⁵ It maintains that the CoFoE gives a clear recommendation for health and healthcare to be made 'a fully-fledged shared EU competence'.

5.3. Reflections on pros and cons of potential Treaty change

5.3.1. Expert opinions. Improvisation, without Treaty change

Experts estimate that a considerable number of the CoFoE recommendations would require a Treaty change to strengthen EU competences in the affected areas. An expert panel led by Alberto Alemanno, EU Law Professor at HEC Paris Business School estimates that only a small proportion of the recommendations - 21 of a total of 178 - require a EU Treaty change. These 21 recommendations call for strengthening EU competences in welfare (7), education (5), institutional reforms (4), health and healthcare (2), taxation (2) and energy (1). The remaining 157 can be implemented by the EU within the current competences or require Member State action, the crucial question being proper implementation.

Legal analysts reviewing the competences under EU law, argue that the EU already has a full spectrum of competences to coordinate action in the area of public health and disaster response, that can be transferred and applied to the COVID-19 response.⁶⁰⁶ In the health domain, these competences include directives on assistance and cooperation on cross-border health and biomedical research, as well as crisis response mechanisms under civil protection such as rescEU. TFEU competences are the legal bases for a wide range of actions to combat cross-border health threats and include for example: directives to keep borders open to essential products in health crisis.

Similarly, Stefan Lehne, Senior Fellow at the think tank Carnegie Europe argues that the EU's management of recent crises is evidence of the possibilities for improvised reform, without recourse to legal revision.⁶⁰⁷ Specifically, Lehne points to the recent history of the EU – from the management of the financial crisis (2007-2008), to the recent COVID-19 crisis and the Russian invasion of Ukraine – is evidence of the EU's ability to manage crisis through improvised action. In the 2007-2008 financial crisis, the EU bailed out Member States by establishing an emergency funding programme and brokering an agreement on a new EU financial architecture without changing the Treaties. Similarly, the EU managed the refugee/migration crisis (2015-2016) partly by externalising migration management to third countries, such as Türkiye. Despite the limited EU competences in health, EU management of the coronavirus pandemic included the collective vaccination programme, joint procurement of medical countermeasures, and a vast recovery package (NextGenerationEU). The EU continues to respond to the Russian invasion in Ukraine with sanctions, welfare and military assistance to Ukraine, and by providing refuge to Ukrainian refugees. This shows that the EU has built the competences to improvise in crises and transitioned from technocratic decision-making to dealing with crisis through operational action.

The stakeholders consulted for this study were largely in agreement with this position. They pointed out that the pragmatic way forward was to make do with what we have. The room for improvisation

⁶⁰⁵ Young European Federalists, [From COVID-19 towards a European Health Union: proposals for treaty reform on health](#), 2022.

⁶⁰⁶ Purnhagen K.P. et al., 'More competences than you knew? The web of health competence for European Union action in response to the COVID-19 outbreak', *European Journal of Risk Regulation*, Vol. 11(2), 2020, pp. 297-306.

⁶⁰⁷ Lehne S., [Does the EU need treaty change?](#), Carnegie Europe, 2022.

within the current Treaty framework was still significant, allowing for the changes to be made to health systems and health outcomes, and better preparedness to future pandemic threats.

5.3.2. Strengthening preparedness: the Regulation on Serious Cross-border Threats to Health

Among the lessons learnt from the COVID-19 pandemic is the need for coordinated measures to become a 'reflex' for Europe and for reinforced public-private partnerships and stronger supply chains for critical equipment and medicines.⁶⁰⁸ To this end, the Regulation on Serious Cross-border Threats to Health has been adopted in November 2022, repealing Decision No 1082/2013/EU.⁶⁰⁹ The regulation shows the possibilities of EU action within the Treaty boundaries.

The background of this regulation starts with Decision No 2119/98/EC, which, back in 1998, set up a network for epidemiological surveillance and control of communicable diseases.⁶¹⁰ A more coordinated and wider approach to health security at the EU level was set out by Decision No 1082/2013/EU.⁶¹¹ This is considered to be a confirmation of the added value of EU coordination on monitoring, early warning of and combatting health threats to the protection and improvement of health.⁶¹² The most recent regulation lays down rules on *inter alia* prevention, preparedness and response planning at the EU and Member State level (including reporting and assessing preparedness at the Member State level), epidemiological surveillance and monitoring, the Early Warning and Response System (EWRS), risk assessment, joint procurement, the Health Security Committee (HSC), and the recognition of a public health emergency at the EU level.⁶¹³

The upgraded EU framework for serious cross-border health threats is considered to strengthen prevention, preparedness and response planning, both at the EU and Member State level. This addresses another lesson learnt: 'preparedness needs constant investment, scrutiny and review'.⁶¹⁴ Whereas the initial Commission proposal mentioned auditing by the Commission and EU agencies⁶¹⁵, the final agreed version of the regulation states that the ECDC 'shall assess the Member States' state of implementation of their national prevention, preparedness and response plans and their relation with the Union prevention, preparedness and response plan'.⁶¹⁶ If applicable, these assessments will be followed by recommendations from the ECDC and action plans by the Member States, which may include regulatory actions, training initiatives and an overview of good practices.⁶¹⁷

Regarding surveillance, the regulation reinforces the network for epidemiological surveillance of communicable diseases and related special health issues, which was already in place.⁶¹⁸ Members of this network are the Commission, the ECDC, and competent Member State authorities. The network aims to *inter alia* monitor trends and outbreaks, contribute to the evaluation and monitoring of

⁶⁰⁸ European Commission, State of Health preparedness report, Communication [COM\(2022\) 669](#), 30 November 2022.

⁶⁰⁹ [Regulation \(EU\) 2022/2371](#) of 23 November 2022 on serious cross-border threats to health.

⁶¹⁰ [Decision No 2119/98/EC](#) of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community.

⁶¹¹ [Decision No 1082/2013/EU](#), of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC.

⁶¹² [Regulation \(EU\) 2022/2371](#) of 23 November 2022 on serious cross-border threats to health.

⁶¹³ *Ibid.*, Article 1(1).

⁶¹⁴ European Commission, State of Health preparedness report, Communication [COM\(2022\) 669](#), 30 November 2022.

⁶¹⁵ European Commission, Proposal for a regulation on serious cross-border threats to health and repealing Decision No 1082/2013/EU, Communication [COM\(2020\) 727](#), 11 November 2020.

⁶¹⁶ [Regulation \(EU\) 2022/2371](#) of 23 November 2022 on serious cross-border threats to health, Article 8(1).

⁶¹⁷ *Ibid.*, Articles 8(2) and 8(3).

⁶¹⁸ *Ibid.*, Articles 13(1) and 13(2).

communicable disease prevention and control programmes (such that EU and Member State level programmes can be improved), and identify and monitor risk factors for disease transmission and populations at risk. The network's aims also include contributing to the assessment of health systems' capacity to diagnose, prevent and treat communicable diseases. Therewith, it provides EU support to Member States to develop, strengthen and maintain their capacity to detect, assess, notify and report potentially significant public health events – an obligation under the International Health Regulations (IHR).⁶¹⁹

To further support the coordination of prevention, preparedness and response planning for serious cross-border health threats, the HSC is given additional responsibilities through the Regulation. The HSC is chaired and hosted by the Commission and consists of representatives of Member States.⁶²⁰ Representatives of EU agencies and bodies are allowed to observe HSC meetings, along the technical representative designated by the European Parliament.⁶²¹ The HSC's responsibilities include enabling coordinated action on prevention, preparedness and response planning, coordinating risk and crisis communication, and adopting opinions and guidance for the prevention and control of health threats.⁶²² The regulation also sets out provisions to facilitate coherence between the EU and Member State prevention, preparedness and response plans. Member States are expected to liaise with each other within the HSC.⁶²³

The regulation also allows the European Commission to formally recognise a public health emergency at the EU level.⁶²⁴ This is a new mandate of the Commission and additional to the WHO's mandate to declare such an emergency (the PHEIC).⁶²⁵ The EU recognition legally triggers mechanisms to monitor shortages of, and to develop, procure, manage and deploy medical countermeasures.⁶²⁶ Also, it activates support from the ECDC via the mobilisation and deployment of its EU Health Task Force.⁶²⁷

Building on the lessons learnt from the COVID-19 pandemic, the regulation aims to strengthen the joint procurement framework of the EU (i.e. the JPA).⁶²⁸ The new regulation enables the European Commission and Member States to jointly purchase medical countermeasures. Hereby, the Commission is required to prepare a joint procurement assessment with envisaged conditions. These conditions may include possible restrictions on parallel procurement and negotiation activities by participating countries. Countries can decide whether to participate on the information provided by the Commission and under the conditions they mutually agreed on.⁶²⁹ Furthermore, the Commission has a coordinating role also for stockpiling under rescEU.⁶³⁰ Together with the services and support potentially available under the UCPM, the rescEU stockpile needs to be reflected in the EU's prevention, preparedness and response plan (see above).⁶³¹

⁶¹⁹ World Health Organization, International Health Regulations, 2005.

⁶²⁰ [Regulation \(EU\) 2022/2371](#) of 23 November 2022 on serious cross-border threats to health, Articles 4(1), 4(5) and 4(6).

⁶²¹ Ibid., Articles 4(2) and 4(10).

⁶²² Ibid., Article 4(3).

⁶²³ Ibid., Article 6(1).

⁶²⁴ Ibid., Article 23.

⁶²⁵ World Health Organization, International Health Regulations, 2005.

⁶²⁶ [Regulation \(EU\) 2022/2371](#) of 23 November 2022 on serious cross-border threats to health, Article 25.

⁶²⁷ Ibid.

⁶²⁸ Ibid., preamble 18.

⁶²⁹ Ibid., Article 12(3).

⁶³⁰ Ibid.

⁶³¹ Ibid., Article 5(3).

Central to the regulation are the One Health (Box 4) and Health in All Policies (HiAP) (Box 5) approaches. These approaches have been recognised by the EU way before the pandemic. For example, already in 2017, the AMR One Health Network brought together the Commission, the agencies ECDC, EMA and EFSA, and Member States representatives responsible for public health, food safety, veterinary matters, plant health and the environment.⁶³² This Commission expert group assists relevant Directorates-General in identifying needs in the area of AMR and support the implementation of EU actions. Nonetheless, the One Health Approach has been given a more important place now (see section 5.5).

In line with the One Health and HiAP approaches, the regulation sets out that the EU needs to support Member States in strengthening the resilience, responsiveness and readiness of healthcare systems in addressing future challenges including pandemics.⁶³³ In particular, the exchange of information with international organisations (i.e. the WHO) and third countries is seen as important to ensure this commitment.⁶³⁴

5.4. Main findings

EU competences in public health

- As set out by the TFEU, the EU has the competence to support, coordinate or supplement the actions of Member States in the protection and improvement of human health.
- Historically, most impact in the area of public health has been made not on the sole basis of Article 168 TFEU, but also by using other Treaty bases such as the internal market and fiscal governance.
- The pandemic has shown that it is difficult to uphold the division between healthcare policy (which is a Member State competence) and public health (which is a shared competence). It had therefore stirred the discussion about the EU's competences in public health.
- This was for example demonstrated in the European Health Union campaign, which is led by civil society and supported by individuals from Ministries of Health, national public health institutes and from the European Commission.
- Within the boundaries of the current Treaties, a shift towards increased EU competences has been observed, which is exemplified in the new Regulation on Serious Cross-border Threats to Health.
- Regardless this shift, there are calls for more ambition in EU health policy, among others in tackling health disparities in and between Member States.
- Strengthening the role of the EU internally is regarded to be needed to ensure a stronger role externally (i.e. in global health).
- In the COVID-19 response, given the cross-cutting nature of health policy, the EU institutions have adopted numerous health-related acts in and outside the area of public health. This strong interlinkage between public health and other policy areas is exemplified by the Farm to Fork Strategy, which links health policy with agricultural, fisheries and climate policy. The other way around, also policies from other areas touch upon health; in some cases going beyond into rebuilding healthcare systems.

⁶³² European Commission, [Call for applications for the selection of members of the Expert Group 'Antimicrobial Resistance \(AMR\) One Health Network](#), 2022.

⁶³³ [Regulation \(EU\) 2022/2371](#) of 23 November 2022 on serious cross-border threats to health, preamble 10.

⁶³⁴ Ibid., preamble 38.

The Conference of the Future of Europe (CoFoE) and reflections on Treaty changes

- The CoFoE, a citizens-led series of discussions on the future of Europe, resulted in recommendations in the areas of long-term EU strategies and investments (into health promotion and affordable, universal healthcare access) and the recent lessons from COVID-19 (e.g. health system resilience).
- Specifically, the CoFoE called for: access to a healthy lifestyle; reinforcement of resilience and quality of healthcare systems; adopting a holistic approach to health in line with the One Health Approach; and guaranteeing equal and universal access to affordable healthcare.
- The EU has adopted many legislative and non-legislative initiatives in the past years that relate to the CoFoE proposals and their objectives and measures.
- Gaps in these policies remain in some areas. For example, taxation of non-healthy processed food has not been harmonised across the EU yet.
- The CoFoE's proposal on equal access to health calls for Treaty changes. Specifically, the proposal includes healthcare to be a shared competence of the EU and Member States.
- Also, the call for affordable care lies outside the EU's competences, although the EU can support Member States via incentive measures (i.e. make budget available). The EU also supports Member States in this area via its policies, notably the Pharmaceutical Strategy.
- Furthermore, the CoFoE concluded that medicines should be universally available. The recently adopted EU global health strategy addresses this by aiming to advance universal health coverage.
- Following the CoFoE, the European Parliament adopted a resolution calling for a convention on Treaty change.
- The Council's technical assessment concluded that the majority of the CoFoE's proposals for health were being addressed by existing and ongoing EU initiatives. Convergence was lacking in the call for making healthcare a shared EU competence.
- The European Commission followed up the CoFoE with a Communication, in which it took a cautious view towards Treaty changes, pointing out that majority of the measures were actionable under the current provisions. The Communication referred to the as yet 'untapped potential' within the existing Treaties, and to using the 'passerelle clauses' to move to qualified majority voting in certain policy fields.
- Opinions among EU Member States differ on the necessity for a Treaty convention.

The Regulation on Serious Cross-border Threats to Health

- The Regulation on Serious Cross-border Threats to Health shows the possibilities of EU action within the limits of the Treaties.
- The Regulation has been adopted to address the need for coordinated measures to become a 'reflex' for Europe and for reinforced public-private partnerships and stronger supply chains for critical equipment and medicines.
- Central to the Regulation are the One Health and Health in All Policies (HiAP) approaches.
- Building on the lessons learnt from the COVID-19 pandemic, the Regulation aims to strengthen the EU's joint procurement framework (i.e. the JPA), and to strengthen prevention, preparedness and response planning, both at the EU and Member State level.
- Regarding surveillance, the Regulation reinforces the network for epidemiological surveillance of communicable diseases and related special health issues, which was already in place.
- It also allows the European Commission to formally recognise a public health emergency at the EU level.

6. Conclusions

6.1. Conclusions Pillars 1 & 2 on the EU vaccines strategy, effectiveness and evidence

Vaccines, together with other countermeasures have been at the core of pandemic control since the outbreak of COVID-19 across the world. Pillars 1 and 2 aimed to provide an overview of the development and procurement process of COVID-19 vaccines in the EU, through the EU vaccines strategy, and to present opinions from different perspectives concerning some more controversial issues, such as the transparency of some steps in the process. The pillars further assessed the vaccination strategies and coverage across EU Member States, and reviewed the effectiveness of four EMA approved COVID-19 vaccines used in the EU/EEA area, drawing on the findings of peer-reviewed clinical trial studies and epidemiological studies.

EU and Member State actions contributed to speeding up the vaccination process in several aspects. The EU vaccines strategy and EU and Member State funding contributed to fast vaccine development, although a public debate arose around whether manufacturers should retain IP rights during the pandemic. The EU also helped accelerate the production of COVID-19 vaccines through the establishment of the Task Force for Industrial Scale-up of COVID-19 vaccines, and subsequently the Commission DG HERA. Also, EU-level Advanced Purchase Agreements (APAs) supported the unified procurement of vaccines across the bloc, although there were concerns around transparency. The Commission has so far failed to disclose detailed information on the public spending on vaccine development, while its published APAs and contracts contain considerable redactions.

The approval and authorisation process of COVID-19 vaccines in the EU followed a different procedure from the US, and the first batch of vaccines reached the EU population two weeks later than in the US. Yet, the EU's conditional marketing authorisation is a well-established and systematic regulatory mechanism, ensuring a positive risk-benefit balance and necessarily rigid post-approval safeguards and controls. The EMA has notably published clinical trials data.

Based on recommendations provided at EU level and under common approaches, national health authorities introduced their own national vaccination strategies. These were similar in the fact that in most cases they included only marketed EMA-authorised vaccines, eventually implementing the use of COVID-19 certificates to access certain public spaces. However, they differed in terms of the recommendations of the products and timing with which to vaccinate certain groups of the population. Some Member States also introduced vaccination mandates for certain categories of the population. The EU added value in national vaccination strategies resides in the publication of non-binding recommendations on vaccination. These EU-level recommendations were deemed helpful, especially for small Member States with less scientific capacity, while some other Member States found them challenging to follow.

Vaccination coverage and progress also differed across Member States. While by mid-2021, countries experienced important disparities in vaccination progress, most countries were able to vaccinate a large part of their population by mid-2022. However, differences between Member States continue to exist when it comes to vaccine coverage of the older population. The coverage among children remains relatively low in all Member States.

Key variables determining vaccination coverage include national vaccination programmes, public opinion, infodemics and trust in authorities. As vaccination programme measures, vaccination mandates did not ramp up vaccine uptake, while the use of COVID-19 certificates in some countries is believed to be a factor behind surges in vaccination progress. Vaccine hesitancy was fuelled by the infodemic spreading through online and offline social networks, but it has dropped significantly

throughout the pandemic. This was largely influenced by the availability of scientific evidence about the effectiveness and safety of vaccines, as well as levels of trust in government.

Finally, the study of peer-reviewed clinical trial studies of four COVID-19 vaccines EMA authorised for the EU/EEA area (AstraZeneca, Johnson & Johnson/Janssen, Moderna and Pfizer-BioNTech) shows that these vaccines sufficiently protect against infection; and analysis of epidemiological studies showed that on average these vaccines are very effective in preventing infection, hospitalisation and death.

6.2. Conclusions: Pillar 3 on the EU public health response to COVID-19

Pillar 3 assessed the EU's public health response to COVID-19. The EU has enacted several tools to react to the COVID-19 pandemic. These are: the Regulation on Serious Cross-border Threats to Health, the creation of HERA, stronger mandates for the ECDC and EMA, as well as several instruments including the JPA, CRII/CRII+, ESI, rescEU and the UCPM.

This study overall concludes that the EU used its resources effectively to provide EU-level protection, prevention, preparedness, and response during the COVID-19 pandemic. However, some points still need to be addressed to enhance this effectiveness. For instance, concern was raised regarding the lack of clarity on the definition of a public health emergency at the EU level, the vaccine delivery's slow initial pace, the lack of choice in vaccine suppliers, and a lack of capacity to deal with all types of emergency. Nonetheless, the resources utilised ensured a faster and more coherent response during the COVID-19 pandemic.

This study found no evidence to suggest a lack of internal coordination and coherence between the various EU agencies and institutions. However, some doubt arises as to the potential duplication of competencies and responsibilities of the newly created HERA and existing EU health DGs and agencies.

Regarding EU added value, it may be concluded that (particularly smaller) Member States were predominantly positive about the EU's COVID-19 response. This is especially regarding the coordinated response to the COVID-19 pandemic, which would have been difficult to achieve by the Member States acting alone. However, according to interviewed stakeholders, EU-level procurement is more likely seen as a complementary tool rather than as a replacement for national procurement in the health domain.

On the resources used to combat COVID-19 globally, it may be concluded that the EU's COVID-19 response did not sufficiently extend solidarity or timely assistance to other parts of the world.

6.3. Conclusions: Pillar 4 on the EU's prevention and preparedness framework

Pillar 4 looked at the strengths and weaknesses of the EU regarding its prevention and response capacity. It may be concluded that the EU response grew stronger during the pandemic. At first, the detection of and response to the COVID-19 pandemic at EU level were lacking or slow. Most of these issues were solved over time by, for example, launching different building blocks of the European Health Union, and notably the expanded mandate of the ECDC and EMA and the creation of HERA. Also, the need for adequate funding for ECDC was resolved in 2021.

Another strength was the launch of the EU's global health strategy, which offers an agenda that focuses on improving existing health systems, better health care, and preventing and combating health threats in the future. The European Commission's one health action plan against antimicrobial resistance (AMR) also sets out an integrated approach to tackling antimicrobial use, aiming at preventing AMR-related health threats.

When looking at the areas for improvement of the EU's prevention and response capacity, this study notes concerns about the expanded mandates of the ECDC and EMA in relation to the Member States, particularly regarding a lack of required competences to make binding recommendations to Member States. Additionally, the pandemic exposed the EU's dependence on external suppliers of key medical countermeasures. Looking at the one health initiative, there is uncertainty about whether and how this could be operationalised. This uncertainty could be seen as a weakness.

6.4. Conclusions: Pillar 5 on considerations regarding EU competences in public health

Pillar 5 aimed to explore the question of potential EU Treaty change. To this end, it illustrated the state of play of the EU's current competences in public health, the public health discussions at the Conference on the Future of Europe (CoFoE, a citizen-led series of discussions), and summarised reflections on the pros and cons of potential Treaty change.

The COVID-19 pandemic highlighted the difficulty in upholding the division between healthcare policy (a Member State competence) and public health policy (a shared competence). The discussion about the EU's competence in public health took form in the European Health Union campaign, the CoFoE, and in reflection on the part of the EU institutions and Member States.

Opinions among EU institutions and Member States differ on the necessity for a Treaty convention. On the one hand, the European Parliament adopted a resolution calling for a convention on Treaty change. Some Member State supporters of Treaty change say this would make the EU more transparent and accountable as well as more resilient when responding to crises such as the COVID-19 pandemic and Russia's war against Ukraine.

On the other hand, many Member States have expressed doubts as to the immediate need for Treaty change. The European Commission also took a cautious view, stating that the majority of the CoFoE's recommendations were actionable under the current Treaty provisions. The Regulation on Serious Cross-border Threats to Health showcases this shift towards increased EU competences without necessitating any Treaty change.

Nevertheless, greater ambition is needed in EU health policy to tackle health disparities in and between Member States and to strengthen the EU's external role (i.e. in global health). The CoFoE also called for EU action in the fields of access to a healthy lifestyle, resilience and on the quality of healthcare systems, the one health approach, and equal and universal access to affordable healthcare. Despite the adoption of many EU policies and legislation relating to these CoFoE proposals, gaps remain.

7. Recommendations

This study has looked at the lessons from the COVID-19 pandemic, the current state of play, as well as challenges and opportunities for improvement. Deriving from the study and its conclusions, this chapter presents 12 actionable, evidence-informed recommendations to improve and strengthen the EU's prevention, preparedness and responses to future cross-border health threats.

Recommendation 1. Improve the transparency of the development, production and procurement of vaccines. One lesson drawn is that concerns about transparency are heightened during crisis. Every crisis is therefore an opportunity for the EU to build or to lose trust. In the context of COVID-19 vaccines, the European Ombudsman underlined the principles of good administration and transparency. Similarly, a 2021 resolution of the European Parliament recognised that 'full transparency regarding all details of research into and the development, purchase and distribution of COVID-19 vaccines is the fundamental prerequisite for enhancing citizens' trust in vaccines'. This resolution was informed by petitions from EU citizens. And indeed, trust is key to dispelling citizens' doubts. Against this backdrop, and in line with the Center for Global Development's Principles on Commercial Transparency in Public Contracts, the Commission should consider providing justification for the redaction of its vaccine contracts. Providing justifications might allow a fairer evaluation of the balance between commercial confidentiality and public interests. Moreover, in line with Article 4 of Regulation (EC) No 1049/2001 on public access to EU documents, which lists the exceptions where the EU institutions can refuse access to a document: any information not falling under this article should be made available to the public.

Recommendation 2. Provide guidelines on joint procurement of vaccines and medical equipment. Following Recommendation 1 of the ECA's Special Report 19/2022, the Commission should provide guidelines on pandemic procurement. Such guidelines should be made available one year from the adoption of the Emergency Framework Regulation (on 24 October 2022) and the revision of the EU's Financial Regulation. The guidelines should clearly state the conditions under which the EU begins a joint procurement process, who represents the EU at the negotiation table with vaccine developers, what expertise and background are required for the negotiators, and what information is disclosed and when.

Recommendation 3. Negotiate more favourable conditions in future contracts with companies. In case of future major pandemics, the Commission should capitalise on the entire Union's support in a joint-procurement process and negotiate more favourable conditions with pharmaceutical companies (e.g. in terms of transparency, price, delivery arrangement and IP sharing). This would require a more transparent negotiation process, and a rule-based governance framework that provides incentives for future innovation while sufficiently protecting public interest.

Recommendation 4. Study the efficiency of the EMA's expedited authorisation. The EU's innovations in the regulatory process during the COVID-19 crisis provided first-hand experience of a new regulatory approach to respond to public health threats, which has a legacy well beyond this pandemic. The EU should consider conducting further evaluation of the use of the expedited authorisation pathway for medicinal products to identify steps to be merged or shortened, while maintaining and respecting a robust scientific standard. By taking stock of good and bad practices during the COVID-19 pandemic, a comprehensive evaluation could prepare the EU for the future, while also helping to optimise the regulatory process for diseases with no existing medical treatment.

Recommendation 5. Invest in new drug and vaccine development technologies. The success of mRNA technology is not a surprise to some, as this technology has been in development for years; however, the pandemic accelerated the development and provided worldwide exposure. To avoid being late in identifying the next upcoming technologies, the EU could take stock of new medical technologies in the pipeline, invest in promising technologies and even acquire partial ownership of their patents through public research institutes and universities. Obtaining a share of the

ownership of the intelligent property rights of a new upcoming technology is most likely when the developer is reliant on public money or lacks bargaining power.

Recommendation 6. Improve communication with Member States. Timely and effective communication between European and national authorities is key to ensuring successful preparedness and response to public health emergencies. It is also absolutely essential to form a coherent and harmonised response throughout the EU. By improving communication between the ECDC and Member States, the EU could establish a single authoritative voice. A single voice, however, does not imply one single uniform recommendation for all. A driving principle for the EU could be to anticipate the risk of having conflicting or inconsistent recommendations and to seek compromises or solutions through enhanced communication with the Member States, while acknowledging that a one-size-fits-all solution may not be optimal. The same lesson applies to EMA. Better communication would help to harmonise the use of vaccines while minimising confusion for citizens, and hence potentially foster vaccine uptake.

Recommendation 7. Improve communication with citizens. For the next pandemic public health emergency or even the next vaccine, EMA should better explain its review process to the public and coordinate with Member States on communication and education. Vaccination strategies and non-pharmaceutical measures meant to counteract the effects of the pandemic would be more successful with a sufficient level of trust. Trust in government and in public services is key to successful implementation of national vaccination strategies and other measures. Providing basic introduction of medical science and terminology would facilitate more effective communication with the public and help counter infodemics. A more transparent surveillance of the effects of vaccines would build trust in authorities, and EMA should reinforce the existing side-effect reporting mechanism by involving Member States in explaining it clearly to the public.

Recommendation 8. Invest in a more comprehensive approach to public health emergency prevention, preparedness and response. To better protect public health, a more comprehensive plan that goes beyond traditional instruments is needed. Investment in foresight, detection and surveillance capacity for future public health threats, as well as innovative diagnosis and treatment technologies, would help the EU prepare for the next public health emergency and enhance resilience to different kinds of crises. The digital transition should be seen as an opportunity for health authorities at the EU and national level to widen their arsenal and enhance their preparedness. Novel and adapted tools could be employed to reach marginalised populations and ensure an equitable protection for all individuals. Protecting vulnerable groups is a priority during crises, and innovative methods to implement vaccinations strategies could help achieve this objective.

Recommendation 9. Study the roots of vaccine hesitancy and enhance public trust. Science has been the core of a healthy democracy, which is especially true in the midst of the digital transition. The EU, together with national governments, could design a communication campaign to raise the average understanding of science and vaccine safety. Fighting infodemics, online and offline, could also enhance public trust in governments. It is inevitably important in a digital world for authorities to ensure a more prominent presence and greater communication with the public. To reiterate, science and the appreciation of science will be the key to maintaining a healthy balance between public health and personal liberty.

Recommendation 10: Adopt balanced disease prevention strategies that account for health system inequalities and community-based approaches. The COVID-19 pandemic revealed deep-seated inequalities and structural weaknesses, with the most vulnerable populations worst affected by the adverse effects of the pandemic. The global vulnerabilities and medical needs within the EU mandate an enhanced level of preparedness at the EU-level, anchored in robust forms of international cooperation and a broader public health approach. Prevention should be prioritised, which in turn could strengthen response; but prevention needs constant investment, scrutiny and review. This would involve a long-term preventive plan that is predicated on resilient health

systems, investments into one health, and root-cause analysis of the social, economic and environmental root causes of ill-health.

Recommendation 11: Secure medical supply chains and ensure strategic autonomy at the EU-level for medicines and medical devices. The EU's open strategic autonomy stresses the importance of managing supply chains in strategic sectors domestically as much as possible, while at the same time keeping the EU market open in alignment with EU values of maintaining free international trade. Within the EU, health system resilience could rely on securing medical supply chains and ensuring strategic autonomy at the EU-level for medicines and medical devices, and a strong healthcare workforce. European Union agencies and HERA have an important role to play in ensuring that essential and priority medicinal products and treatments (such as, biotechnology solutions) are available at the EU-level. Towards global health, this could involve building international collaborations and partnerships to support pharmaceutical manufacturing capacities outside Europe, and to ensure the availability and access to medical countermeasures at the global level.

Recommendation 12: Invest in resilient healthcare systems that are responsive to the needs of citizens and communities. European citizens called for a health system that is responsive to their everyday needs through the CoFoE: equal and universal access to healthcare, promotion of healthy lifestyles, and a secure health system workforce. This could mandate continued investment in health and social care, including long-term care, increased awareness and early diagnosis of mental health, cancer screening, and the promotion of healthful lifestyles.

Annex I

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Annex II

List of interviewed stakeholders

	Organisation	Date of interview
1	ECDC	12 September 2022
2	Corporate Europe Observatory	21 September 2022
3	DG ECHO	22 September 2022
4	OECD, Health Division	26 September 2022
5	Ministry of Social Affairs and Health, Finland	26 September 2022
6	European Public Health Alliance	29 September 2022
7	European Committee of the Regions	29 September 2022
8	DG GROW	29 September 2022
9	DG SANTE – Health Security Committee (HSC)	29 September 2022
10	EMA	30 September 2022
11	DG ECHO	3 October 2022 (two participants)
12	HERA	4 October 2022 (three participants)
13	Ministry of Health, Welfare and Sports, The Netherlands	4 October 2022
14	European Parliament - COVI Special Committee Secretariat	14 October 2022
15	European Federation of Pharmaceutical Industries and Associations (EFPIA)	14 October 2022 (two participants)
16	Public Health Directorate, Slovenia	20 October 2022
17	European Parliament - Committee on the Environment, Public Health and Food Safety ENVI	25 October 2022 (two participants)
18	Centre for Disease Prevention and Control, Latvia	28 October 2022 (written feedback)
19	Health Board, Department of Communicable Disease Surveillance and Control, Estonia	28 October 2022 (written feedback)
20	Health Promotion and Disease Prevention Directorate, Noncommunicable Disease Prevention and Control Unit, Malta	30 October 2022 (written feedback)
21	Ministry of Human Capacities, Department for Hospital Hygiene and Epidemiology Surveillance, Hungary	2 November 2022 (written feedback; two participants)
22	The Hellenic National Public Health Organisation, Greece	10 November 2022
23	The Danish Health Authority and Statens Serum Institut, Denmark	25 November 2022 (written feedback)

Annex III

Intellectual property sharing

An intellectual property system can significantly influence the access to existing innovations, including COVID-19 vaccines and medical countermeasures, as well as their development, manufacturing and production. Intellectual property rights are considered to be important to secure return on investment and in fostering pharmaceutical innovation and accelerating the availability of innovative medicines. The COVID-19 pandemic reinvigorated the discussions around a possible waiver of IPR on essential medicinal products to facilitate access to vaccines worldwide. Academic literature presents arguments advocating for an IP waiver (Erfani et al., 2021; Thambisetty et al., 2022) and arguments cautioning against the waiver (Ann et al., 2021; Mercurio, 2021). The TRIPS Council is the relevant body which regulates IP issues at international level under the TRIPS Agreement. On 2 October 2020, India and South Africa presented a communication to the World Trade Organization (WTO) Council for TRIPS asking for a temporary waiver from certain provisions of the TRIPS agreement.⁶³⁵ The Communication was further endorsed by a high number of WTO Member States. According to the proponents, a temporary waiver from certain IPR would give more companies the ability to produce COVID-19 vaccines and drugs and ultimately ensure a more equitable distribution of life-saving technologies. However, whether and to what extent IP rights actually represent a barrier to equitable access to vaccines remains an open question. Other barriers can be related to vaccines hesitancy, misconceptions about the disease, structural inefficiency in logistics (Afrifa-Anane et al., 2022), as well as lack of technological know-how, high prices or market forces leading to high demand and vaccines nationalism (through mechanisms such as the APAs, for example) (Boro and Stoll, 2022). On 25 November 2020 the European Commission adopted an Action Plan on Intellectual Property ('Better tools to facilitate access to critical IP in times of crisis'): The Action Plan includes proposals to fine-tune the existing toolbox in order to enable and further incentivise transfer of IP-protected technologies in times of crisis, such as possible mechanisms for rapid voluntary IP pooling – and voluntary licensing (partnerships are already in place worldwide) – and better coordination if the last resort measure of compulsory licensing is to be used.

Box A 1 Types of licensing

Voluntary licensing: The vaccine developer and producer agree voluntarily to work together. This is usually coupled with a transfer of know-how and technology. It is driven by needs, and fosters cooperation and efficiency.

Compulsory licensing: Government grants a targeted license allowing a willing producer to make a vaccine without the consent of the patent holder. The patent holder receives adequate remuneration. Transfer of know-how is not ensured.

Waiving IP rights: All relevant rights are waived, i.e. the protection granted by patents, copyright or other IP rights ceases to exist for the duration of the waiver. The vaccine developer is not remunerated and has no role or information on the product. The absence of interaction between the vaccine developer and the producers makes the transfer of know-how unlikely.

On this basis, the Commission believed that the TRIPS agreement is already able to override IP in an emergency (European Commission, 2020). On 4 June 2021 the European Commission presented a communication to the WTO Council for TRIPS that urges WTO Members to agree as soon as possible on a global trade initiative for equitable access to COVID-19 vaccines and therapeutics without

⁶³⁵ World Trade Organization, [Waiver from certain provisions of the TRIPS agreement for the prevention, containment and treatment of COVID-19. Communication from South Africa and India](#), 2020. (Accessed 31 October 2022).

asking for a temporary waiver of IP rights.⁶³⁶ This position reflects the recognition of additional barriers to entry in the production of COVID-19 vaccines that go beyond IP, therefore an IP waiver would have a limited effect.⁶³⁷ Contrary to the statement of the European Commission at the WTO, on 10 June 2021 Members of the European Parliament adopted a resolution⁶³⁸ (355 votes in favour, 263 against and 71 abstentions) to start negotiations for a temporary waiver of the WTO TRIPS Agreement in the short term. Members also specified that voluntary licencing as well as know-how and technology transfers are important ways to scale up global production in the long term.⁶³⁹ Finally, on 17 June 2022 at the WTO 12th Ministerial Conference (MC12) WTO members adopted a Ministerial Decision on the TRIPS Agreement on the basis of informal negotiations between the members of the 'Quad' – India, South Africa, the United States of America (US) – and the EU. The Ministerial Decision proposes a flexible use of compulsory licensing as a way to ensuring accessibility of vaccines.⁶⁴⁰

The study of intellectual property rights has been evolving for decades and one of the focal points of the economics of industrial organisation.⁶⁴¹ The debate surrounds the trade-off between enhancing social welfare and encouraging innovations. Intellectual property rights protection provides the private sector monetary incentives to innovate and some innovations will increase social welfare in the future. The protection is often provided by patents. In the pharmaceutical industry, companies may also enjoy protections from Supplementary Protection Certificates (SPC) and a period of market exclusivity. These protections aim to reward companies for innovations, which involve investment costs and are not always successful. On the other hand, once a successful innovation enters into the market, the investment cost is sunk and any values created above the production cost add to the social welfare. Therefore, the question is to what extent the economy should protect and incentivise innovations while maximising social welfare. In an emergency, the argument for waiving the protection becomes stronger since the innovation could have helped more people. However, releasing the technology also implies losing part of the potential profit generated by applying the same technology to other medicinal products. It is unimaginable that companies would be willing to do it voluntarily. Forcing companies to do so by a derogation would set a precedent that discourages future innovations by private firms; the economy should maintain a rule-based governance framework. From the societal perspective, a reasonable arrangement for the future is to enforce a patent pool early on when companies are facing high risk of failure and public money would be most needed to de-risk the investment. When companies are more reliant on governments or the EU, negotiators representing the public should be more able to bargain for a better price and more favourable conditions. Further research is required in this regard while taking the lessons learnt from the pandemic.

Transparency in the EU in relation to intellectual property sharing

In the Communication on the EU vaccines strategy, the European Commission affirmed that the APAs negotiated with pharmaceutical companies would aim at supporting and securing an adequate supply of vaccines, de-risking the necessary investments related to both vaccine

⁶³⁶ World Trade Organization, [Urgent trade policy responses to the COVID-19 crisis: intellectual property. Communication from the European Union](#), 2021. (Accessed 31 October 2022).

⁶³⁷ Along the same line, see [the opinion of Patrick Gaulé in the World Trade Report 2021](#). (Accessed 31 October 2022).

⁶³⁸ European Parliament, [Resolution](#) of 10 June 2021 on meeting the global COVID-19 challenge: effects of the waiver of the WTO TRIPS Agreement on COVID-19 vaccines, treatment, equipment and increasing production and manufacturing capacity in developing countries (2021/2692(RSP)).

⁶³⁹ European Parliament, Parliament calls for temporary COVID-19 vaccine patent waiver, [press release](#), 16 June 2021.

⁶⁴⁰ World Trade Organization, [Ministerial Decision on the TRIPS Agreement](#), adopted on 17 June 2022 (Accessed 31 October 2022).

⁶⁴¹ Besen S.M. and Raskind L.J. [An introduction to the law and economics of intelligent property](#), *Journal of Economics Perspectives*, Vol. 5(1), 1991, pp. 3-27.

Denicolo V. [Patent races and optimal patent breadth and length](#), *Journal of Industrial Economics*, Vol. 44(3), 1996, pp. 249-265.

development and clinical trials, and the preparation of the at-scale production capacity along the entire vaccine production chain. All these activities are intended to allow the deployment of doses of vaccine in the EU and also globally. Indeed, in the Strategy, the EU committed to global solidarity, i.e. universal, equitable and affordable access to COVID-19 vaccines. Ensuring a universal, equitable and affordable access to COVID-19 vaccines also entails that IPR should not be an obstacle for access to vaccines both in developed countries and developing countries. In other words, by signing APAs the European Commission contributed to de-risking investment of pharmaceutical companies to develop the vaccines, but beside exceptional circumstances, IPR are able to provide the incentives for companies to carry out R&D and innovations. For these reasons, some stakeholders argue that, on the one hand, the European Commission supported with public money pharmaceutical companies to accelerate and de-risk the research activities for the development of COVID-19 vaccines, but, on the other hand, the European Commission did not negotiate more favourable conditions in the APAs aimed at ensuring universal, equitable and affordable access to COVID-19 vaccines worldwide. According to some stakeholders interviewed for this study, considering the public financial support given by the EU to pharmaceutical companies, the negotiation of better conditions in the APAs for COVID-19 vaccines could entail specific clauses to ensure the sharing of some IPR to allow a broader production in different locations of the world where production capacity is well developed but innovation is not. However, it should be noted that to share some IPR an IP waiver is not the only solution; voluntary licencing, pooling of IP rights, partnerships or compulsory licencing are also viable options. In addition, the European Commission mobilised resources through international pledging for donations and joined forces with countries and global health organisations through the ACT Accelerator and through COVAX. Despite the global efforts, vaccines uptake continues to lag in some parts of the world. Some commentators believe that this is due to logistical problems in distribution (multiple pharmaceutical companies noted during COVI Committee hearings that the bottleneck in vaccinating low-and middle-income countries was in distribution logistics and infrastructure, not supply) and growing vaccine hesitancy. However, other commentators believe that negotiating better conditions in the APAs to ensure universal, equitable and affordable access to vaccines would have given to the EU a greater role in the global sphere, position itself as a major global actor in the emergency, and increasingly comply with its commitment of global solidarity stated in the EU vaccines strategy.

Annex IV

Information on vaccine development, funding, procurement and delivery

To supplement the analysis and to provide readers some additional information about vaccine contracts, four sources of information are evaluated and briefly commented on. Information as per 26 October 2022.

Table A.1: Data sources of COVID-19 vaccine contract information

Title	Developer	Website	Description	Updated	Data downloadable	Comments
COVID-19 Market Dashboard	UNICEF	https://www.unicef.org/supply/COVID-19-market-dashboard	The platform provides information on the world's COVID-19 vaccine market, the COVAX Facility's vaccine deliveries, and also UNICEF deliveries of COVID-19 therapeutics since 2022.	Regularly updated	Yes	▪ Bilateral donation information is available but not downloadable. ▪ Agreement information is not always extracted from official documents (the contract). ▪ Price information is not extracted from official documents. ▪ No information of vaccine's origins and destinations is available.
The COVID-19 Health Funding Tracker	The Economist Intelligence Unit	https://covidfunding.eiu.com/	The platform synthesises global, health-related funding efforts, from pledge to disbursement.	Last 25/09/2021	Yes	▪ It does not have disaggregated funding information to private companies.
COVID-19 Deals Tracker	Bloomberg	https://www.bloomberg.com/graphs/covid-vaccine-tracker-global-distribution/contracts-purchasing-agreements.html	The website shows several interactive maps, reporting the following information: where each vaccine type is delivered and in which quantity, the percentage of the population that is covered by the vaccines contract.	Last 1/03/2021	No	▪ The information was useful when countries urgently needed vaccines, but not very useful when vaccines are more available. ▪ Bloomberg ceased to update the information in March 2021.
ACT-Accelerator Commitment Tracker	WHO	https://www.who.int/publications/m/item/access-to-COVID-19-tools-tracker	The tracker provides transparent reporting on funding commitments made between donors and ACT-A agencies against ACT-Accelerator Pillar budgets.	Last 5/09/2022	Yes	▪ Funding information is very detailed. ▪ It requires some supplementary information to understand the dataset.

Annex V

List of clinical trials and epidemiological studies included in section 2.3

Clinical trials

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This study has been drawn up to support the work of the European Parliament's Special Committee on the COVID-19 pandemic. It examines the European Union's public health response to the COVID-19 pandemic across the following five pillars: (i) the EU vaccines strategy and national vaccination strategies; (ii) independent scientific evidence on vaccine effectiveness; (iii) the EU public health response to COVID-19, addressing the EU framework for crisis response; (iv) the EU's prevention and preparedness efforts for future health threats; and (v) considerations regarding EU competences in public health.

By assessing the lessons of the COVID-19 pandemic, the current state of play, challenges, and opportunities for improvement in EU public health governance, a series of recommendations are proposed to strengthen the EU's resilience and preparedness for future cross-border health threats.

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