Study on the coherence, complementarity, and continued relevance of actions in the Council Recommendation on strengthened cooperation against vaccine-preventable diseases in view of possible similar policy initiatives in the future

Final report

Written by EY France
For the Directorate General for Health and Food Safety
October / 2023

DG SANTE

EUROPEAN COMMISSION

Directorate General for Health and Food Safety
Directorate B — Public health, Cancer and Health Security
Unit B.4 – Disease Prevention and Health Promotion

European Commission
L-2920 Luxembourg

Study on the coherence, complementarity, and continued relevance of actions in the Council Recommendation on strengthened cooperation against vaccine-preventable diseases in view of possible similar policy initiatives in the future

LEGAL NOTICE

PDF ISBN 978-92-68-08384-0 doi:10.2875/307035 EW-05-23-380-EN-N

Manuscript completed in October / 2023

Luxembourg: Publications Office of the European Union, 2023

How to cite this report: "Study on the coherence, complementarity, and continued relevance of actions in the Council Recommendation on strengthened cooperation against vaccine-preventable diseases in view of possible similar policy initiatives in the future".

Table of content

List of abbreviations

CCBI	Competence Centre on Behavioural Insights
CPME	Standing Committee of European Doctors
DTP	Diphtheria-Tetanus-Pertussis
ECDC	European Centre for Disease Prevention and Control
EFN	European Federation of Nurses Associations
EEA	European Economic Area
EHDS	European Health Data Space
EMA	European Medicines Agency
ETAGE	European Technical Advisory Group of Experts on Immunization
EU	European Union
EVC	European Vaccination Card
EVIS	European Vaccination Information Sharing System
HPV	Human Papillomaviruses
IIS	Immunisation Information System
EU-JAV	European Joint Action on Vaccination
MAH	Marketing Authorisation Holder
MCV	Measles Containing Vaccines
MMR	Measles, Mumps and Rubella
NCA	National Competent Authority
NITAGs	National Immunization Technical Advisory Groups
NGO	Non-Governmental Organisation
OMCL	Official Medicines Control Laboratories
PGEU	Pharmaceutical Group of the European Union
SAGE	Strategic Advisory Group of Experts on Immunization
UN	United Nations

WHO	World Health Organization
WP	Work Package

Abstract

Since 2018, the work of the European Commission on vaccination has been guided by the Council Recommendation on strengthened cooperation against vaccine-preventable diseases. Along with the Commission Communication accompanying the Council Recommendation, this policy initiative called for a large number of actions to be implemented by the Commission, the EU Member States, and stakeholders with the overall objective of improving the uptake of vaccination across the EU in a life-course perspective. To implement the actions, a Commission Roadmap was drawn up, defining 28 actions and 62 deliverables. This 'Study on the coherence, complementarity and continued relevance of actions in the Council Recommendation on strengthened cooperation against vaccine-preventable diseases in view of possible similar policy initiatives in the future' aims to support the Commission for possible policy developments in the future. The Study (i) assesses the relevance of the actions in the Roadmap in the short to medium term (2-5 years) (ii) assesses the coherence and complementarity with other related policy initiatives in order to identify possible synergies and avoid duplication and (iii) identifies the most relevant actions that could be further developed and made sustainable to remain relevant on a longer term (+10 years).

Executive Summary

Objective and scope of the study

Since 2018, the European Commission's work on vaccination has been guided by the Council Recommendation on strengthened cooperation against vaccine-preventable diseases (hereafter 'Council Recommendation'). Along with the Commission Communication on 'Strengthened Cooperation against Vaccine Preventable Diseases' (hereafter 'Commission Communication'), this policy initiative called for a large number of actions to be implemented by the Commission, EU Member States and stakeholders, with the aim of improving the uptake of vaccination across the EU in a life-course perspective. A Roadmap for the implementation of the initiative and its actions was published, consisting of 28 actions divided into 62 deliverables to be completed by the end of 2022.

The general aim of this Study is to support possible policy developments in the future. The Study aims to assess the relevance of the actions in the Roadmap in the short to medium term and to identify the most relevant actions that could be further developed on a longer term. The Study had three specific objectives:

- To assess the relevance of the actions in the Roadmap in the short to medium term (2-5 years)
- To assess the coherence and complementarity with other related policy initiatives in order to identify possible synergies and avoid duplication
- To identify the most relevant actions that could be further developed and made sustainable to remain relevant on a longer term (+10 years).

To achieve these objectives, the Study team elaborated an analytical framework shaped around nine Study questions. They are based on the criteria of relevance, coherence, and complementarity.

The methodology

The Study team collected both qualitative and quantitative, primary as well as secondary data. In relation to the data gathered, no specific gaps were identified. The following tools were deployed:

75+ documentary resources were reviewed	43 interviews undertaken by the Study team	1 Online Survey	4 Case studies on specific areas covered by the study
• EU Policy Documents • Eurostat and other statistical Reports • Information from Research Institutes and International Organisations (WHO, OECD) • Preparation of Action Fiches per Individual Action of the Commission Roadmap • Scientific Literature	• National Health Ministries and Public Health Authorities • EU Institutions • Civil Society Organisations • Health professionals and student associations • Stakeholders of the vaccine industry	• Extensive survey covering all fields of the Study and all stakeholder groups	• Case Study on clinical research and trials on vaccine • Case Study on communication on vaccination benefits & issues impeding sufficient vaccination coverage • Case Study on preparedness, anticipation & prevention against future global health pandemics and cross-border health threats • Case Study on EU strategic autonomy, supply chain, shortages & EU capacities

Findings

Relevance

To answer Question 1 "To what extent did the 27 Actions defined at the time of the Recommendation address the needs existing?" the Study team mapped the needs identified at the time of adoption of the Council Recommendation: 1) Unequal vaccine coverage rates across the EU, 2) Vaccination hesitancy including for healthcare workers, 3) Mis and disinformation/lack of accurate information, 4) Difficulties in accessing

vaccinations and vaccination structures, 5) Lack of access and sharing of health data across borders for citizens, professionals and national authorities, 6) Suboptimal monitoring of vaccination, 7) Lack of focus on vaccination in a life course perspective, 8) Varying vaccination programmes across the EU, 9) Lack of coordination between EU Member States and at international level in relation to vaccination programmes and preparedness, 10) Risk of vaccine shortages / suboptimal monitoring of stocks, and 11) Underdeveloped R&D landscape. The Study found that all needs identified were addressed by the actions of the Roadmap, either directly or indirectly. All actions in the Roadmap contributed to the overall need to address suboptimal vaccination coverage rates across the EU, which is the main and final need to be addressed. Two needs were specifically addressed by the actions of the Roadmap: 1) the need to combat vaccine hesitancy of the EU population, including hesitancy of healthcare workers, as well as 2) the need to fight against mis- and disinformation. Finally, the establishment of HERA played an important role in the completion of several actions of the Roadmap.

With regards to Question 2 "To what extent have the needs existing at the time of adoption of the Council Recommendation evolved or have new needs arisen?", the need to tackle suboptimal vaccination coverage rates across the EU is still relevant, though addressing this need was hindered by other needs such as vaccine hesitancy and mis- and disinformation following the COVID-19 pandemic. Some needs directly linked to citizens' uptake of vaccinations have increased in priority level after COVID-19 pandemic: access to vaccination, vaccine hesitancy and mis- and disinformation. As the importance of data becomes more evident, the needs relating to access and sharing of health data continue to be of key importance. The need to address the risks of vaccine shortages has been put in the forefront of debates as a result of experience gained through the COVID-19 pandemic.

With regards to Question 3 "To what extent will the 27 actions remain relevant and address the needs still existing in the short to medium term? (2-5 years)", considering the analysis of the evolution of needs and taking into account the completion status of the different actions as well as their potential to be maintained and further developed, the Study found that approximately 75% of them will continue to be especially relevant in the short and medium term. In particular, the relevance of the actions relating to vaccine hesitancy and mis- and dis-information will continue to grow in the short and medium term. The remaining 25% of actions are still relevant to some extent, notably actions related to data and covered by the establishment of HERA.

With regards to Question 4 "*Which actions are expected to still be relevant in the long term (+10 years) and why?*", the heightened relevance of around 50% of the actions is expected to stabilise, notably actions related to preparedness thanks to the establishment of HERA and to data and information sharing, as well as Action 2 "Vaccine Confidence Report" and Action 3 "Coalition for Vaccination" that are already well established. Depending on structural evolutions, in particular concerning political consensus and needs, some action's relevance may increase again: Action 3 to increase the access to vaccination, and the Actions 8, 9 with regard funding and cooperation. Also, Action 11 consisting in countering misinformation will continue to be highly relevant with the evolution in online information sharing.

Coherence & Complementarity

The Study Questions on coherence concern both internal coherence (i.e. the coherence of the actions between themselves) as well as external coherence (i.e. the coherence of the Roadmap and actions with other policy initiatives). This has been undertaken through the examination of the objectives of the specific actions to identify synergies, complementarities and/or overlaps.

With regards to Question 5 "*To what extent are the actions coherent and complementary to the other 27 actions?*", overall, the analysis of the 27 actions showed that the Roadmap is internally coherent, as all the 27 actions contribute to increasing the vaccination coverage rates across the EU, which is the primary need to be addressed through the Roadmap. The categorisation of the 27 actions showed that (i) several actions contribute in different ways to the same specific issues covered by the Roadmap, (ii) some actions can also contribute to several areas of interventions being therefore complementary in a more transversal way, (iii) complementarity between the 27 actions can be also assessed through the variety of stakeholders, from national authorities, researchers, and citizens, targeted by the actions. However, actions are not specifically organised and identified within categories, with specific objectives and a list of related actions. The logical presentation of the individual actions can be questioned, since their simple organisation by number, rather than by category, leaves the Roadmap without a logical categorisation of the types of actions that have been defined. Moving forward, when considering the manner in which the actions could be further fine-tuned, the categorisation of actions could be further considered by the Commission in order to provide a Roadmap for future policy initiatives that is more streamlined in its rationale and easier to communicate to stakeholders.

With regards to Question 6 "*To what extent are the actions coherent and complementary to other Commission policy initiatives?*", the Roadmap was found coherent and complementary to the EU initiatives analysed. With the European Health Union, the Commission Roadmap was found to propose a coherent rationale and complementary

actions tackling different needs and different stakeholder groups than the EU Health Union. The Roadmap had specific actions contributing directly to the objectives of the EHDS, being coherent and complementary, in particular regarding Action 1 on the EU citizen's Vaccination Card. The Study's assessment found that the actions in the Roadmap were coherent with Europe's Beating Cancer Plan in relation to ensuring prevention of specific diseases through vaccination. Overall the complementarity Europe's Beating Cancer Plan is also identified for two reasons : (i) by acting for the improvement of vaccine coverage rates, that indirectly contributes to having more people vaccinated, which is complementary to the development of a specific vaccine against HPV cancer (ii) by raising the awareness of healthcare professionals and to help Member States to communicate. The actions under the Commission Roadmap are overall coherent and complementary with the Pharmaceutical Strategy for Europe, by proposing a different approach in line with the Pharmaceutical Strategy for Europe's objectives.

With regards to Question 7 "To what extent are the actions coherent and complementary to policy initiatives undertaken at international level?", coherence is observed between the Roadmap and the WHO European Vaccine Action Plan (2015-2020), as both initiatives aimed to address the same needs (e.g. mis- and dis-information) through similar actions. Complementarity was also found with the WHO European Vaccine Action Plan, as the Roadmap presented several actions that were a step forward of the primary objective of the WHO initiative. It also proposed a complementary approach to strengthening vaccination at EU level by targeting the supply chain and the healthcare workers, as well as EU Member States. The Roadmap was found to be coherent with the WHO European Immunisation Agenda 2030 (EIA 2030) as it aimed at addressing the same needs. It was also found complementary as it targeted different types of stakeholders, other than decision-makers, national and subnational leaders and national authorities, and ministries targeted by the WHO initiative.

Further Development of the Roadmap and its actions

A number of actions were identified as increasingly relevant in the longer term (+10 years). To ensure the maximum impact when developing these actions and future deliverables, the Study team considered the manner in which synergies can be created in line with other Commission policy initiatives in health and at large and to identify any risks of duplication.

With regards to Question 8 "Which actions, that are expected to still be relevant in the longer term (+10 years), can be further developed to build on possible synergies/avoid duplication with other Commission policy initiatives in health?", 13 out of 27 actions were identified as being relevant in the longer-term. The Study proposed 7 areas of intervention, where actions can be categorised: (i) Communication and Raising Awareness; (ii) Access to Vaccination; (iii) Data used in relation to Vaccination in the EU; (iv) Supporting Research; (v) Preparedness; (vi) Cooperation; (vii) Monitoring Vaccine Production and Effectiveness. This would also help address the lack of knowledge by stakeholders relating to the specific actions and deliverables falling under the Roadmap. The current absence of categorisation of the actions do not permit stakeholders to monitor specific actions of interest to them. Further development of the Roadmap should take advantage of the policies in Health sector and other sectors to work on data, communication, access to vaccination, funding support of research and innovation, cooperation, preparedness, and monitoring vaccine production and effectiveness.

With regards to Question 9 "*What could be the enablers and barriers for such further development?*", the Study team identified five categories of enablers and barriers: (i) Financial (ii) Human (iii) Political (iv) Health (v) Innovation. These enablers and/or barriers can impact further development of actions moving forward. Key enablers for further development of actions focus on funding, communication, mobilisation of industrial capabilities, emerging technologies, and governance structures, and will contribute to ensuring the correct development and implementation of actions in relation to vaccination throughout the EU. Certain factors can be identified both as enablers and barriers to the development of future actions: citizen trust in national policies and strategies, stakeholder impetus, coordination and national priorities and strategies. The demographic shifts and the shifting health contexts have been identified as key barriers to future development of actions.

1 Introduction

This final report is the final deliverable of the 'Study on the coherence, complementarity and continued relevance of actions in the Council Recommendation on strengthened cooperation against vaccine-preventable diseases in view of possible similar policy initiatives in the future'. The aim of this report is to provide a sound analysis of findings with factually based conclusions, in answer to all Study questions formulated for this assignment.

The main report presents, in full, the results of the analysis and conclusions arising from the Study. It features:

- A methodological chapter with a presentation of the methodology followed, of its strengths, weaknesses and encountered limits and consequential mitigation measures, as well as new developments from the interim report drafted for this assignment.
- Analytical chapters based on the intervention logic formulated for this assignment, which aim to provide critical assessments of each Study question. The analysis relies on the triangulation with the collected quantitative and qualitative data to ensure the robustness of the findings.
- A conclusive chapter, which presents logically the analysis and findings and how they relate to the Study questions.

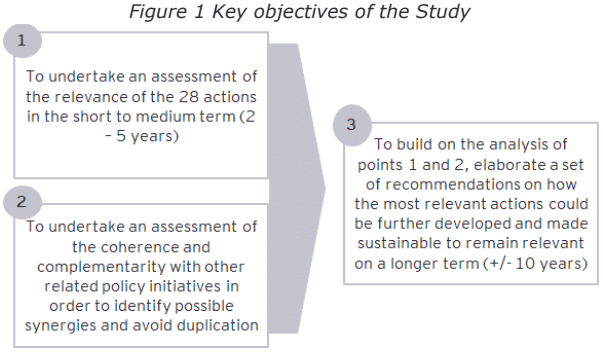
1.1 Aims and Objectives of the Study

Since 2018, the Commission's work on vaccination has been guided by the Council Recommendation on strengthened cooperation against vaccine-preventable diseases1 (hereafter 'Council Recommendation'). Along with the Commission Communication on 'Strengthened Cooperation against Vaccine Preventable Diseases'[2] (hereafter 'Commission Communication'), this policy initiative called for a large number of actions to be implemented by the Commission, EU Member States and stakeholders, with the aim of improving the uptake of vaccination across the EU in a life-course perspective. In the Roadmap developed to support the implementation of the initiative, 28 Actions and 62 deliverables were defined and set to be completed by the end of 2022.

The aim of this Study is to support possible policy developments in the future. The Study aims to assess the relevance of the actions in the Roadmap in the short to medium term and to identify the most relevant actions that could be further developed on a longer term. The Study had three specific objectives, presented in the Figure below.

When assessing the relevance of the actions in the Roadmap, the Study focussed on a needs assessment which examined the needs identified at the time of adoption of the Council Recommendation in 2018 and determined the manner in which these needs evolved in level of priority since 2018, taking also into consideration the impacts of the COVID-19 pandemic. By identifying the needs that were most relevant to the stakeholders, the Study was then in a position to identify the relevant actions and deliverables relating to those needs. This approach shaped the responses to the Study questions for this assignment.

Figure 1 Key objectives of the Study



[1] Council Recommendation of 7 December 2018 on strengthened cooperation against vaccine preventable diseases : EUR-Lex - 32018H1228(01) - EN - EUR-Lex (europa.eu)

[2] Commission Communication to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - Strengthened Cooperation against Vaccine Preventable Diseases: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2018%3A245%3AFIN

1.2 Presentation of the Context and Scope: Council Recommendation, Commission Communication and Commission Roadmap including Presentation of Intervention Logic

1.2.1 Presentation of the Context: Council Recommendation, Commission Communication and Commission Roadmap

Vaccines are one of the biggest medical success stories in the world. The World Health Organization (WHO) estimates that 2-3 million deaths are prevented worldwide each year, and that between 2000 and 2018 measles vaccination resulted in a 73% global drop in measles deaths[3]. However, at the time of publication of the Council Recommendation, national vaccination programmes were becoming increasingly fragile, and the EU was experiencing significant resurgences of vaccine-preventable diseases such as measles due to suboptimal uptake of vaccination.

An Open Public Consultation on 'Strengthened cooperation against vaccine-preventable diseases' was launched by the Commission in December 2017[4] in order to gather information from stakeholders. The responses to this consultation brought forward –among other issues- calls for more transparent and accessible information on vaccination, particularly regarding the safety and potential side effects of vaccines.

On 19 April 2018, the European Parliament published a resolution on vaccine hesitancy and the diminution of vaccination rates across Europe. On 26 April 2018, the Commission published the Commission Communication, and on 7 December 2018, the Council adopted the Recommendation, based on a Commission proposal.

In conjunction with the Commission Communication, the Council Recommendation had, as its key purpose, to increase the uptake of vaccination across the European Union (hereafter 'EU') in a life-course perspective. The document proposed a series of recommendations split into three sections:

- **Recommendations 1-8** focussed on the objective of accelerating the development and implementation of national vaccination programmes with a need to simplify and broaden the opportunities for vaccination – including a more targeted outreach to vulnerable groups. There was a specific emphasis on measles, given the resurgences in the EU. These recommendations called on educational authorities to strengthen and provide continuous vaccination training in medical curricula and emphasised the requirement for increased communication and awareness activities on the benefit of vaccination.
- **Recommendations 9-15** focussed on the Commission's actions, in close cooperation with Member States, to establish a European Vaccination Information Sharing system (hereafter 'EVIS') which could collate related vaccination information and expertise with the national public health authorities. Under this information sharing system, stakeholders could (i) develop the guidelines for a possible EU vaccination schedule; (ii) share common methodologies for monitoring coverage; and (iii) launch a web portal with transparent evidence on vaccines' benefits and risks (including the tracking of misinformation). Furthermore, these recommendations highlighted the need to reinforce the effective application of EU rules on the protection of workers from risks related to exposure to biological agents at work[5] and the need to increase support to vaccine research and innovation for a rapid advancement of new or improved vaccines and facilitate the prompt uptake of the results.
- **Recommendations 16-24** focussed on other actions to be carried out by the Commission, such as presenting the options for a common EU Vaccination Card and a report on the State of Vaccine Confidence in the European Union, reinforce and establish new partnerships and research infrastructures, Invest in behavioural and social science research on the determinants of vaccine hesitancy.

[3] Retrieved from Who.int website: https://www.who.int/en/news-room/fact-sheets/detail/immunization-coverage

[4] Open Public Consultation available at Open Public Consultation on "Strengthened cooperation against vaccine preventable diseases" (europa.eu)

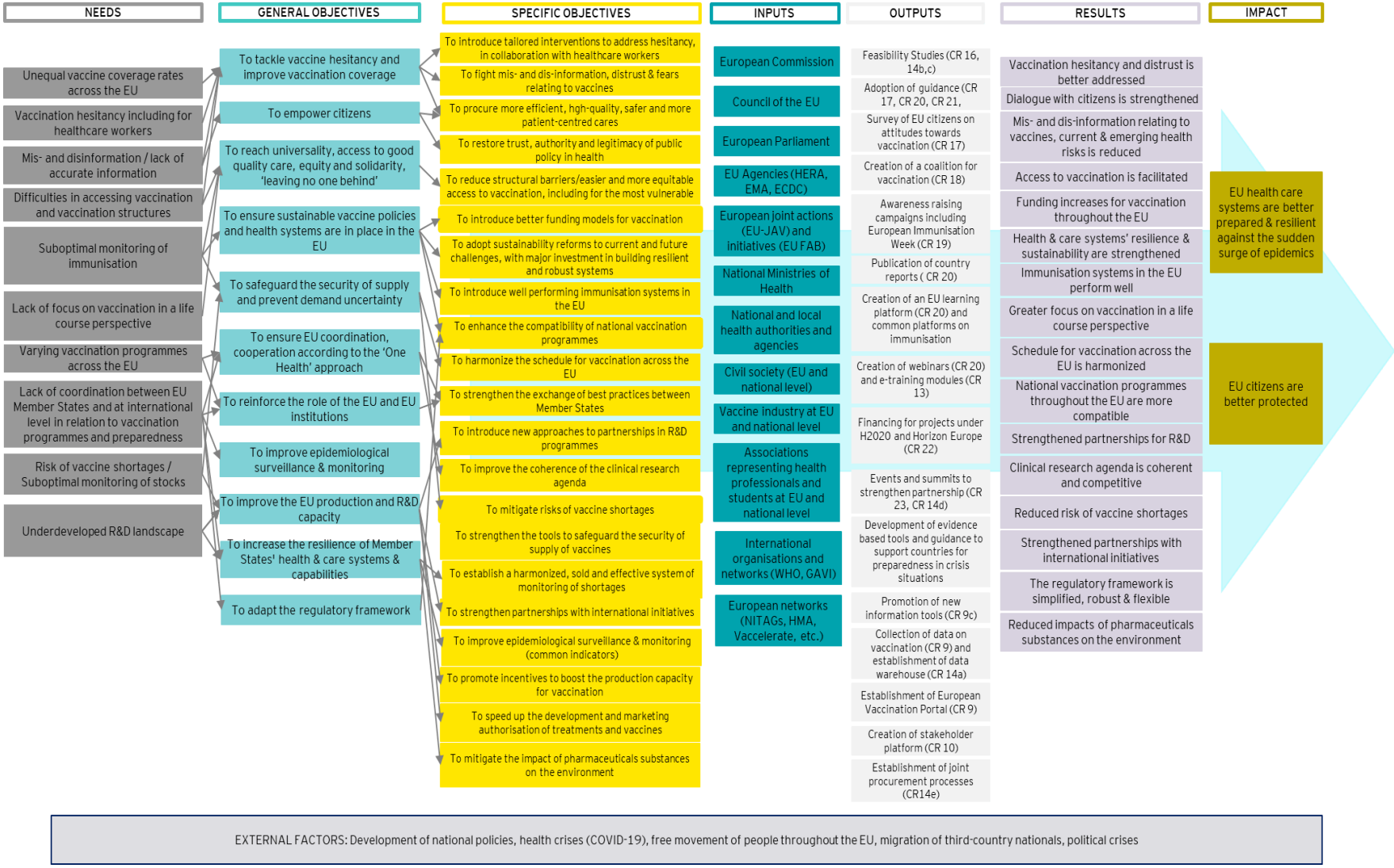
[5] Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 262 17.10.2000, p. 21) and Council Directive 2010/32/EU of 10 May 2010 implementing the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector concluded by HOSPEEM and EPSU (OJ L 134, 1.6.2010, p. 66).

Within the framework of the Council Recommendation and the Commission Communication, a Roadmap for the implementation of the actions called for[6] was published on 23 May 2019, consisting of 28 actions divided into 62 deliverables. The Roadmap aimed to plan, monitor, and report on the implementation of the Recommendations carried out by the European Union, its agencies, and other partners. In particular, a large share of the deliverables (44%, 27 out of the 62 deliverables) were carried out under the European Joint Action on Vaccination (EU-JAV), a complementary policy initiative launched in 2018 where teams from 20 EU/EEA countries worked together to design a common approach on vaccines and deliver and share concrete tools for stronger national responses to vaccination challenges. The Roadmap was updated in July 2022.

The reconstituted and adapted intervention logic for the Study is presented in the figure below.

[6] Roadmap for the implementation of actions https://health.ec.europa.eu/publications/roadmap-implementation-actions_en

Figure 2 Intervention Logic



Study on the coherence, complementarity, and continued relevance of actions in the Council Recommendation on strengthened cooperation against vaccine-preventable diseases in view of possible similar policy initiatives in the future

1.2.2 Scope of the Study

The Study assessed the continued relevance, coherence, and complementarity of the actions in the Roadmap. While the Roadmap has 28 actions, the last one (**Action 28**) corresponds to the execution of this particular Study. This action is therefore not considered when responding to the Study questions formulated for this assignment, with the Study focussing on Actions 1-27. Throughout the report, the terms "Action" and "Deliverable" are used in reference to the Roadmap's components. "Action" generally refers to specific objectives and activities to be carried out, and "Deliverable" usually make reference to specific reports, studies or events that took place in order to work towards completing the Action.

The Study considered both the public Roadmap (the updated version from July 2022) as well as an unpublished internal Roadmap that was made available to the Study team at the beginning of its work and later updates. As of June 2023, practically all actions and deliverables have been completed. An overview of the 27 actions, with state of play as of June 2023, is available in Annex 7.

2 Methodological Approach

2.1 Data collection tools used

To achieve the objectives, the Study was structured around four key tasks, presented in the figure below.

Figure 3 Overview of Study approach

A number of tools were deployed to gather data for this Study.

These tools aimed to gather both qualitative and quantitative data through primary and secondary data collection. In relation to the data gathered, no specific gaps were identified.

An overview of these tools, as well as any challenges faced in relation to these tools and mitigation measures deployed, are presented below.

2.1.1 Interviews

A minimum of **40 interviews needed to be undertaken for this Study**. Throughout the consultation activities, **a total of 43 interviews were undertaken**. A full overview of the interviews undertaken is presented in Annex 2.

Challenges and limitations identified and solutions sought

The organisation of the interviews for the Study was undertaken successfully overall, with stakeholders from all stakeholder groups interviewed. Initial gaps existed in relation to the data collection through interviews, which led the Study team to schedule new interviews with representatives of key General-Directorates and agencies of the European Commission (i.e. HERA, European Medicines Agency) as well as with representatives from national health ministries and public health authorities in the Member States.

Some challenges were recurrent in the organisation of the interviews. These related to the availability of stakeholders and the identification of relevant individuals within the different organisations. In this regard, the Study team actively worked to identify additional stakeholders to be consulted through requesting specific stakeholders to propose additional contacts within their specific Member States. Moreover, the Study team presented at an EU Health Security Committee meeting on 28 April 2023[7] with a view to promoting the Study and the importance of contributing to the Study.

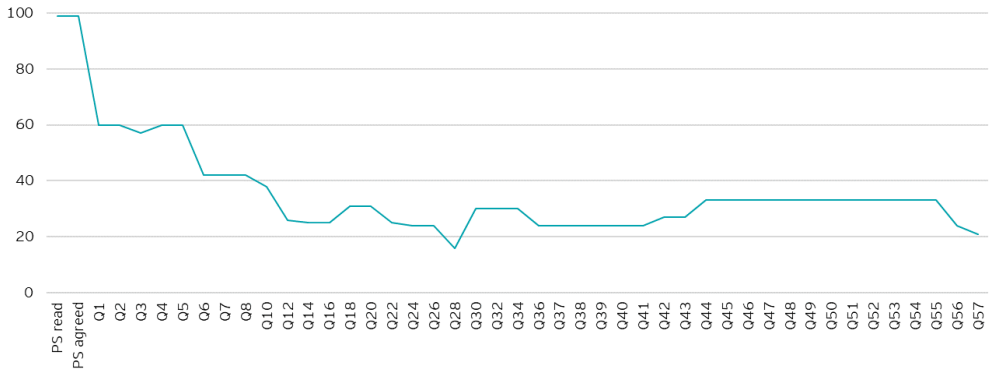
Moreover, the stakeholders' level of knowledge of the Roadmap was often limited: National authorities were the most aware of the Council Recommendation even if not all were comprehensively informed of the accompanying actions in the Roadmap. Non-Governmental Associations and health professionals' associations were partially aware of the 28 actions and the Roadmap, even if they were not all involved in activities within the EU vaccination ecosystem. Stakeholders from industry were less aware of such EU initiatives. This lack of comprehensive and updated knowledge and understanding was a limitation of this Study and at the same time appears as a genuine finding. To mitigate this phenomenon, a reminder of the actions in the Roadmap was sent prior to the interviews, as well as key documents.

2.1.2 Online survey

An online survey was also deployed for this Study. The online survey targeted (i) national health ministries and public health authorities, (ii) vaccine industry stakeholders, (iii) civil society organisations, and (iv) healthcare workers and student associations. The online survey was deployed following rigorous testing by the Study team and validation by the Commission. The survey was open from 21 March to 20 April 2023.

147 individual participations were registered on the closing of the survey. The majority of them (67%) proceeded past the privacy statement. As shown in the figure below, there was a strong initial dropout rate that stabilised in the later questions. 60 respondents provided answers beyond the question aimed at expressing consent and responded to questions 1 (country of origin), 2 and 3 (stakeholder group and organisation). Only 48 respondents replied to questions 4 and 5 (level of knowledge of the Commission Communication and of the Council Roadmap). Beyond these initial questions, most respondents completed the questionnaire.

Figure 4 Participation rate to Online Survey questions (excluding questions with qualitative reply boxes)

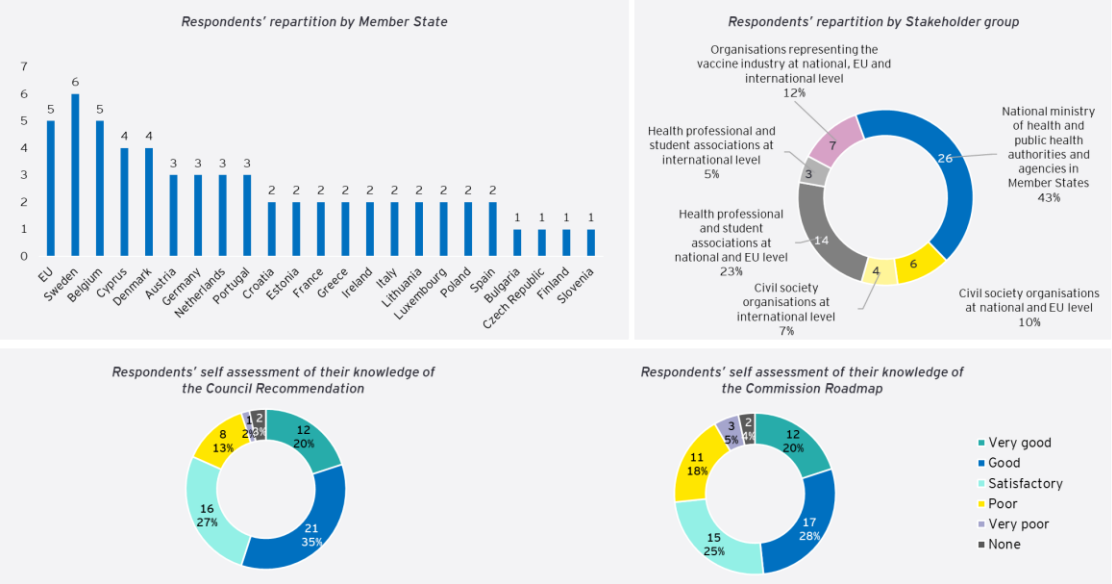


Respondents came from a wide array of EU Member States and all stakeholder groups. 11% judged their knowledge of the Council Recommendation to be limited (poor, very poor or no knowledge), and 16% of them judged their knowledge of the Commission Roadmap to be limited. The Study took this into account while analysing stakeholders' contributions and assessing the relevance, coherence, and complementarity of the actions. Only 45% of the respondents who indicated having limited knowledge of the documents (n=5) continued

[7] security_ev_20230428_sr_en.pdf (europa.eu)

with the survey, and the analysis of their response profile shows that they did not answer exhaustively to all questions or indicated that they did not know. This suggests that most respondents to the survey with limited knowledge of the Roadmap self-censored themselves, which may explain the high initial drop in terms of response numbers, and the subsequent implication of the respondents with a higher knowledge of the Roadmap.

Figure 5 Repartition of participants per country, stakeholder group and knowledge of the Council Recommendation and Commission Roadmap



Source: Online Survey (60 respondents)

NB: 86% of stakeholders in the group "Health professional and student associations at international, national and EU level" come from pharmacy associations. In addition, 30% of respondents who identified themselves as Civil society organisations are also pharmacy associations.

Challenges and limitations identified and solutions sought

A key challenge in deploying the online survey was the identification of email addresses to deploy the survey to specific stakeholder groups. To respect the protection of personal data, all stakeholders that were contacted were identified through publicly available contact details (namely email addresses available through online websites). To target the stakeholders for the Online survey, the Study team focused on identifying national authorities through the deployment of the Study team's network in order to identify relevant stakeholders at national level. For representatives from the other stakeholder groups for the online survey, the Study team identified stakeholders through (i) deploying the online survey to representatives of European umbrella organisations of these stakeholder groups, and (ii) identifying stakeholders that previously responded to the Public Consultation launched in 2017. Since interviews were undertaken in parallel to the deployment of the Online survey, the Study team promoted the survey to interviewees and invited them to circulate the survey to their network.

2.1.3 Case studies

The final data collection tool for this Study was the deployment of case studies. The aim of the case studies was to analyse specific areas covered by the actions in the Roadmap, with a focus on four areas:

1. Case Study on clinical research and trials on vaccine
2. Case Study on communication on vaccination benefits & issues impeding sufficient vaccination coverage
3. Case Study on preparedness, anticipation & prevention against future global health pandemics and cross-border health threats
4. Case Study on EU strategic autonomy, supply chain, shortages & EU capacities

Challenges and limitations identified and solutions sought

Initially, interviews for the case studies were limited due to a number of case studies requiring input from EU Institutions. As indicated under Section 1.1.2.1 above, the Study team targeted additional stakeholders from General-Directorates and agencies (HERA, European Medicines Agency), industry as well as national authorities to complete these interviews and subsequent case studies.

3 Findings relating to Relevance (Questions 1 – 4)

The Study responded to the following questions in relation to relevance.

Study Questions	Q1: To what extent did the 27 actions defined at the time of the Recommendation address the needs existing at the time of adoption? Q2. To what extent have the needs existing at the time of adoption of the Council Recommendation evolved or have new needs arisen? Q3. To what extent will the 27 actions remain relevant and address the needs still existing in the short to medium term? (2-5 years) Q4. Which actions are expected to still be relevant in the long term (+10 years) and why?

Our approach to responding to the Study questions

To be in a position to respond to the Study questions relating to Relevance, the Study team mapped the needs identified at the time of adoption of the Council Recommendation. The Team subsequently identified the manner in which each of the actions set out in the Roadmap were linked to those specific needs identified (Question 1). The Study team subsequently examined the manner in which the needs had evolved since the adoption of the Council Recommendation and identified any new needs or reiteration of needs (Question 2) with a view to being able to identify which of the actions still remain relevant and address the needs existing in the short to medium term (Question 3) and in the longer term (Question 4). As outlined in Section 1.2.2 above, the Study undertook analysis on 27 out of the 28 Actions of the Roadmap.

3.1 Q1: To what extent did the 27 Actions defined at the time of the Recommendation address the needs existing?

The Council Recommendation adopted in 2018, following the Commission Communication, identified key needs that needed to be addressed by the actions called for. These needs identified in 2018, and the associated actions, are presented in the table below. The Study team has undertaken a mapping as to whether the specific actions in the Roadmap are directly or indirectly linked to the needs identified through the review of the Council Recommendation and Commission Communication.

Key findings

- All 10 needs identified were addressed by the actions of the Roadmap, either directly or indirectly.
- All actions in the Roadmap contributed to the overall need to address suboptimal vaccination coverage rates across the EU, which is the main and final need to be addressed
- Two needs were specifically addressed by the actions of the Roadmap: the need to combat vaccine hesitancy of the EU population, including hesitancy of healthcare workers, as well as the need to fight against mis- and dis-information.
- The establishment of HERA played an important role in the completion of several actions of the Roadmap.

Table 1 Overview of needs identified in 2018 in the Council Recommendation (CR) and in the Commission Communication (CC) and associated actions

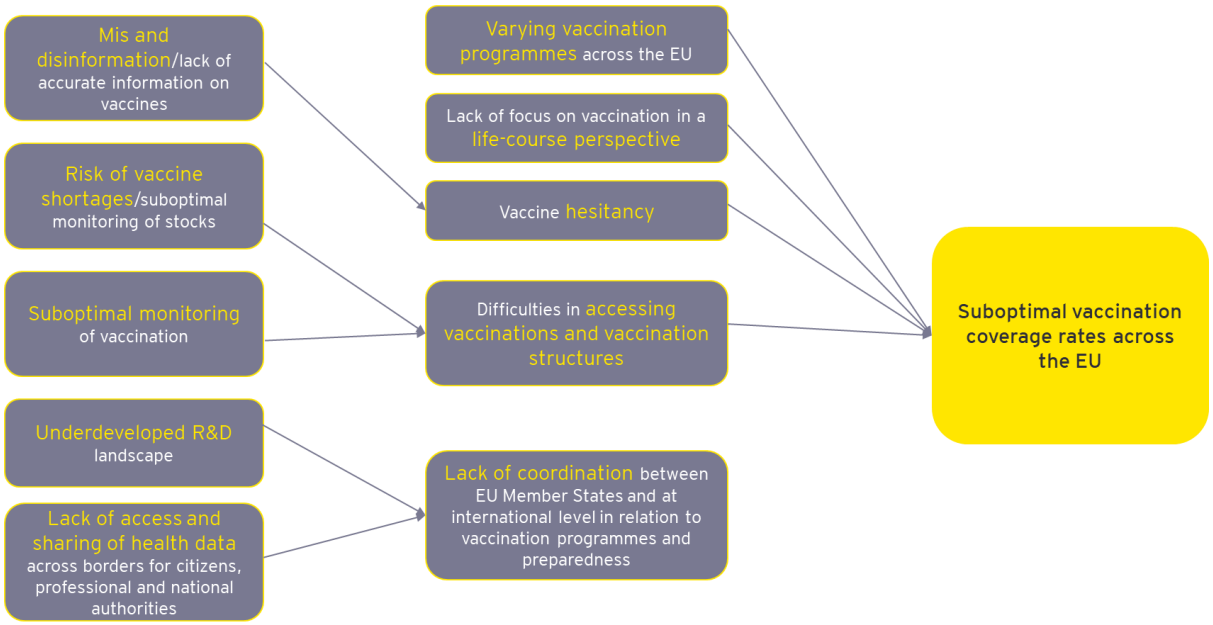
Needs \ Actions	Recitals of Council Recommendation and Pillars of Commission's Communication	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
Unequal vaccine coverage rates across the EU	Recital 18 of CR Introduction of CC	I	I				I		I	I			X										I	I			X	X
Vaccination hesitancy including for healthcare workers	Recital 6 of CR Recital 7 of CR Recital 22 of CR Pillar I of CC		X	X	X	X						I				X	X										X
Mis and disinformation/ lack of accurate information	Recital 5 of CR Recital 23 of CR Pilar I of CC	I	I	X	X							X		X			X											
Difficulties in accessing vaccinations and vaccination structures	Recital 9 of CR Recital 18 of CR Pillar I of CC					X																					X	X
Lack of access and sharing of health data across borders for citizens, professionals and national authorities	Recital 15 of CR Pillar II of CC	X					X	X					X															
Suboptimal monitoring of vaccination	Recital 14 of CR Pillar II of CC	I					X	I		X			X	I														
Lack of focus on vaccination in a life course perspective	Recital 10 of CR Pillar II of CC												I														X	X
Varying vaccination programmes across the EU	Recital 8 of CR Pillar II of CC						I						X		X			I									I	
Lack of coordination between EU Member States and at international level in relation to vaccination programmes and preparedness	Recital 17 of CR Pillar III of CC									X	X				I			X		X	X	X		X	X			
Risk of vaccine shortages / Suboptimal monitoring of stocks	Recital 11 of CR Pillar II of CC										X							X	X	X	X	X	X	X	X			
Underdeveloped R&D landscape	Recital 12 of CR Recital 21 of CR Pillar III of CC								X																X	X	X	

Source: Council Recommendation, Commission Communication, Roadmap

X Actions **directly** addressing the need
I Actions **indirectly** addressing the need

As outlined in the table above, a number of specific needs were identified through the Council Recommendation and the Commission Communication. When considering the needs existing, a causality link can be identified between the various needs identified, as illustrated in the figure below.

Figure 6 Causal link between needs existing



The subsequent sub-sections present each of the needs identified in turn including an analysis of the overall relevance of the specific actions in the Roadmap that address these needs.

3.1.1 Suboptimal vaccination coverage rates across the EU

Need identified in 2018	High vaccination rates across the EU are a major health policy goal, and equitable access to immunisation is an essential component of the right to health. Coverage gaps persist between countries and within countries which need to be addressed at EU-level, while simultaneously maintaining existing coverage vaccination rates, in a context where some vaccine-preventable diseases are coming back due to insufficient vaccination rates in some countries and communities.

3.1.1.1 While all actions in the Roadmap contributed to the overall need to address suboptimal vaccination coverage rates across the EU, specific actions addressed this need through specific deliverables

As outlined in Figure 6 above, all actions aimed to contribute to the need to address suboptimal vaccination coverage rates across the EU. The interviews with stakeholders confirmed this causal link that exists between specific policy actions and the suboptimal vaccination coverage rates. By addressing other needs indirectly linked to the suboptimal vaccination coverage as presented in the figure above, these actions have a contributory effect to addressing suboptimal vaccination coverage rates. Nevertheless, some actions aimed, through their deliverables, to address this need directly.

The first key action to address the need of suboptimal vaccination coverage within the EU was the reinforcing of partnerships and collaboration. **Action 9**[8] had, as its key deliverable, the organisation of the Global Vaccination Summit, which was co-hosted by the European Commission and the WHO on 12 September 2019 in Brussels. To coordinate forces and boost political commitment against vaccine-preventable diseases, the Summit hosted

[8] Action 9: Strengthen existing partnerships and collaboration with international actors and initiatives, such as the WHO and its Strategic Advisory Group of Experts on Immunization (SAGE), the European Technical Advisory Group of Experts on Immunization (ETAGE), the Global Health Security Initiative and Agenda processes (Global Health Security Initiative, Global Health Security Agenda), Unicef and financing and research initiatives like Gavi, CEPI, GloPID-R and JPIAMR (the Joint Programming Initiative on Antimicrobial Resistance).

approximately 400 participants, including political leaders, high-level representatives from international organisations, health ministries, leading academics, scientists and healthcare workers, the private sector, Non-Governmental Organisations (hereafter 'NGO'), social media influencers, and notorious figures from the civil society9. The Summit was organised around three themes: (i) stepping up action to increase vaccine confidence, (ii) boosting vaccine research, development, and innovation, and (iii) galvanizing a global response to assure health, security, and prosperity through immunization. The formal outcome of this summit was a document summarising ten actions towards vaccination for all10. The themes covered by the Summit were thus relevant to address the needs relating to suboptimal vaccination coverage not only within the EU but globally. This assessment is confirmed by the survey: 45% (17/38) of respondents found this action to be relevant to address this need, with 26% (n=10) ranking this action as very relevant, which further emphasises how this action is relevant in terms of taking steps in the right direction but leaving other aspects of this need to be addressed by other actions11.

The exercise of establishing a common political groundwork, an essential stepstone in affirming the need to increase vaccination coverage rates, is also a component of **Action 26**[12]. Although Action 26 mostly focussed on defining common priorities for vaccine research funding and priority vaccines, one of its deliverables (Deliverable 56) aimed, however, at establishing **a Roadmap on unmet population needs, thus laying a common agreement on the actions aimed at reducing vaccination coverage gaps**. The contribution to the increase of vaccination rate was acknowledged by interviewees from Civil Society organisations representing patients as well as national authorities in charge of public health. They underlined the relevance of such an action in supporting the research and agenda that promotes vaccination for specific people and communities. This finding was validated by the survey respondents on this action, who confirmed the relevance of Action 26: 76% (29/38) considered that Action 26 was at least relevant to address this need, of which 36% (n=14) highly relevant.

Actions relating to enhanced information sharing in relation to vaccination were also identified as relevant to address the needs in relation to suboptimal vaccination coverage rates. Several deliverables of **Action 12**[13], led by ECDC, were relevant to the need relating to suboptimal vaccination coverage rates, **making this action one of the major contributions to addressing this need.** Most surveyed stakeholders (n=38) rated this action as either highly relevant or relevant, with only three responses considering the action to be slightly relevant or not relevant, with these respondents representing national Ministries of Health and public health authority services. Establishing an EVIS, which has been partially delayed so far, would require (i) the assessment of what can be mutualised and mutually beneficial for the Member States (Deliverable 36, delayed), (ii) what underlying methodologies need to be agreed on for homogeneously assessing vaccination plans and ensuring the production of coherent monitoring data at EU-wide level (Deliverable 37, delivered), and (iii) what can be strengthened and harmonised in terms of information sharing (Deliverables 38 and 39, delivered).

Deliverable 36 in particular aimed to examine the feasibility of establishing, by 2020, guidelines for a core EU vaccination schedule taking into account WHO recommendations for routine immunisation, aiming to improve the compatibility of national schedules and promote equity in EU citizens' health protection. This deliverable, upon completion, would be especially relevant in terms of its possible contribution to increase vaccination coverage rates across the EU.

Deliverable 37 initiated a collaboration between ECDC and EU/EEA NITAGs in October 2018[14], with the **aim of strengthening consistency, transparency, and methodologies in the assessment of national and regional vaccination plans**, through the facilitation of tools and information sharing between the different

---

[9] Global Vaccination Summit (who.int)

[10] https://ec.europa.eu/health/sites/default/files/vaccination/docs/10actions_en.pdf

[11] Half of survey respondents were National ministry of health and public health authorities and agencies in Member States: this stakeholder group rated even less often the Action as highly relevant (only 17% of them) or relevant (39% of them), which suggests that they may be less directly concerned by this Action.

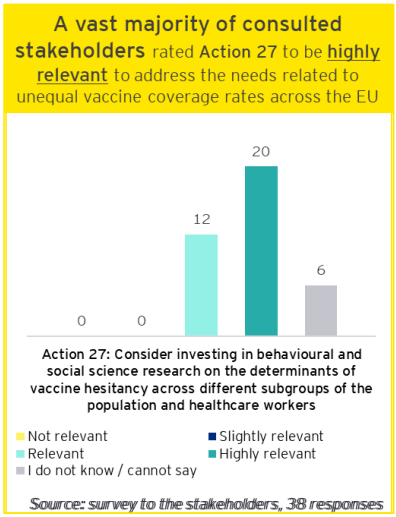
[12] Action 26: Seek consensus on unmet population needs and agreed priorities for vaccines that can be used to inform future vaccine research funding programmes at national and EU level, including leveraging the advantages of the Coalition for Epidemic Preparedness Innovations (CEPI) and the Global Research Collaboration for Infectious diseases Preparedness (GloPID-R)

[13] Action 12: Establish a European Vaccination Information Sharing System. Action 12 has 6 deliverables from Deliverable 35 to Deliverable 40. Deliverable 35 on the launch of European Vaccination Information Sharing System has been delayed, due to COVID-19. The same applies to Deliverable 36.

[14] https://www.ecdc.europa.eu/en/about-us/partnerships-and-networks/national-immunisation-technical-advisory-groups-nitag

committees and their integration within an information system. It is up and running, with a large number of meetings having been held during the COVID-19 pandemic.

Finally, two Deliverables covered challenges dedicated to gathering and harmonisation of data collection , which respond to a prerequisite in terms of building the necessary tools to harmonise vaccination coverage rates: **Deliverable 38** - Design EU methodologies and guidance on data requirements for better monitoring of vaccination coverage rates across all age groups, including healthcare workers, in cooperation with the WHO and collect such data and share them at EU level, and **Deliverable 39** - Collect vaccination coverage data and share them at EU level.



In addition to the above, certain deliverables falling under **Action 6**[15] aimed to monitor vaccine coverage rates and target specific coordinated campaigns in relation to specific diseases. In Deliverable 19, a Report[16] was published by EU-JAV that aims to describe existing reminder systems and provides recommendations for future systems. This report noted that **vaccine reminder systems have been shown to increase vaccination coverage**, with some noting that they also increased awareness about the correct registration of vaccinations. The recommendations for future reminder systems emphasised the importance of tailoring reminder messages to reach relevant populations and adapting them to local settings. The Report, however, noted that tailoring reminders to target populations requires countries to be aware of the individuals that have not received the recommended vaccines, further reiterating the need for the consistent monitoring of vaccine coverage.

Deliverable 20 of Action 6 consisted of a report that analysed the feasibility of conducting coordinated cross-border measles vaccination campaigns, carried out under EU-JAV's Work Package (hereafter 'WP') 5. This study mostly found that insufficient cross-border data is available on under vaccinated target populations. The study aimed to provide a review of experience and best practices on what has already been done across borders and what can be gained by 'teaming up'. While a number of barriers to working across borders were reported in the survey, platforms for the exchange of knowledge and practice were reported as possible facilitators of enhanced cross-border collaboration which would ultimately contribute to addressing issues of hesitancy and suboptimal coverage.

The exchange of knowledge in relation to what causes diverging vaccine coverage rates was also realised through Action 27[17]**.** In addition to the majority of respondents to the survey rating it as a highly relevant action, interviews confirmed that national authorities particularly considered Action 27 and its scope of intervention as a relevant topic to work on, to better target the challenges and inner difficulties of people getting vaccinated. Deliverable 61 synthesizes the key learnings of a large project on vaccination acceptance and demand, which comprised several activities, including several large scale studies, literature reviews and a Symposium on behavioural science and vaccination[18]. These activities were conducted by the Competence Centre on Behavioural Insights, hereafter referred to as 'CCBI'.

One of the key learnings resulting from this set of activities was that vaccination programmes launched in Member States should be guided by a strong empirical understanding of behavioural determinants (population knowledge, concerns, and expectations). Understanding the main determinants of vaccine hesitancy paints the landscape of the many contrasts in vaccination coverage and attitudes towards vaccination on several scales:

A country scale (behavioural determinants of vaccine hesitancy were analysed in a sample of 7 Member States)

[15] Action 6: Develop EU guidance for establishing comprehensive electronic immunization information systems for effective monitoring of immunization programmes

[16] https://eu-jav.com/wp-content/uploads/2022/11/D5.4-Report-on-reminder-systems.pdf

[17] Action 27: Consider investing in behavioural and social science research on the determinants of vaccine hesitancy across different subgroups of the population and healthcare workers

[18] https://publications.jrc.ec.europa.eu/repository/handle/JRC131583

A sub-group scale (focuses were made on parents of children aged 19 months to 18 years, but also on gender differences regarding attitudes towards vaccination, and finally healthcare providers, especially paediatricians)

From the activities covered in Deliverable 61, several spill-over programs were implemented, including actions to promote the establishment and maintenance of effective national Behavioural Science Units and activities in the EU/EEA. These efforts were coordinated in collaboration with WHO Europe, ECDC, national competent authorities, and national research groups[19].

Action 27 thus also played its part in laying a common groundwork of EU-wide knowledge, which is at the basis of all further actions aiming at harmonising and sustaining sufficient vaccination coverage rates across the EU.

3.1.2 Vaccine hesitancy of the EU population including hesitancy of healthcare workers

Need identified in 2018	Vaccine hesitancy is defined as a "behaviour, influenced by a number of factors including issues of confidence (e.g. low level of trust in vaccine or provider), complacency (e.g. negative perceptions of the need for, or value of, vaccines), and convenience (e.g. lack of easy access)"[20]. Vaccine hesitant people, standing in a middle ground between those who accept vaccines and those who strongly reject them, are a key group to be targeted when aiming to increasing vaccine uptake[21]. Prior to the adoption of the Council Recommendation and the Commission Communication, the European Parliament Resolution of 19 April 2018[22] on vaccine hesitancy and the drop in vaccination rates in Europe called for Member States to take steps to ensure sufficient vaccination coverage among healthcare workers as well as to take steps against misinformation. The Council Recommendation as well as the Commission's Communication outlined, in its Pillar II, the aim of establishing an EVIS which would, amongst others, counter online vaccine misinformation and develop evidence-based information tools and guidance in order to support Member States in their response to vaccine hesitancy

A number of actions were defined in the Commission Roadmap to directly address vaccine hesitancy, with a focus on specific groups as well as on healthcare workers.

3.1.2.1 The Roadmap directly addressed needs relating to vaccine hesitancy including among healthcare workers through the collection of evidence relating to attitudes to vaccination

A key focus of the Roadmap to address vaccine hesitancy was the **collection of data necessary to ensure that policymakers, both at EU and national level, are informed of drivers that can impact vaccine hesitancy**: vaccine hesitancy is a multifaceted challenge, with mechanisms that may differ depending on the subgroups of the population and may also vary according to national culture and context.

Firstly, **Action 2**[23] of the Roadmap, which focussed on the **Production of a report on the State of Vaccine Confidence in the European Union** collects data which can provide guidance to policymakers that can support Member States in countering vaccine hesitancy. 68% of survey respondents found Action 2 to be at least relevant to address vaccine hesitancy. Among them, 63% of stakeholders representing National Ministries of health and public health authorities and agencies in Member States shared this view. Interviews confirmed that this Report is highly important for the Member States to have relevant and up-to-date information of the situation across the EU. The development of the deliverables under Action 2 were executed under a backdrop of a 67-country

[19] https://knowledge4policy.ec.europa.eu/projects-activities/behavioural-insights-eu-bi4eu_en

[20] Source: Larson HJ, Jarrett C, Eckersberger E, Smith D, Paterson P. Understanding vaccine hesitancy around vaccines and vaccination from a global perspective: A systematic review of published literature, 2007–2012. 2014. Vaccine. 32: 2150-2159

[21] Vaccine hesitancy in health-care providers in Western countries: a narrative review https://doi.org/10.1080/14760584.2022.2056026

[22] https://www.europarl.europa.eu/doceo/document/TA-8-2018-0188_EN.html

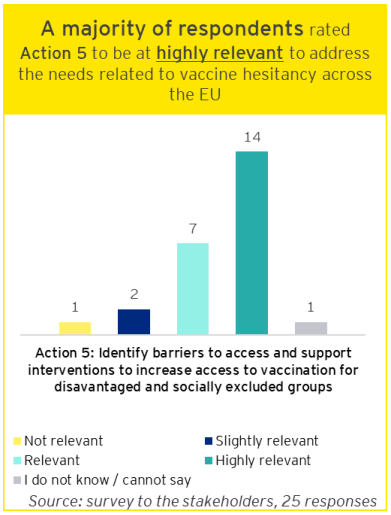
[23] Action 2: Produce on a regular basis a report on the State of Vaccine Confidence in the European Union, to monitor attitudes to vaccination

survey undertaken in 2016, which found that Europe had a lower confidence[24] in the safety of vaccines than other world regions[25]. The report found that confidence in the safety and importance of vaccines fluctuates over the years and across countries.

In 2022, the Commission published a Report on the State of Vaccine Confidence in the European Union [26]. This followed the previous biennial 2020[27] and 2018[28] reports, completing Deliverable 3 of the Commission Roadmap. The report found notably that while many of the respondents held positive beliefs towards vaccines, many of the gains seen in 2020 had since faded. This continuing series of vaccine confidence reports highlight the complexity of vaccine hesitancy and contributed to healthcare workers' and public health experts' understanding of the problem, in order to permit the development of countermeasures[29] which was particularly well welcomed by the national authorities interviewed. With vaccine hesitancy being context-specific, the Report's breakdown of survey respondents by country, vaccination type and sociodemographic characteristics are vital to ensuring the effectiveness of countermeasures.

This action is thus **relevant in addressing the need to measure and better understand vaccine hesitancy** and is also important to help predict future trends to inform interventions to directly address vaccine hesitancy. Moreover, the deployment of a report on a biennial basis presents the overall relevance of this action to be further deployed in future years, with the 2022 report in fact concluding that regular monitoring of vaccine confidence must continue because it is difficult to determine whether change in the data over a two-year period represent short-term fluctuations or more permanent shifts. The overall relevance of the Reports on the State of Vaccine Confidence in the European Union was confirmed by certain national authorities interviewed who indicated the added value of identifying trends in confidence for citizens throughout the EU.

In addition to Action 2, **Action 5**[30] identified barriers to access and supported interventions to lift them. A key approach to combatting vaccine hesitancy is the need to ensure access to vaccination for specific disadvantaged and socially excluded groups. The **link between access to vaccination and vaccine hesitancy was confirmed through interviews undertaken for the Study** both with representatives of civil society organisations representing parents and patients as well as representatives of national health authorities in the EU Member States, and health professionals' and student associations. 75% of the stakeholders from this last category (at EU and national level, n=6) rated this action as being highly relevant. Action 5 of the Commission Roadmap aimed, through its four completed deliverables (3 of which were carried out by the EU-JAV Work Package 8), to support the identification of barriers to access to vaccination and to support interventions to increase access to vaccination for disadvantaged and socially excluded groups. A webinar on vaccine hesitancy and uptake took place[31], presenting their work on monitoring social media and the web data sources (real-time indication of the volume of vaccine-related conversations on social media and web



[24] Vaccine confidence refers to trust in the effectiveness and safety of vaccines as well as trust in the healthcare system that delivers them.

[25] Larson HJ, de Figueiredo A, Xiahong Z, Schulz WS, Verger P, Johnston IG, Cook AR, Jones NS. The State of Vaccine Confidence 2016: Global Insights Through a 67-Country Survey. EBioMedicine. 2016 Oct;12:295-301. doi: 10.1016/j.ebiom.2016.08.042. Epub 2016 Sep 13. PMID: 27658738; PMCID: PMC5078590. Accessed at: link

[26] European Commission (2022) https://health.ec.europa.eu/system/files/2023-02/2022_confidence_rep_en.pdf

[27] European Commission (2020) https://health.ec.europa.eu/system/files/2022-11/2020_confidence_rep_en.pdf

[28] European Commission (2018) https://health.ec.europa.eu/system/files/2018-11/2018_vaccine_confidence_en_0.pdf

[29] Ibid.

[30] Action 5: Identify barriers to access and support interventions to increase access to vaccination for disadvantaged and socially excluded groups, including by promoting health mediators and grassroots community networks, in line with national recommendations.

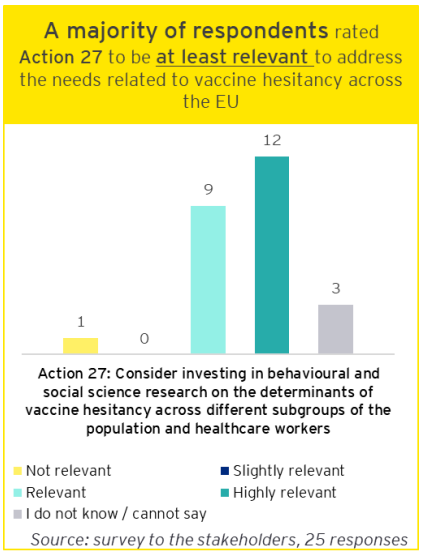
[31] EU-JAV's Work Package 8

searches), to detect early signals of lowering public confidence and the most influential online players (either against or in favour of vaccination).

Action 16[32], not entirely delivered[33],also aimed to address issues relating to vaccine hesitancy for healthcare workers. Although the interaction between patients and healthcare providers is essential in addressing vaccine hesitancy, healthcare workers themselves can also be hesitant to get vaccinated. The hesitancy to vaccinate themselves can subsequently have a knock-on effect on encouraging patients to get vaccinated. The existence of vaccine hesitancy amongst healthcare workers was confirmed through interviews undertaken with representatives of these stakeholders, with the need to address this specific group identified as a priority moving forward. Action 16 thus aims at addressing this interaction between healthcare workers and their patients, providing both resources for vaccine-hesitant healthcare workers, and tools to help them in their discussions with patients. Initially delayed due to the COVID-19 pandemic, a series of e-learning modules, available to those registered to the platform, was thus launched in June 2022 in the ECDC Virtual Academy[34]. They are "designed to support public health practitioners and risk communicators in fighting the spread of vaccination misinformation on social media and other digital platforms". The course aimed at introducing learners to the spectrum of vaccine decision-making and the factors affecting vaccine acceptance (including mis- and dis-information), and also featured a tool to assess people's vaccine literacy skills. However, it is important to note that Action 16 is not entirely completed, as the creation and development of the European Schoolnet was delayed.

In this context, this action is especially relevant in both addressing the factors of vaccine hesitancy in the general population through their interactions with their healthcare providers, while also increasing the healthcare workers' own knowledge and skills. This is also confirmed by the survey: 56% of survey respondents judged this action to be very relevant to address this need (overall 76% found this action either relevant or very relevant). No respondent from the health professionals' and student associations at national and EU level rated this action as being irrelevant, and this further confirms the relevance of tailoring resources dedicated to fighting vaccine hesitancy in education. One stakeholder also outlined that educational content on vaccination in schools are important to increase awareness from early age.

Finally, **Action 27**[35] aimed at better identifying the subgroups of the population that have the most important level of vaccine hesitancy as well as to refine the specific actions to be implemented to address the factors of vaccine hesitancy among specific publics, with a focus on parents and healthcare workers. This was addressed by a set of projects funded by the EU funding programme for research and innovation Horizon 2020[36], as well as actions undertaken by ECDC, and through a behavioural study on vaccination to identify determinants of vaccine hesitancy across different subgroups of the population and healthcare



[32] Provide evidence and data, including through the European Schoolnet, to support Member States' efforts to strengthen the aspects related to vaccinology and immunization in their national medical curricula and postgraduate education

[33] Action 16 is supported by one deliverable that consists in the development of e-learning training modules for GP's and primary healthcare providers to improve their skills to address hesitant population and to promote behavioural change. Deliverable 44 is so far delayed but currently in the process of being finalised with the upcoming launch of a 45-minute e-learning on "Vaccine acceptance and behaviour change" and other products.

[34] https://www.ecdc.europa.eu/en/news-events/ecdc-launches-e-learning-course-how-address-online-vaccination-misinformation

[35] Consider investing in behavioural and social science research on the determinants of vaccine hesitancy across subgroups of the population and healthcare workers

[36] Projects funded under Horizon 2020 can be found in Cordis portal: CORDIS | European Commission (europa.eu)

workers carried out by the CCBI. A report[37] by the CCBI synthetised this large range of research, which comprised: 1) a literature review, 2) a cross-sectional survey, 3) a case study in Italy on knowledge, attitudes, and practices towards vaccination among paediatricians, 4) the key learnings of the symposium on behavioural science and vaccination, and 5) additional studies made of literature review and studies on vaccination during the pandemic[38] . The overall relevance of Action 27 was confirmed through the Online survey where 12 of the 25 responses rated this action to be highly relevant, and 9 ranking it as relevant.

Concerning parents, the literature review and a cross-sectional survey highlighted key factors in vaccine hesitancy in this group, across multiple countries, that can be summarised as: perceptions around safety and accessibility, exposition to critical information, trust in the government and healthcare system, procrastination, misbalancing of the benefits and risks of drawbacks, and finally the amplification of narratives within smaller groups or their spread to other groups. This deliverable has not only underscored but also reaffirmed the critical necessity of equipping healthcare providers, particularly paediatricians, with the tools and resources essential for addressing vaccine hesitancy effectively.

Stakeholders interviewed outlined the need to have greater research on the reasons for vaccine hesitancy in order to be in a position to effectively propose a solution. This need is addressed in several actions as described above (**Action 5**, **Action 27**): this viewpoint thus shows the need to sustain these types of actions, as well as the reach given to the communication and utilisation of their outcomes.

3.1.2.2 Specific actions of the Roadmap also aimed to address vaccine hesitancy through enhanced collaboration between key stakeholders

Action 3[39] of the Roadmap established the **Coalition for Vaccination,** aimed at bringing together health professionals' and students' associations in order to exchange best practices and deliver accurate information to the public and combat myths about vaccines[40]. The Coalition was set up formally as a group of European associations of healthcare professionals and student associations in the field of vaccination and public health. Co-chaired by the Standing Committee of European Doctors (hereafter 'CPME'), the European Federation of Nurses Associations (hereafter 'EFN') and the Pharmaceutical Group of the European Union (hereafter 'PGEU'), the Coalition is supported by the European Commission which provides coordination and administrative support. The Coalition has been strengthened through the IMMUNION project (Improving IMMunisation cooperation in the European UNION), an EU co-funded project launched precisely for that purpose. IMMUNION ended in March 2023 and, in particular, developed a website and several social media channels for the Coalition. Since its establishment, **a number of actions have been undertaken by the Coalition which are directly relevant to addressing needs existing in relation to vaccine hesitancy.** This has particularly been through the deployment of campaigns with communication materials to raise awareness, such as an advocacy campaign undertaken in 2020 by the Coalition to promote the uptake of vaccines among health professionals and their patients. Several informational videos were produced, including for nurses, pharmacists, and doctors[41]. A recent key activity was the Coalition for Vaccination Conference 2023, which brought together 100 experts from across Europe to discuss European and national vaccination policies and health care professionals' role in increasing vaccine confidence and uptake[42]. This action was also judged to be relevant in relation to the need (with 76% of the 25 respondents to this question judging it as at least relevant, although only 36% highly relevant).

In addition to actions directly addressing vaccine hesitancy, specific actions indirectly addressed this need through increased public awareness raising and monitoring of data

---

[37] JRC Publications Repository - Applying lessons from behavioural sciences to vaccination acceptance and demand (europa.eu)

[38] https://publications.jrc.ec.europa.eu/repository/handle/JRC131583; https://publications.jrc.ec.europa.eu/repository/handle/JRC133066; and https://publications.jrc.ec.europa.eu/repository/handle/JRC124542

[39] Convene a Coalition for Vaccination to bring together European associations of healthcare workers as well as relevant students' associations in the field, to commit to delivering accurate information to the public, combating myths, and exchanging best practice

[40] See press release of September 2019 from the Standing Committee of European Doctors.

[41] Communication Materials | IMMUNION (coalitionforvaccination.com)

[42] Coalition for Vaccination (2023). Press release of 17th January 2023 – European healthcare professionals unite for the future of vaccination.

Action 4[43] of the Roadmap contributed indirectly to addressing the needs relating to vaccine hesitancy through placing an increased focus on communicating and raising public awareness through the annual European Immunisation Week. Since 2020, the ECDC has contributed annually to the European Immunisation Week with an EU public awareness initiative. In 2020, the European Vaccination Information Portal was launched during the European Immunisation Week. This resource, co-developed by the ECDC, in partnership with the European Commission and the European Medicines Agency (hereafter 'EMA'), contains up-to-date information about vaccination and vaccines with the goal of providing the public with easy access to reliable information on the topic. Spreading awareness about this tool contributes to amplifying the importance of vaccines and to equalising access to quality information about vaccines, and ultimately to help counter vaccine hesitancy to address suboptimal vaccination coverage rates across the EU. 76% of respondents to the online survey also confirmed the relevance of this action (44% judge it highly relevant).

In addition to enhancing communication and awareness raising, the Roadmap also focussed on the effective monitoring of immunisation programmes. Enhanced monitoring ensures more concrete data is collected on the state of immunisation throughout EU Member States, enabling Member States to adapt their approaches to address immunisation trends. This has been done through **Action 6**[44] of the Roadmap, which was largely completed under EU-JAV's WP5 (7 deliverables out of 8). Vaccination programmes are complex public health interventions that can be vulnerable to shifts in public confidence and opinion and be subject to public controversy. Immunisation Information Systems (hereafter 'IIS') hold data empowering individuals to make informed decisions on vaccination and enabling researchers and policy makers to better detect patterns of vaccination and improve the targeting of vaccination programmes[45]. IIS contribute to demonstrating the efficacy and favourable safety profile of vaccines to reassure patients and health care professionals, which is important to mitigate against feelings of hesitancy around vaccines. **Action 6** thus also indirectly contributes to creating an environment favourable to the fight against vaccine hesitancy and is therefore **indirectly relevant to this need**.

3.1.3 Mis- and dis-information and lack of accurate information

Need identified in 2018	Misinformation is defined as false and misleading information spread without deliberate intent to harm, and disinformation refers to its deliberate spread. Both are rising in the social media landscape and are found to increase vaccine hesitancy and limit vaccine uptake. In 2019, the World Health Organization (WHO) listed misinformation among their top 10 list of global health threats[46]. The spread of mis- and dis-information on vaccination can lead to decreased confidence in vaccines and is a key factor for vaccine hesitancy. Prior to the adoption of the Council Recommendation in 2018, a Commission Action Plan on Fake News and Online Disinformation was adopted which aimed to contribute to the development of an EU Strategy on tackling the spread of disinformation, with the Commission Communication on tackling disinformation aiming to address challenges in relation to online platforms regarding the spread of disinformation (Pillar I of the Commission Communication). Following the Commission's words on mis and disinformation in Pillar I of its Communication, the Council Recommendation highlighted the need to 'counter online vaccine misinformation', aligned with the Commission Communication on tackling disinformation, through the establishment of an EVIS. In relation to misinformation, the Council Recommendation outlined in its Preamble 5 that misconceptions have been fuelled through the rapid spread of misinformation through social media and by anti-vaccination activists. A need was identified to

[43] Strengthen the impact of the annual European Immunisation Week by hosting an EU public awareness initiative and supporting Member States' own activities

[44] Develop EU guidance on establishing comprehensive electronic immunization information systems for effective monitoring of immunization programmes

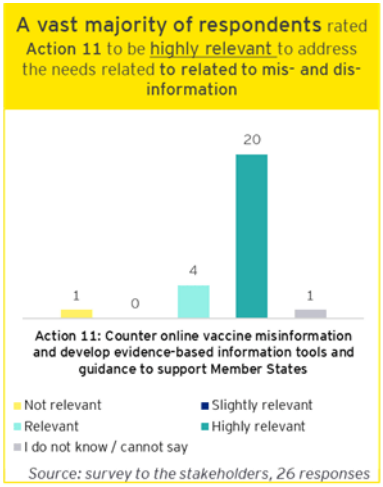
[45] ECDC (2018): Technical Report – Designing and implementing an immunization information system. A handbook for those involved in the design, implementation, or management of immunization information systems.

[46] https://www.who.int/news-room/spotlight/ten-threats-to-global-health-in-2019

strengthen dialogue with citizens in order to understand their concerns and doubts regarding vaccination. The European Parliament, in its resolution of 19 April 2018 also called on taking effective steps against misinformation in order to reduce vaccine hesitancy.

3.1.3.1 A key action focussing on countering online vaccine misinformation and developing evidence-based information tools was defined by the Roadmap to directly address the needs relating to mis-and dis-information

The primary action of the Roadmap to counter mis-and dis-information was **Action 11**[47] which aimed to counter online vaccine misinformation and develop evidence-based information tools and guidance to support Member States in responding to vaccine hesitancy.[48]



Action 11 produced two deliverables. The first was a technical report commissioned by ECDC in 2018 and published in 2021, which aimed to study the landscape of vaccine misinformation in the EU and European Economic Area (hereafter 'EEA'), exploring 1) the main sources of online vaccine misinformation, the most exposed groups, main online platforms used to relay misinformation, misinformation common narratives (e.g. vaccine-injured children, adverse effects, conspiracy theories, limitations to freedom, questioning of the scientific evidence, etc.), 2) the evidence base to counter online vaccine misinformation, 3) the current strategies for countering used by public health authorities and other organisations, and 4) their training needs to develop effective strategies. This was intended to help the ECDC develop a training package for public health authorities. Its scope focused on vaccination against measles (combined with mumps and rubella), Human Papillomaviruses (hereafter 'HPV'), influenza, and COVID-19 (for the latter, no vaccine was available at the time of the study, and the scope was broadened to include general COVID-19 related misinformation). It used a combination of quantitative and qualitative methods and also scanned available monitoring tools and general strategies and techniques to fight mis- and dis-information.

The second deliverable of **Action 11** was a Social Media Toolbox, #SafeVaccines. It includes editable templates, visuals, videos, pictures and factsheets dedicated to the promotion of safe vaccination (COVID-19 and other vaccines) across the EU. The Commission succeeded in giving more visibility on science-based information and data thanks to these tools, according to a member of an EU Agency in the area of medicine and vaccine. This deliverable's contribution to addressing the needs is however more difficult to assess, as little information is known about who the toolbox's users are, and how widely it was used across EU Member States and institutions. Nonetheless, one national authority underlined that all that had been done by the Commission on dis- and misinformation online was relevant and powerful thanks to its "non-political posture" according to the stakeholder interviewed.

Additional actions were foreseen by the Roadmap through training and communication to counter mis- and dis-information

In addition to developing evidence-based tools through Action 11, **Action 16**[49] which focussed primarily on addressing vaccine hesitancy also included the development of e-learning training modules targeting GPs and primary healthcare providers, which included techniques aimed at addressing patients' discourses influenced by misinformation. The e-learning course included within its aims to teach about "basic concepts of misinformation,

[47] Counter Online Vaccine Misinformation and develop evidence-based information tools and guidance to support Member States in responding to vaccine hesitancy, in line with the Commission Communication on tackling online disinformation

[48] This action is aligned with Council Recommendation 9c which aimed to 'Counter Online Vaccine Misinformation and develop evidence-based information tools and guidance to support Member States in responding to vaccine hesitancy, in line with the Commission Communication on tackling online disinformation'.

[49] Action 16: Provide evidence and data, including through the European Schoolnet, to support Member States' efforts to strengthen the aspects related to vaccinology and immunisation in their national medical curricula and postgraduate education. The deliverable is delayed so far but currently in the process of being finalised with the upcoming launch of a 45-minute e-learning on "Vaccine acceptance and behaviour change" and other products.

social listening, health and vaccine literacy, pre- and debunking techniques to counter misinformation, and evaluating interventions that aim to address online vaccine misinformation". Additionally, the upcoming launch of a 45-minute e-learning on "Vaccine acceptance and behaviour change" and other products will complement the available materials. Their reach is however limited to English-speaking learners, with around 360 registered learners in April 2023. In the online survey, one stakeholder from the vaccine industry pointed out the relevance of healthcare professionals, being the first source of information for patients regarding vaccination and thus especially well placed as existing capacity for communication campaigns. This stakeholder also reminded the role that community pharmacists could hold in this endeavour, as they already hold counselling roles towards patients.

Action 4 also tackled this need with the introduction of an EU public awareness initiative to the European Immunisation Week, informing the public about the ECDC European Vaccination Information Portal, whose goal is to provide the public with easy access to reliable information about vaccination and vaccines. The platform thus provides reliable online information to the public and resources to combat misinformation. Highlighting the platform in the public awareness initiative contributed to strengthening dialogue with citizens, indirectly serving the need to combat mis-and dis-information.

Respondents to the online survey, representing health professional and student associations at national and EU level, highlighted the need to address mis- and dis-information among specific groups (migrants for example), but also to support key stakeholders in combating mis- and dis-information, especially healthcare professionals. While these points are addressed in several of the actions in the Roadmap and thus further confirm their relevance, it suggests that there is an additional need to communicate more broadly, in order to amplify the reach of those actions.

The Coalition for Vaccination, established through **Action 3**, also addressed needs relating to mis-and dis-information. 73% of the survey respondents considered this action to be at least relevant to addressing this need, with 38% being of the view that this action is highly relevant, particularly through the establishment of communication campaigns to raise awareness, with one of the main goals being to communicate evidence-based information about vaccination. Notably, in 2020, the Coalition undertook an advocacy campaign with informational videos aimed at nurses, pharmacists, and doctors to promote the uptake of vaccines among health professionals and their patients.

Finally, **Action 13**[50] contributed to **addressing the needs relating to mis-and dis-information through the production of accurate information through strengthened cooperation and mandates between EMA and ECDC**[51] (Deliverable 41 - Create a sustainable and multi-stakeholder platform for EU post-marketing surveillance studies monitoring the safety, effectiveness, and impact of vaccination). Both agencies launched in 2022 the Vaccine Monitoring Platform (VMP), enabling the coordination and overseeing of "EU-funded, independent post-authorisation studies on vaccines safety, and effectiveness"[52], aiming at producing real-world evidence (RWE) on vaccine safety and effectiveness. The results of this cooperation are notably contributing to generating additional reliable information on the effectiveness and safety of vaccines, with several studies funded by both agencies currently ongoing.

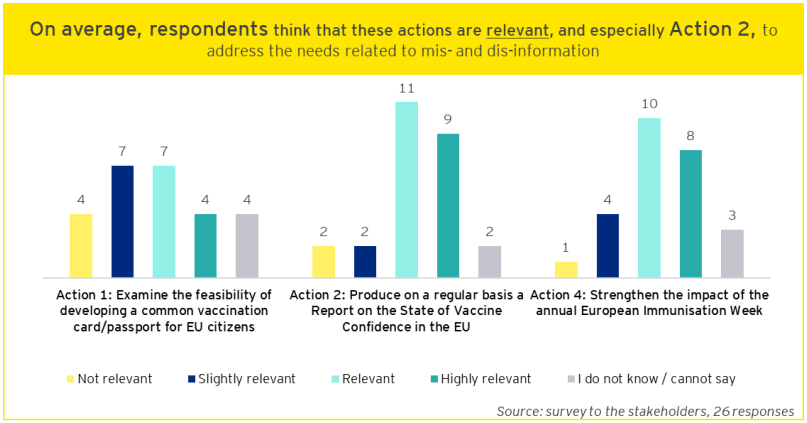
[50] Action 13: Continuously monitor the benefits and risks of vaccines and vaccinations at EU level through post-marketing surveillance studies

[51] https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/promoting-our-european-way-life/european-health-union_en

[52] https://www.ema.europa.eu/en/about-us/what-we-do/crisis-preparedness-management/vaccine-monitoring-platform

3.1.3.2 The collection of evidence on vaccine confidence in the EU can also have an indirect impact on addressing needs relating to mis-and dis-information

As outlined under Section 3.1.2 above, **Action 2** of the Commission Roadmap aimed to produce on a regular basis a **report on the State of Vaccine Confidence in the European Union** in order to monitor attitudes to vaccination. While this action and deliverables had as a primary objective the measurement of citizens' attitudes and thereby of increasing knowledge on vaccine hesitancy, this action is also **indirectly relevant to fight mis- and dis-information in relation to vaccines** since it provided knowledge to policymakers regarding overall attitudes to vaccines and therefore permits policymakers to measure citizens' attitudes with evolutions in relation to mis-and dis-information.



3.1.4 Structural barriers to vaccination

Need identified in 2018	Access to vaccination has been a key focus at EU level, dating back to the 2006 Council Conclusions on common values and principles in European Health Systems[53] which highlighted the importance of ensuring equity of access to vaccination services regardless of social status, age, or geographical location. Recommendation 4 of the Council Recommendation recommended the facilitation of access to national and/or regional vaccination services through two steps: (i) Simplify and broaden opportunities to offer vaccination, leverage community-based providers (ii) Ensure targeted outreach to the most vulnerable groups. Moreover, Recommendation 20 recommended the Commission to identify barriers to access and support interventions to increase access to vaccination for disadvantaged and socially excluded groups. Access to vaccination for the most vulnerable and intervention to make barriers fall was also outlined in the Commission Communication in Pilar I.

3.1.4.1 Actions in the Roadmap addressed structural barriers to vaccination for specific population groups

Stakeholders consulted through the Survey mostly judged **Action 5**[54] to be at least relevant to address this need: it focused on identifying barriers to access and support interventions to increase access to vaccination for disadvantaged and socially excluded groups. This action was carried out under EU-JAV's Work Package 8. This was primarily undertaken through the completion of four key deliverables:

- Deliverable 9: Guidance on increasing access to vaccination for disadvantaged and socially excluded groups
- Deliverable 10: Country reports on research-based determinants behind high and low vaccination coverage
- Deliverable 11: E-learning platform to share country reports, provide a database on structured country reports
- Deliverable 12: Series of webinars about specific cases, projects and initiatives dealing with vaccine hesitancy and uptake-related issues, involving broad range of stakeholders

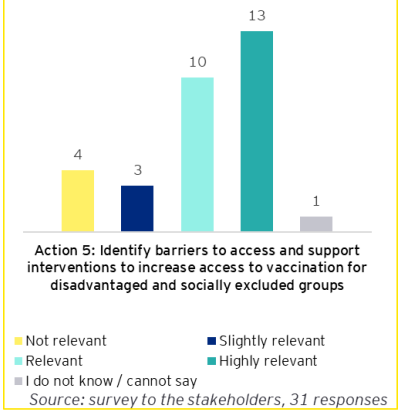
[53] Council Conclusions on Common values and principles in European Union Health Systems (2006/C 146/01) https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52006XG0622%2801%29

[54] Action 5: Identify barriers to access and support interventions to increase access to vaccination for disadvantaged and socially excluded groups, including by promoting health mediators and grassroots community networks, in line with national recommendations

Since 2020, in continuity with these deliverables, the European Commission has released two funding and tender opportunities for topics related to this action in its Annual Work Plan (AWP):

- Increased access to vaccination for newly arrived migrants in first line, transit and destination countries: this tender funded the project Increased Access to Vaccination for Newly Arrived Migrants (AcToVax4NAM) which aims to improve vaccination access to NAM by providing guidance, characterise system barriers to vaccination, strengthen health literacy and responsiveness of organisations and develop country-specific solutions and actions.
- Increased access to vaccination for disadvantaged, isolated and difficult to reach groups of population. Two projects were funded: Innovative Immunisation Hubs (ImmuHubs) and Reaching the hard-to-reach: Increasing access to vaccine uptake among prison population in Europe (RISE-Vac).

A majority of respondents rated **Action 5** to be **at least relevant** to address difficulties in accessing vaccinations and vaccination structures



Source: survey to the stakeholders, 31 responses

Although not explicitly connected to Action 5', these subsequent works continue to address the issues linked to reaching the "hard to reach", **further outlining the relevance of Action 5 and the continued need to work in this direction**.

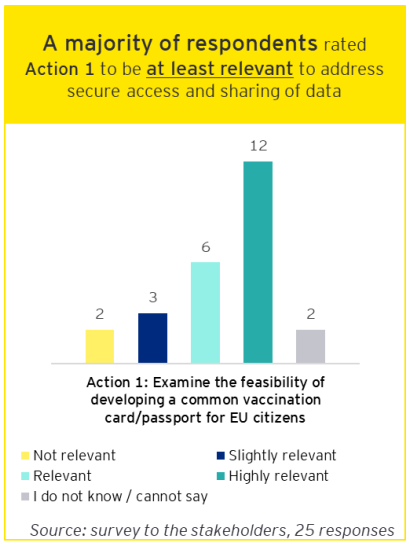
In addition, **Action 27** specifically addressed the investigation of barriers to vaccination linked to vaccine hesitancy across different subgroups of the population and healthcare workers and thus also directly contributes to addressing the need to better identify and understand the drivers behind access barriers to vaccination. Moreover, the overall aim of **Action 26** was to seek consensus on unmet population needs and agreed priorities for vaccines that can be used to inform future vaccine research funding programmes at national and EU level. It therefore contributed to the diagnosis of barriers to vaccination through a roadmap (Deliverable 56) of unmet needs. The relevance of both actions was judged positively by stakeholders (77%), particularly for Action 27, for which the balance of "highly relevant" ratings was higher.

Need identified in 2018	Accessing and sharing health data across the EU was identified in the Commission 2019 Recommendation on a European Electronic Health Record Format to have a strong potential for impact in improving the quality of care for patients, diminishing the cost of healthcare, modernizing the systems and facilitating citizens' lives in cross-border situations. In addition to Pillar II of the Commission Communication, Recommendation 21 of the Council Recommendation recommended the Commission to 'develop guidance to overcome the legal and technical barriers impeding the interoperability of national IIS' in order to empower citizens and build a healthier society

3.1.4.2 The Commission Roadmap fostered reflections on increasing the sharing of health data for citizens' and Member States' benefit through an EU Vaccination Card

Action 1[55] focussed on the feasibility of developing a common EU Vaccination Card for EU citizens.

[55] Examine the feasibility of developing a common vaccination card for EU citizens



A common EU Vaccination Card would aim to empower EU citizens with a better access to their own personal data as highlighted in Action 1's Deliverable 2[56]. In the online survey, 44% of respondents from the stakeholder group "National ministry of health and public health authorities and agencies in Member States" (n=16) rated the relevance of this action to be high, and an additional 13% as relevant.

The need in relation to the access to data has been emphasised through the COVID-19 pandemic, which has shown even further the importance of electronic health data to inform interventions to respond to health emergencies[57]. It has also been emphasised by Deliverable 1, which included a survey on EU citizens' opinion on an EU Vaccination card[58]. Beyond helping to select the most relevant template for a card, this survey to EU citizens also revealed that most participants do not have a clear vision of their vaccination schedule nor a tool for vaccination follow-up, underlining the need for access to reliable data. This study also showed that 8 out of 10 EU citizens declared that they would use such a card in case if it was implemented, corroborating the relevance of Action 1.

The relevance of the EU Vaccination Card feasibility study was also raised through certain interviews undertaken for the Study. While stakeholders from civil society, from some Member States and medical practitioners highlighted the benefits of such a Card, issues were raised with regard to the overall feasibility for introducing it, for policy reasons at national level as well as due to issues raised in relation to the sharing and protection of data of citizens, as well as the additional administrative burden.

In parallel to Action 1, there were evolutions in relation to the European Health Data Space (hereafter 'EHDS')[59] with a 2022 proposal aiming to create a 'common space where natural persons can easily control their electronic data'. The aim of this Data Space is also to create an environment where it is possible for researchers, innovators, and policy makers to use electronic health data in a manner that is secure and trusted.

This action thus proved its continued relevance to sustain political reflection and decision-making regarding the need to securely access and share health data across borders.

3.1.4.3 In addition to considering how data can be shared for the benefit of citizens, the Roadmap also addressed issues in relation to interoperability of data

Action 7[60] of the Commission Roadmap aimed to develop guidance to overcome the legal and technical barriers impeding the **interoperability of national IIS**, having due regard to rules on personal data protection, as set out in the Commission Communication on enabling the digital transformation of health and care in the Digital Single Market, empowering citizens, and building a healthier society[61]. 76% of respondents to the online survey judged this action to be at least relevant (although only 36% judged it to be highly relevant).

Action 7 was considered delivered as part of the 2019 Commission Recommendation on a European Electronic Health Record exchange format[62], which is set to achieve secure, interoperable, cross-border access to, and

[56] Deliverable 2: Commission proposal for a common vaccination card for EU citizens

[57] Commission proposal p. 1.

[58] European Health, and Digital Executive Agency, Provision of Opinions and recommendations for an EU citizen's vaccination card. Annex 2, Design and testing of three dual templates, 2022.

[59] https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space_en

[60] Action 7: Develop guidance to overcome the legal and technical barriers impeding the interoperability of national immunization information systems (IIIS)

[61] Commission Communication on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society (COM/2018/233) of 25 April 2018 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2018%3A233%3AFIN

[62] Commission Recommendation on a European Electronic Health Record exchange format (C(2019)800) of 6 February 2019. Accessed at: Recommendation on a European Electronic Health Record exchange format (europa.eu)

exchange of electronic health data in the Union. The framework includes a set of principles that should govern access to, and exchange of, electronic health data in the Union. It also encourages Member States to ensure secure access to electronic health record systems at the national level. As a baseline format for electronic health records, the Commission recommends it includes: i) patient summary; ii) ePrescription/eDispensation; iii) laboratory results; iv) medical imaging and reports; v) hospital discharge reports.

While the interoperability of data systems throughout the EU remains a salient challenge, Action 7 contributed directly to progress in relation to this need.

While **Action 6**[63] of the Commission Roadmap focussed primarily on monitoring of immunisation programmes, the ECDC developed in 2018 a Handbook on designing and implementing an immunisation information system [64]. It comprised technical guidance based on IIS experts' experiences and case studies, and is intended to "all those involved in the design, implementation, management or continuous improvement of IIS: primarily immunisation programme managers and operational IIS staff; more broadly public health experts and policymakers, health researchers, health information specialists, IT developers, and healthcare professionals and providers".

The technical guidance aimed to (i) define IIS; (ii) provide information on IIS and their added value to immunisation programmes; (iii) share best practices to advocate for IIS towards main stakeholders; (iv) describe the functionalities and attributes that IIS can offer and (v) give step-by-step guidance on the major steps to be considered for the design, implementation, or further development of an IIS. The action thus **directly responded to the needs existing in relation to interoperability of data by developing guidance** to overcome the legal and technical barriers impeding the interoperability of national IIS.

Finally, **Action 12**[65] that has been partially completed[66], also **directly contributed to responding to this need**. As previously shown, this action covered a wide range of works related to enhancing information sharing between EU Member States and NITAGs, and to producing coherent monitoring data at EU level. Stakeholders confirmed the relevance of establishing a European Vaccination information system, with 80% of respondents judging it to be at least relevant, and over half of all respondents judging it highly relevant. As such, completing this action will remain relevant.

3.1.5 Suboptimal monitoring of immunisation through specific actions focused on the monitoring of immunisation programmes, and of the stocks and effects of vaccines

Need identified in 2018	The Council Recommendation outlined the need for additional monitoring in relation to vaccination. Prior to the adoption of the Recommendation, the Council Conclusions on childhood immunisation[67] called for the refinement of immunisation registries and information systems in order to improve the monitoring of vaccination programmes. To reach this objective, Recommendation 9 aimed to establish a European Vaccination Information System in order to further design EU methodologies and guidance on data requirements with a view to better monitoring vaccination coverage rates, as it was already underlined in the Commission Communication (Pillar II).

3.1.5.1 Two specific actions in the Roadmap addressed the need relating to suboptimal monitoring of immunisation programmes

The main actions contributing to addressing the need to optimise monitoring and monitoring guidelines were Actions 6 and 7.

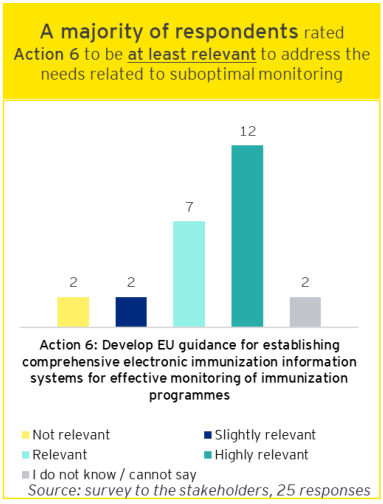
[63] Action 6: Develop EU guidance for establishing comprehensive electronic immunization information systems for effective monitoring of immunization programmes.

[64] Handbook on designing and implementing an immunisation information system (europa.eu)

[65] Action 12: Establish a European Vaccination Information Sharing system.

[66] Deliverables 35 and 36 are still pending.

[67] Council conclusions on childhood immunisation: successes and challenges of European childhood immunisation and the way forward (europa.eu)



Deliverable 14 of **Action 6**[68] which presented an outline of core functionalities for information sharing and vaccine coverage assessment pilot platform) addressed in its conclusions the need for better monitoring of vaccination coverage so as to identify immunity gaps and better target under-vaccinated populations during national immunisation programmes.

The need was directly addressed in Deliverable 15, which established a protocol for harmonised estimations of vaccination coverage of first and second dose with the measles-mumps-rubella vaccine (hereafter 'MMR'1 and MMR2), which are currently being reported by EU Member States using different methods to obtain data on vaccination coverage (e.g., national or subnational surveys, administrative methods, and vaccination registries).[69]

Deliverable 16 elaborated on the previous deliverables to develop and make available an open-source computer algorithm that can be shared and run by regions or countries with electronic IIS or other similar data sources. Once downloaded, the algorithm allows data to be extracted from national measles-containing vaccines (hereafter 'MCV') information systems to present it at the European level and can be visualised on the pilot online platform[70] (launched as part of Deliverable 17). This tool allows for example to identify and qualify the immunisation gaps (for example, immunity gaps can be linked to differences in vaccination times and schedules and not necessarily imply real immunity gaps), further contributing to high quality surveillance of vaccination coverage.

In parallel, and with a broader focus than MCV, two reports were published. Firstly, a report on interoperability of IIS in the EU area (**Deliverable 18**, 2022)[71], studying current IIS implementation in the EU area, regulatory compliance, and data quality and data collection processes. Secondly, a report on reminder systems (**Deliverable 19**, 2021)[72], studying automatic reminders by the regional or national IIS in place as well as potential barriers towards the implementation of vaccine reminder systems. This is closely linked to monitoring strategies, in their implementation and in what becomes possible when efficient monitoring is in place.

Overall, the **completeness of Action 6**, from need identification to the development of a concrete and usable solutions to enhance measles containing vaccine (MCV) coverage monitoring at EU level, made it especially relevant in terms of contributing to address the needs to optimise monitoring of vaccination. In addition to Action 6, **Action 7** directly tackled addressing the pre-existing limits to having effective EU-wide monitoring: **Deliverable 21 aimed to provide guidance on overcoming legal (and technical) barriers to the interoperability of national IIS in order to make** national IIS more interoperable. This action also stood out to the surveyed stakeholders, with 80% of the respondents rating it as at least relevant to this need, and 48% highly relevant. In particular, all representatives from health professionals' and student associations at national and EU level judged the action to be at least relevant, and 63% of them highly relevant, which particularly reveals the practical relevance of this action.

In addition, two deliverables falling under **Action 12** (Deliverables 38 and 39), sustaining and underlying the establishment of a EVIS system, also **involved defining monitoring methodologies in order to monitor and collect data on vaccination coverage across all age groups. This is directly relevant in terms of addressing the need to optimise monitoring.**

In addition to actions relating to the monitoring of programmes, the Roadmap defined an action relating to the availability of vaccines on the market

[68] Action 6: Develop EU guidance for establishing comprehensive electronic immunization information systems for effective monitoring of immunization programmes. NB: 7 out of the 8 deliverables were carried out by EU-JAV under the Work Package 5

[69] The aim of Task 5.2 was thus to establish common methodological guidelines, data structure and criteria for standardised estimations of measles containing vaccines (MCV) coverage within and between countries to identify immunity gaps at the national and regional level.

[70] https://eujav-platform.com/

[71] Buble, T (2022), Report on interoperability of IIS in the EU area. Croatian Institute of Public Health.

[72] Emborg HD (2021), Report on reminder systems. Statens Serum Institut.

Action 13[73] aimed at producing knowledge on the effectiveness and safety of vaccines through the Vaccine Monitoring Platform under EMA and ECDC joint mandate. In this regard, it contributed to the need to optimise vaccine monitoring, by notably (i) Maintaining a system for the prioritisation, launch, registration, and supervision of vaccine studies at the EU level, and (ii) Facilitating and coordinating the conduct of post-authorisation safety and effectiveness studies to monitor vaccine performance and impact over time.

The Roadmap adopted specific actions that indirectly contributed to addressing the need relating to suboptimal monitoring of vaccination

Action 1 in the Roadmap focused on a feasibility study for the development of a common EU vaccination card. It aimed to address challenges in relation to access and sharing of electronic health data as well as for EU citizens' empowerment, notably via the consultation of 78.000 citizens who in majority welcomed such an idea. Though the focus of Action 1 was not directly linked to monitoring of immunisation and did not aim at overriding existent mandates, it contributed indirectly to bringing reflections on favourable conditions for a better monitoring through the focus placed on increased data sharing in relation to vaccinations and the interfacing of existing systems. This was reflected in the online survey, with most respondents (48%) placing the relevance of the action as standard, and only an additional 16% rating it as highly relevant.

The same relevance pattern was placed on Action 9, which was mostly considered to be relevant but whose relevance was not stressed in comparison to other actions. Indeed, **Action 9**[74] also indirectly tackled the policy foundations needed to establish common priorities related to strengthen collaboration required for better monitoring of immunisation. The 2019 Global Vaccination Summit co-hosted by WHO and the Commission resulted in a communication summarising the lessons learned and identifying important actions to undertake[75]. Concerning monitoring, it was agreed that a priority was to "build strong surveillance systems for vaccine-preventable diseases, particularly those under global elimination and eradication targets"; "harness the power of digital technologies, so as to strengthen the monitoring of the performance of vaccination programmes"; "sustain research efforts to continuously generate data on the effectiveness and safety of vaccines and impact of vaccination programmes" and "mitigate the risks of vaccine shortages through improved vaccine availability monitoring (…) systems and collaboration with producers and all participants in the distribution chain".

3.1.6 Varying vaccination programmes across the EU

Need identified in 2018	Recital 8 of the Council Recommendation states that "The variation in vaccination schedules between Member States with regard to recommendations, type of vaccines, used, number of doses administered, and timing increases the risk that citizens, particularly children, miss a vaccination while moving from one Member State to another." According to the Commission Communication, the variation in vaccination programmes is often due to "social, economic and historical factors or simply, how the healthcare system is organised". The Commission Communication also pointed out that the variations may lead to a misunderstanding of EU citizens of "the rational for different policies across countries, raising doubts on the scientific base for the decision-making of vaccination policies".

To address the varying vaccination programmes across the EU, actions in the Roadmap focussed on contributing to information sharing and strengthening of knowledge

The actions that were implemented through the Commission Roadmap focussed to a large extent on enhanced information sharing as well as strengthening knowledge.

[73] Action 13: Continuously monitor the benefits and risks of vaccines and vaccinations at EU level, including through post-marketing surveillance studies

[74] Action 9: Strengthen existing partnerships and collaboration with international actors and initiatives, such as the WHO and its Strategic Advisory Group of Experts on Immunization (SAGE), the European Technical Advisory Group of Experts on Immunization (ETAGE), the Global Health Security Initiative and Agenda processes (Global Health Security Initiative, Global Health Security Agenda), Unicef and financing and research initiatives like Gavi, CEPI, GloPID-R and JPIAMR (the Joint Programming Initiative on Antimicrobial Resistance).

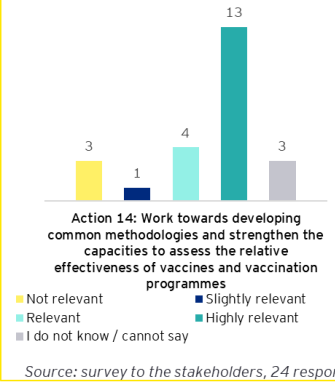
[75] ECDC, Designing and implementing an immunisation information system, Technical Report. Nov 2018 A handbook for those involved in the design, implementation, or management of immunization information systems https://ec.europa.eu/health/sites/default/files/vaccination/docs/10actions_en.pdf

Firstly, **Action 6** which focussed on developing guidance for establishing comprehensive electronic IIS included a deliverable (Deliverable 20) which concentrated on the feasibility of conducting coordinated cross-border measles vaccination campaigns. Given the limitations in collecting data for under vaccinated target populations, a lack of comparable cross-border data on the reasons for low coverage and the heterogenous nature of vaccination programmes in the EU/EEA, this deliverable was modified from a feasibility study to "a review of experience and best practice on what has already been done across borders and what can be gained by teaming up, as well as the facilitators and barriers". A *Study for future coordinated cross-border vaccination campaign in EU and non-EU countries* [76] was therefore delivered by EU-JAV under WP 5. The study reviewed the experience and best practice of cross-border vaccination campaigns, expanding the scope to include all vaccines in national childhood vaccination programmes, as well as the COVID-19 vaccination, to inform future cross-border vaccination campaigns. While not directly seeking solutions to unharmonised vaccination programmes, it provided tools to help solve gaps arising from such differences. This is confirmed by the online survey, with 79% of respondents rating this action as being at least relevant to addressing this need.

In addition, **Action 12** of the Roadmap, which aimed to establish EVIS, included a Deliverable (Deliverable 36, delayed) to **examine the feasibility of a core EU vaccination schedule** for routine immunisation, aiming to improve the compatibility of national schedules and promote equity in Union citizens' health protection, thus complementing Deliverable 1(feasibility of creating a common vaccination card). **The completion of this Deliverable would be highly relevant to the need to address immunisation gaps that may occur in an EU citizen's mobility path across the EU**. The majority of surveyed stakeholders also rated this action as at least relevant (75%), indicating its continued relevance and the need to keep delivering these guidelines, although certain Member States interviewed suggested that vaccination schedules should remain a national competence responding to national specific situations and needs.

The Roadmap also focussed on addressing the needs existing in relation to the variation of vaccination programmes through the development of common methodologies and the strengthening of capacities to assess the relative effectiveness of vaccines and vaccination programmes. Deliverable 42 of **Action 14**[77] was a study on guidance on methodologies to assess the performance of vaccination programmes, which was delayed due to the COVID-19 pandemic but is now being delivered under EU4Health Annual Work Programme 2021. While the study is still ongoing, it seems to take the necessary steps to identify gaps and potentially detrimental variations between Member States, and to take a problem-solving oriented method.

A majority of respondents rated **Action 14** to be **highly relevant** to address unharmonised vaccination programmes



Source: survey to the stakeholders, 24 responses

3.1.7 Lack of focus on vaccination in a life-course perspective

Need identified in 2018	The Council Recommendation identified in 2018 that demographic changes, mobility of people, climate change and waning immunity are contributing to epidemiological shifts in the burden of vaccine-preventable diseases, which require vaccination programmes with a life-course approach going beyond childhood years. This approach aims to ensure adequate lifelong protection and contributes to healthy living and healthy ageing as well as the sustainability of healthcare systems. In addition, the Commission Communication also underlined in its Pillar II that adult vaccination, questions on the loss of immunity over time as well as the development of new vaccines for adults and elders are becoming topics of importance, contributing to shed light on the need to have a life course perspective approach.

[76] Blomquist & Andersson (2018). Report on feasibility study for future coordinated cross-border vaccination campaign in EU and non-EU countries. Public Health Agency of Sweden.

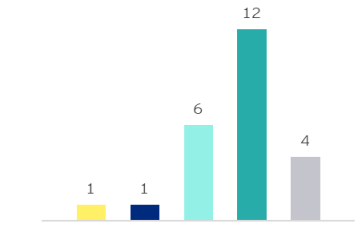
[77] Action 14: Work towards developing common methodologies and strengthen the capacities to assess the relative effectiveness of vaccines and vaccination programmes

The actions in the Roadmap address indirectly the need to ensure a life course perspective to vaccination

Analysis undertaken by the Study identified actions within the Roadmap that address indirectly the need identified at the time of adoption of the Council Recommendation in 2018 in relation to addressing the lack of focus on vaccination in a life course perspective.

Deliverable 56 of **Action 26** focussed on establishing a Roadmap of unmet population needs and agreed priorities for vaccines. As part of this deliverable, the EU-JAV's Work Package 7[78] defined as its main objective to "define tools and methods for priority-setting and identify mechanisms to increase collaboration and cooperation in vaccine and vaccination research and research funding programmes among Member States", and specifically to "Identify a small number of vaccines based on unmet needs for specific age categories to be used as examples to develop such a framework (e.g. a paediatric, an adolescent and an adult/elderly vaccine)". This contributes to showing how a life-course perspective related to immunisation is integrated to the roadmap's various objectives, including R&D, and is still relevant to addressing vaccine coverage gaps.

A majority of respondents rated Action 27 to be **at least relevant** and **half highly relevant** to address the lack of focus of vaccination in a life-course perspective



Action 27: Consider investing in behavioural and social science research on the determinants of vaccine hesitancy across different subgroups of the population and healthcare workers

Not relevant
Slightly relevant
Relevant
Highly relevant
I do not know / cannot say

Source: survey to the stakeholders, 24 responses

While **Action 27** of the Roadmap[79] did not focus specifically on a life course perspective in relation to vaccination, it did include sections in the studies involving adults and their perceptions of the necessity of a life-course approach to vaccination: 75% of the stakeholders consulted through the survey considered this action to be relevant. This outlines the importance placed by stakeholders on further investment in behavioural and social science with a view to improving the life course perspective for vaccinations.

The Roadmap also aimed to increase knowledge and data relating to the manner in which vaccination needs change over the lives of citizens. This was done through increased monitoring of vaccination rates across all age groups. When fully completed, **Action 12**[80] will contribute to this through Deliverable 36 (delayed) which examined the feasibility of establishing guidelines for a core EU vaccination schedule, taking into account WHO recommendations for routine immunisation. This aimed to improve the compatibility of national schedules and promote equity in Union citizens' health protection which steering towards a life course perspective on vaccination. It should, however, be noted that this action has not yet been completed due to delays linked to the Covid-19 pandemic.

The integration of a life-course perspective into vaccination considerations is a challenge for which the stakes merge so completely with other needs (such as effective monitoring and harmonisation of EU vaccination programmes, or addressing vaccine hesitancy) that its specificity is not as relevant as other equivalently focused needs.

3.1.8 Lack of coordination between EU Member States and at international level in relation to vaccination programmes and preparedness

Need identified in 2018	In complement of the Pillar III of the Commission Communication, the Council Recommendation called for strengthening coordination both between EU Member States but also between the EU and international actors in order to strengthen vaccination programmes and ensure preparedness.

[78] https://eu-jav.com/the-project/wp7/

[79] Action 27: Consider investing in behavioural and social science research on the determinants of vaccine hesitancy across different subgroups of the population and healthcare workers

[80] Action 12: Establish a European Vaccination Information Sharing system

	While preparedness was referred to in the Council Recommendation and in the Commission Communication, the focus on preparedness through specific Recommendations and in the Commission Communication was minor

Actions in the Roadmap aimed to strengthen partnerships and collaboration between EU Member States and actors at international level

The online survey found that all actions listed in the survey to address the needs relating to coordination between Member States and international policymakers were relevant, with at least 70% of the respondents rating these actions to be relevant. It can be noted that over half of the respondents to the survey on that subtheme were national Ministries of health and public health authorities and agencies in Member States.

The first key action in this regard is **Action 9** which aimed to strengthen existing partnerships and collaboration with international actors and initiatives. So far, however, the tasks undertaken under **Action 9** have consisted of a single participation and co-organisation of the 2019 Global Vaccination Summit, as previously presented. While this action was relevant to the need to better coordinate EU Member States and international stakeholders, as confirmed by Member State interviews, its output can be considered as lacking sustainability in the long term to continue to address this need moving forward.

In the interviews, one of the key areas of improvement which was identified by the Member State stakeholder group but also by European umbrella organisations was the need to enhance the partnerships and collaboration in place between the EU and international actors. Indeed, one of the concerns raised in the interviews was the overall lack of coherence existing in relation to actions undertaken by these actors, as further outlined in Section 3 below in relation to coherence.

Actions in the Roadmap also focused on enhancing joint procurement of vaccines

Action 21[81] in the Roadmap focused on enhancing possibilities relating to the joint procurement of vaccines. Efforts evolved in relation to the joint procurement of vaccines since the adoption of the Council Recommendation and subsequent Commission Roadmap. On 29 March 2019, 15 EU Member States[82] and the European Commission signed a framework contract for the production and supply of pandemic influenza vaccines under the so-called Joint Procurement Agreement to procure medical countermeasures. The Joint Procurement itself enables participating Member States to purchase jointly medical countermeasures for serious cross-border threats to health. The aim of the joint procurement is to ensure equal treatment Member States, obtain more balanced prices and demonstrate a high level of solidarity between EU Member States that agree to share limited availabilities of flu vaccines during a pandemic[83]. It also allows for a greater exchange of best practices and pooling of expertise and ensures equal access to all Member States participating in the Joint Procurement. Member State satisfaction with the relevance of this action is reflected through the Online Survey: 56% of respondents from the stakeholder group national authorities and ministries (n=16) found its relevance high and another 25% standard.

Action 21 therefore stands out as an especially relevant and performative way to test operational collaborations between Member States within its broader aim to explore the possibilities of joint procurement of vaccines. **Its contribution to addressing the abovementioned need is therefore very significant.**

3.1.9 Risk of vaccine shortages / Suboptimal monitoring of stocks

Need identified in 2018	In line with the Commission Communication, the Council Recommendation underlined in 2018 that vaccine shortages have direct consequences for the delivery and implementation of national vaccination programmes; Member States face various vaccine supply disruptions, production capacities in the EU remain limited and difficulties persist in sharing vaccines across borders, while the lack of coordinated forecast planning contributes to demand uncertainty. In this context,

[81] Acton 21 exploits the possibilities of joint procurement of vaccines or antitoxins to be used in cases of pandemics, unexpected outbreaks and in case of small vaccine demand (small number of cases or very specific populations to be covered)

[82] Belgium, Croatia, Cyprus, Estonia, France, Germany, Greece, Ireland, Luxembourg, Malta, the Netherlands, Portugal, Slovakia, Slovenia, and Spain.

[83] Memo- 2019 Framework contracts for pandemic influenza vaccines ev_20190328_memo_en_0.pdf (europa.eu)

the European Union and its citizens remain vulnerable in the event of outbreaks of communicable diseases.

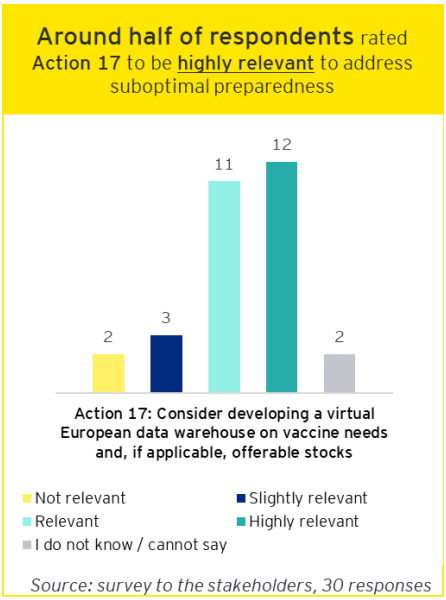
Actions in the Roadmap was forward-thinking in terms of enhancing Member States' approaches to address vaccine shortages

Action 10[84] aimed to identify manners in which Member States could collaborate more for strengthening preparedness and anticipation, by analysing previous experiences with vaccine shortages and stockouts and by developing guidance on how to respond to such situations. In addition, the EU-JAV Work Package 6 study on "Vaccine supply and Preparedness"[85] provided guidelines for vaccine forecasting and is "of central importance to ensure vaccine security"[86] as it can address and help prepare for shortages and stockouts. Action 10 also integrated a review of current funding of vaccine procurement methods (entirely funded by public funding when part of national immunisation programmes, but often lacking a longer-term perspective to comprehensively assess vaccine demand).

Overall, the completeness and multifaceted approach of these activities made Action 10 highly relevant in its contribution to addressing the lack of coordination between EU Member States in relation to vaccination programmes and preparedness. Mainly, these activities contributed to further highlighting the continued need for the EU/EEA Member States to develop ways to collaborate in vaccine procurement, including sharing of market information, using joint procurements or a regional EU data warehouse of supply and demand, and suggests tools for ensuring the continuation of this work after the end of the EU-JAV. 73% of survey respondents also rated this action to be at least relevant to address needs related to suboptimal preparedness, and around one third (n=12) deemed this action to be highly relevant.

In addition to Action 10, **Action 17**[87] responded to a need to develop EU Member States' coordination and forecasting methodologies as well as improving the exchange of medical countermeasures in the event of an outbreak. Preparedness is thus addressed through a series of deliverables prepared by EU-JAV's Work Package 6[88]. Firstly, Deliverable 45 focused on the development of common principles for vaccine demand forecasting. It identified several key mechanisms:

- To ensure sufficient supply for immunisation programs and preparedness in the EU: early warnings from suppliers and manufacturers, and at national level, sufficient stockpiles (sufficient still needs to be defined) and emergency stockpiles of vaccines, and a comprehensive overview of vaccine demand and stocks.
- To improve forecast of vaccine demand and manufacturing: long-term vaccine forecast from government agencies and procurers, timely input from them on future demand evolutions that rise from national immunisation programs changes, and a harmonised labelling of vaccines (also a recommendation of the following key mechanism).



- To better enable exchange of vaccines between EU countries: rapid exchange mechanism on available vaccines between EU Member States, harmonised labelling, liability protection for parties involved in the exchange

[84] Action 10: Develop evidence-based tools and guidance at EU level in order to support countries to anticipate, pre-empt or respond to crisis situations – NB: all deliverables were carried out under EU-JAV WP6 and WP4

[85] Deliverable 25: EU-JAV (2022). Guidelines on procedures to estimate vaccine needs and procurement in EU. Accessed at: link

[86] Ibid.

[87] Consider developing a virtual European data warehouse on vaccine needs and, if applicable, offerable stocks, to facilitate the voluntary exchange of information on available supplies, possible surpluses, and global shortages of essential vaccines

[88] https://eu-jav.com/the-project/wp6/

Moreover, Deliverable 46 provided a *report on possibilities, gaps and options for building a "concept type" for regional or European virtual stockpiles*. It **outlined the need for further discussions on legal aspects** and common electronic packaging leaflets. The relevance of an online platform to exchange information of vaccine supply and demand may be viewed as higher for specific vaccines (in particular emerging diseases), alongside with options to jointly purchase vaccines.

Further work on this action is part of the establishment of DG HERA (European Health Emergency Preparedness and Response Authority). HERA has two modes: a preparedness phase (concerning medical countermeasures, its responsibilities involve their production and distribution, stockpiling capacity improvement, etc.) and an emergency phase (where, after activation of the Emergency Framework Regulation[89], HERA notably ensures the availability, supply and deployment of medical countermeasures and monitors them and may, inter alia, act as a purchasing body complementary to other instruments, such as the joint procurement procedure[90] and the European Innovation Partnerships[91])[92].

The establishment of HERA addressed the need to address vaccine shortages

In addition to Action 17**,** the Roadmap foresaw other actions which aimed to address issues in relation to vaccine supply, and which were subsequently delivered through the establishment of HERA. **Action 19**[93] has been delivered, with HERA aiming to support Member States in their supply by finding solutions to address Member State needs through better cooperation and good allocation of production according to demand. Moreover, Action 20[94] addressed needs in relation to vaccine shortages by providing HERA with the mandate to consider possibilities for improving capacity of EU manufacturing. Both actions stood out in the survey, with over half of respondents deeming each action highly relevant to address vaccine shortages in the EU (16/30 for Action 19 and 17/30 for Action 20; and around an additional third of respondents considering both actions relevant).

In addition to the above-mentioned actions, **Action 23**[95] also contributed to addressing supply risks. The medicine distribution chain is complex and goes through manufacturers, medicinal products manufacturers, wholesalers (final or intermediary), third-party repackagers, before arriving at dispensers and finally the patient. This creates multiple bottlenecks that can cause shortages: manufacturing problems, insufficient stocks available on the market, to economic reasons (prices, exports, etc.)**.** Article 81 of Directive 2001/83/EC obliges the marketing authorisation holders (hereafter 'MAH') of a medicinal product and the distributors of the said medicine to ensure, within the limits of their responsibilities, appropriate and continued supplies so that the needs of patients are covered.

Deliverable 53 took the form of a survey to Member States (and Norway) on their measures under Article 81, with the goal to exchange information on the efficient addressing of shortage of medicines. The Survey results were presented to the Member States in an ad-hoc technical meeting under the Pharmaceutical Committee on shortages of medicines, on 25 May 2018[96], and found that the obligation is transposed into Member State regulation, but rarely enforced or with shortage mitigation or even definition. To build on this study, a paper on the obligation of continuous supply to tackle the problem of shortages of medicines was presented and adopted at the meeting[97], intending to provide a common understanding of Member States expectations and the Commission understanding of the obligation to supply, without constituting a formal interpretation of Union Law.

---

[89] Council Regulation (EU) 2022/2372: *Publications Office (europa.eu).

[90] Article 12 of Regulation (EU) 2022/2371.

[91] Regulation (EU) 2021/695.

[92] Factsheet on the European Health Emergency preparedness and Response Authority (HERA) (europa.eu)

[93] Action 19: Consider developing a concept for a mechanism for exchanging vaccine supplies from one Member State to another in case of an outbreak, improving the links between supply and demand for vaccine

[94] Action 20: Consider possibilities for improving EU manufacturing capacity, ensuring continuity of supply, and ensuring diversity of suppliers

[95] Action 23: Monitor compliance with the obligation of continuous supply of medicines placed on marketing authorisation holders (Article 81 of Directive 2001/83/EC) and explore ways to enhance compliance with that obligation

[96] Ad-hoc technical meeting under the Pharmaceutical Committee on shortages of medicines, 25 May 2018 (europa.eu)

[97] ev_20180525_rd01_en_0.pdf (europa.eu)

This action thus contributed to establishing ways forward in terms of obligation of supply and shortage risks at Member State level, which was recognised by the respondents to the survey (22 out of 30 respondents judged it at least relevant). Its relevance did not however stand out as being especially relevant compared to other actions (30% of respondents judged it highly relevant), which may be attributed to its regulatory-focussed angle.

Action 18[98] was also relevant to address the need relating to vaccine shortage risks, and this was also the opinion of 70% of respondents to the online survey (n=21, 30 responses). However, this action was overcome by the creation of the Health Emergency Preparedness and Response Authority (HERA). Among specific actions expected, HERA will have "to monitor and pool production capacity and development facilities, raw material requirements and availability, and ensure that supply chain vulnerabilities are addressed"[99], as well as to "ensure that sufficient production capacity will be available, when necessary, as well as arrangements for stockpiling and distribution"[100].

While the above actions have been identified as 'completed' due to the establishment of HERA, their long-term results and impacts and the manner in which they are overall relevant are yet to be observed. Indeed, while HERA has been identified by European umbrella organisations as well as EU Institution representatives through interviews as a positive evolution to address needs relating to shortages and preparedness, it was acknowledged that time is needed to examine how HERA will evolve. Moreover, it was acknowledged by representatives of national authorities and EU Institutions that further reflection is needed to define what the key policies should be in relation to stockpiling and addressing potential shortages moving forward.

3.1.10 Underdeveloped Research and Development Landscape

Need identified in 2018	The Council Recommendation identified the need to rapidly advance the research and development of new vaccines as well as improve or adapt existing vaccines, in the same perspective of what had been done with the CHO, GloPID-R, CEPI, as summed up in the Commission Communication in Pillar III. To do so, a need was identified to develop innovative partnerships and platforms as well as create stronger links between disciplines and sectors. Recommendation 15 recommended to increase the effectiveness and efficiency of EU and national vaccine research and development through reinforcing existing partnerships as well as considering investing in behavioural and social science.

The Roadmap foresaw actions to boost research and development primarily through the financing of projects under the Horizon Programmes

A number of actions in the Roadmap aimed to boost the research and development landscape in relation to vaccines. **Action 8**[101] focused on supporting research and innovation through the financing of projects under Horizon 2020 and Horizon Europe. Through its Deliverable 22, a number of significant projects, such as Vaccelerate[102] and TRANSVAC2, were funded to support research and innovation., Action 8 thereby directly contributed to meet the need of a better developed R&D landscape in the EU. This is confirmed by stakeholders who responded to the online survey: this action stood out, as half respondents considered Action 8 to be highly relevant to address the fragmented vaccine R&D landscape across the EU, and an additional 30% considered it to be relevant.

[98] Explore feasibility of physical stockpiling and engage in a dialogue with vaccine producing companies on a mechanism to facilitate the stockpiling and availability of vaccines in case of outbreaks, taking into account global shortages of essential vaccines.

[99] Commission Communication Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0724&from=EN

[100] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0724&from=EN

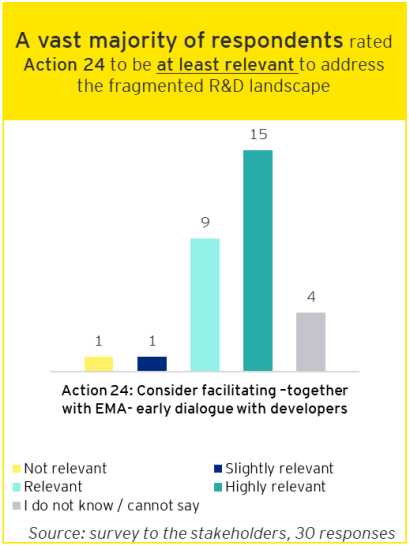
[101] Action 8: Continue to support research and innovation through the EU framework programmes for Research and Innovation for the development of safe and effective new vaccines, and the optimisation of existing vaccines.

[102] Link to the project website: https://vaccelerate.eu/

Action 26[103] was the framework of several deliverables that were aiming to bring out the identification of unmet population needs, consensus on the list of vaccines of high priority, an annual list of research priorities and a report on a proposal for shared funding mechanisms for research and development. All of the deliverables under Action were carried out under EU-JAV's WP7. With these deliverables, the action was relevant in addressing the need of a better developed R&D landscape, as it proposed milestones to develop research for vaccine needs of specific populations where R&D were considered as underdeveloped. Its relevance was confirmed through the online survey where 73% of respondents considered this action to be relevant, among whom 9 respondents (30% of all respondents) rated the action as 'highly relevant'.

The Roadmap also foresaw actions to ensure greater synergies with key actors in the R&D landscape for vaccines

Action 24[104] was identified by stakeholders as contributing to enhancing the innovation landscape through facilitating early dialogue with developers and EMA as well as policy makers and regulators in order to better secure the development and overall production of 'new' vaccines[105]. Half of the respondents to the online Survey did indeed rate this action to be highly relevant (n=15, 30 responses), and an additional 30% (n=9) rated it to be relevant.



In addition, **Action 25**[106] aimed at addressing the needs identified in the Council Recommendation to increase the effectiveness and efficiency of EU and national vaccines research and development. The Commission Communication recommended to create an "operational structure to enhance EU cooperation in order to address vaccine challenges, including the current fragmented vaccine research and development landscape". Through Deliverable 55 that established Vaccelerate, a clinical research network for the coordination and conduction of COVID-19 vaccine trials, launched in 2021, Action 25proved to be relevant to address the need of a better developed R&D Landscape. It acted in favour of better cooperation and coordination of public health authorities, vaccine developers, clinical trial sites and laboratories, and existing study networks across Europe. In terms of funding, the action also reinforced the European & Developing Countries Clinical Trials Partnership (EDCTP), a partnership between countries in Europe and Africa, that aims to accelerate the clinical development of new or improved health technologies for the identification, treatment and prevention of poverty-related and neglected infectious diseases, including (re-)emerging diseases. This action also stood out to stakeholders, with a higher proportion of stakeholders judging it to be only relevant (40% judged it relevant, and 40% highly relevant).

3.2 Q2: To what extent have the needs existing at the time of adoption of the Council Recommendation evolved or have new needs arisen?

The Study presents in the following sub-sections the manner in which the needs identified at the time of adoption of the Council Recommendation have evolved and identify the manner in which new needs have arisen.

The figure below presents an overview of stakeholders' perception of the relevance of the needs in 2018 and the evolution of their perception on these needs in 2023. When looking at the evolution of the priority ranking between 2018 and 2023, it seems that **all needs are thought to be overall even more of a priority.** It should

[103] Action 26: Seek consensus on unmet population needs and agreed priorities for vaccines that can be used to inform future vaccine research funding programmes at national and EU level, including leveraging the advantages of the Coalition for Epidemic Preparedness Innovations (CEPI) and the Global Research Collaboration for Infectious diseases Preparedness (GloPID-R).

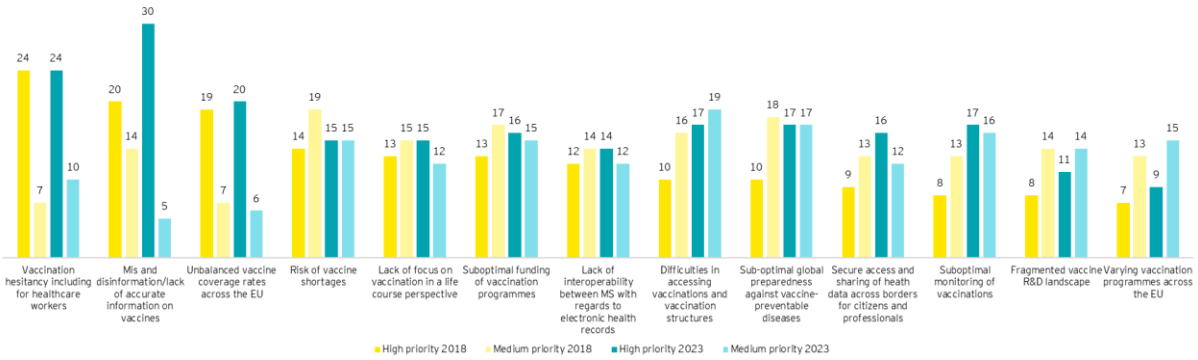
[104] Consider facilitating –together with EMA- early dialogue with developers, national policy makers and regulators in order to support the authorisation of innovative vaccines, including for emerging health threats.

[105] Action 24 was formulated after Recommendation 14h of the Council Recommendation.

[106] Reinforce existing partnerships and research infrastructures and establish new ones through clinical trials

however be noted that the ranking may also be linked to the respondents' individual areas of expertise and interest.

Figure 7 Comparison: priority level ranking at the time of adoption of the Council Recommendation in 2018 and as of Today (2023)



Source: Online Survey to the stakeholders (n=42)

In particular, there is a **sharp increase in the perception of the priority to address mis-and dis-information**, with the opinions shifting from medium priority to high priority between 2018 and 2023.

Lesser-prioritised needs in 2018 have also sharply risen in 2023, notably **the suboptimal preparedness against vaccine-preventable diseases and the suboptimal monitoring of vaccination coverage**.

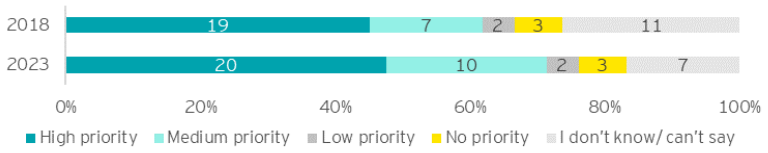
Key findings

- The need to tackle suboptimal vaccination coverage rates across the EU is still relevant, though addressing this need was hindered by other needs such as vaccine hesitancy and mis- and disinformation following the COVID-19 pandemic
- Needs directly linked to citizens' uptake of vaccinations have increased in priority level after COVID-19 pandemic: access to vaccination, vaccine hesitancy and mis- and disinformation.
- As the importance of data becomes more evident, the needs relating to access and sharing of health data continue to be of key importance
- The need to address the risks of vaccine shortages has been put in the forefront of debates as a result of experience gained through the COVID-19 pandemic

3.2.1 The need to tackle suboptimal vaccination coverage rates across the EU is still there, though addressing this need was hindered due to the shift in prioritisation following the COVID-19 pandemic

The need to tackle suboptimal vaccination coverage rates was identified by stakeholders through interviews as a continuous need which has not changed in priority between 2018 and 2023: its priority level was already among the highest and has slightly increased in stakeholders' perceptions, as also shown by the online survey results.

Figure 8 Stakeholders' perception of the priority level of the need "Unbalanced vaccine coverage rates across the EU" in 2018 and 2023 (n=42)

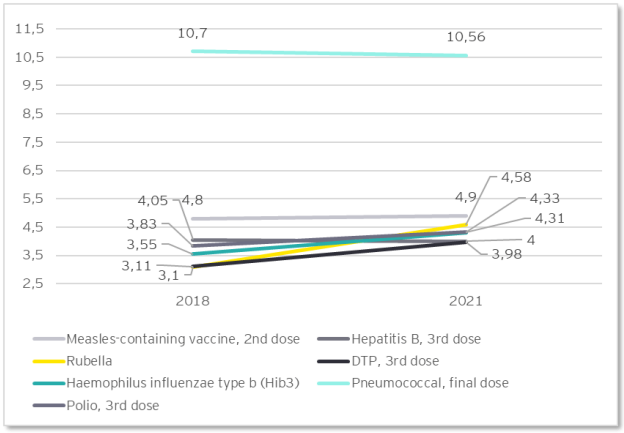


Source: Online Survey to the stakeholders

Suboptimal vaccination coverage was identified by stakeholders from all categories as an end-result of the needs and challenges previously referenced under Question 1 above.

Interviews highlighted several factors which can lead to suboptimal vaccination coverage across the EU, including the differences in price of vaccines in EU Member States (interview with association representing EU patients), the coverage of national immunisation programmes (interview with civil society organisations advocating for better vaccination coverage and public health), the relation of the population with national institutions and government (certain national authorities and association representing healthcare workers), as well as measures undertaken to combat vaccine hesitancy. According to interviewees, the COVID-19 pandemic has also contributed to the suboptimal vaccination coverage since the focus of vaccination programmes has been placed on specific vaccinations rather than focusing on vaccination programmes overall. Stakeholders from pharmaceutical associations who responded to the online survey suggested that some actions to respond to this need could be for instance to support EU Member States on how to achieve increased and sustainable financing for life-course Immunisation Programmes (with a report, guidelines, sharing of best practices on how to reallocate public funding, etc.), and a stakeholder from a non-governmental association considered that this could be achieved with greater alignment of vaccination schedules across the EU.

Figure 9 Standard deviation of national coverage rates in the EU between 2018 and 2021



Source: WHO/UNICEF Estimates of national Immunisation Coverage

3.2.2 Needs directly linked to citizens' uptake of vaccinations have increased in priority level, particularly due to the impacts of the COVID-19 pandemic on access to vaccination, vaccine hesitancy and mis- and disinformation

To date, the Study has found that a number of needs have risen in level of priority. Addressing these needs have a particular impact on citizens since they directly impact the overall uptake in vaccination. These are presented in turn below.

Addressing vaccine hesitancy was identified as a priority need by stakeholders, who emphasised that this should be addressed through a broader educational approach

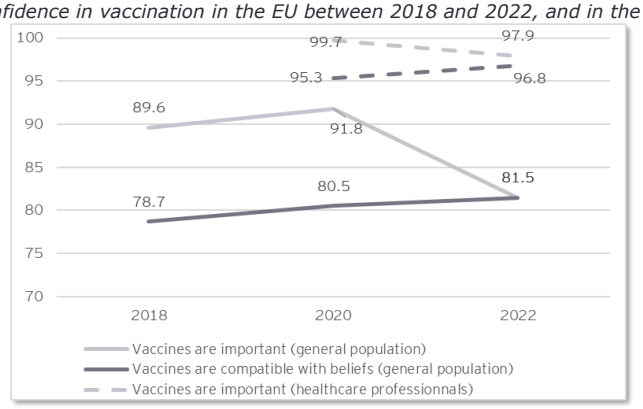
Prior to the adoption of the Council Recommendation, the European Parliament Resolution of 19 April 2018 on vaccine hesitancy and the drop in vaccination rates in Europe[107] called for Member States to take steps to ensure the sufficient vaccination of healthcare workers as well as to take steps against misinformation. The Commission Communication outlined the aim to combat vaccine hesitancy as its first pillar of action. As outlined under Section 3.1.2 above, a number of actions in the Roadmap are dedicated to fighting vaccine hesitancy, from actions providing guidelines and materials to Member States and professionals to the building of trustworthy and robust data and network, like the EVIS. These actions aimed to develop and provide evidence-based information tools and guidance in order to support Member States **in response to vaccine hesitancy**.

Vaccine hesitancy in the EU population since the publication of the Council Recommendation has increased. The Vaccine Confidence Project[108] surveyed EU citizens in order to assess confidence in vaccination and monitor public opinion. Since the adoption of the 2018 Council Recommendation, vaccine hesitancy has increased. Although two years after Council Recommendation publication a decrease was observed, vaccine hesitancy increased among EU population between 2018 and 2022 from 89.6% in 2018 to 81.5% in 2022.

[107] European Parliament resolution of 19 April 2018 on vaccine hesitancy and the drop in vaccination rates in Europe (2017/2951(RSP)), source: EUR-Lex - 52018IP0188 - EN - EUR-Lex (europa.eu).

[108] Source: The Vaccine Confidence Project.

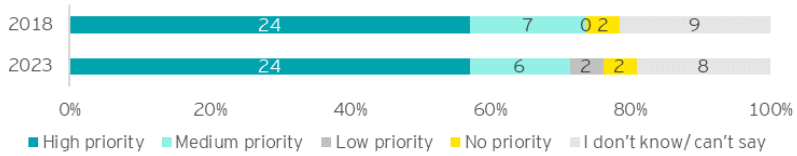
Figure 10 - Levels of confidence in vaccination in the EU between 2018 and 2022, and in the healthcare professionals



Source: A. de Figueiredo, R.L. Eagan, G. Hendrickx, E. Karafillakis, P. van Damme & H.J. Larson, Report on the State of Vaccine Confidence in the European Union, August 2022. Healthcare professional data are population-weighted averages of national confidence rates for each Member State.

Among stakeholder groups, such as national authorities, civil society organisations and healthcare professional organisations, addressing vaccine hesitancy emerged as a key priority since the COVID-19 pandemic. According to these stakeholders, the national debates with regard to vaccination and the innovation related to COVID-19 vaccines had a spill over effect in relation to hesitancy for other vaccines which is clearly reflected in the survey in 2022 of the Vaccine Confidence Project[109]. Therefore, the need to address vaccine hesitancy is still particularly relevant, together with work on access issues.

Figure 11 Stakeholders' perception of the priority level of the need "Vaccination hesitancy including for healthcare workers" in 2018 and 2023 (n=42)



Source: Online Survey to the stakeholders

There are multiple reasons for vaccine hesitancy including institutional mistrust, lack of information or disinformation and a lack of education to vaccination and immunisation. However, there is still a need for a better understanding of all the reasons leading to vaccine hesitancy, including behavioural ones. As several tools to combat vaccine hesitancy have already been deployed, stakeholders identified the need to combat vaccine hesitancy with a broader approach and specific focuses on specific sub-groups. For national authorities as well as healthcare professional associations for instance, this approach would need to enhance actions relating to onboarding more professionals in relation to vaccine information, with a focus not only on healthcare workers but also on members of education systems such as teachers. Similar to the viewpoints of organisations representing civil society, national authorities foresee a need to incorporate in education training and courses to raise awareness of children on the importance of vaccination. In light of the current geopolitical context, some stakeholders from NGOs in the area of public health also emphasised the need to address specific situations, such as vaccine hesitancy among displaced persons from Ukraine. **As a result, the need continues to be there. However, perceptions of the solution to address the need appear to have evolved among stakeholders, who would prefer a broader educational approach to address it.**

Tackling mis- and disinformation was identified by stakeholders as a key priority moving forward, with this need evolving since the adoption of the 2018 Council Recommendation

Lack of information and disinformation has continued to be identified as a hurdle for high vaccination coverage rates. In 2021, the ECDC's report on Countering Online Vaccine Misinformation[110] in the EU/EEA outlined that the phenomenon has become more important in media coverage in the past years, particularly through the rise of

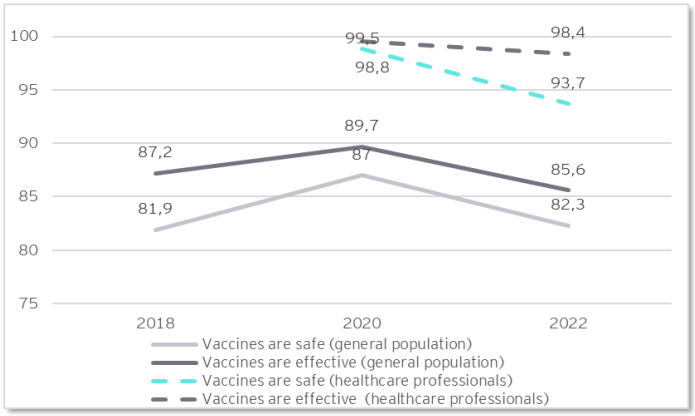
[109] Source: The Vaccine Confidence Project.

[110] Source: ECDC launches the report 'Countering online vaccine misinformation in the EU/EEA' (europa.eu).

social networks and online forums. In addition, the Vaccine Confidence Project tested the levels of agreement with the statements that vaccines are safe and effective in the 2022 report on the State of Vaccine Confidence in the European Union[111]. A decrease of around 1 percentage point was identified between 2020 and 2022 in the general population, in the context of the COVID-19 pandemic. The decreasing positive perception of vaccine was observed in the levels of agreement with the statement that vaccines are effective. The general population's view has dropped from 87.2% in 2018 to 85.6% in 2022.

In relation to the availability of accurate information in relation to vaccines, the 2022 report on the State of Vaccine Confidence in the European Union [112]found that the level of information for healthcare professionals is higher, with healthcare professionals having a more positive view regarding the safety and effectiveness of vaccines, in comparison to the general population. Nevertheless, the overall trend has also decreased in this regard since 2018.

Figure 12 Levels of information about vaccines in the EU between 2018 and 2022



Source: 2022Report on the State of Vaccine Confidence in the European Union

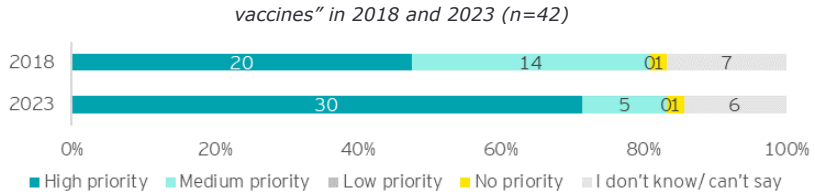
Combatting mis- and disinformation was identified by all stakeholder groups as a key priority moving forward. According to NCAs interviewed, the COVID-19 pandemic has been a trigger with greater number of citizens wishing to be better informed on vaccines particularly due to misinformation disseminated on the internet and the increase in disinformation by specific actors. Since the COVID-19 pandemic, healthcare workers have been in first line to provide patients and individuals with relevant and up-to-date information in order to respond to critical questions. National authorities interviewed therefore identified an evolving priority need to provide a higher quality of information to citizens through the provision of robust and trustful information on vaccination and vaccines, including on safety aspects. Among sources of good information, interviews showed that the European Commission is considered to be a good vehicle to provide citizens with information as it represents a more neutral administration.

Based on the interviews, it can be noted that misinformation is already a need addressed by the different measures of the Roadmap, even though a better dissemination would be welcomed by healthcare workers and national authorities. On the contrary, stakeholders interviewed highlighted the need for a stronger response in relation to addressing disinformation, particularly due to the increased use of social media. This was also confirmed through interviews with the Commission where it was highlighted that the challenges faced by disinformation are more difficult to combat and require targeted responses. The online survey also showed the heightened sense of priority concerning the specific challenges related to mis and dis-information after the COVID-19 pandemic:

Figure 13 Stakeholders' perception of the priority level of the need "Mis and disinformation/lack of accurate information on

[111] *State of Vaccine Confidence in the European Union*, August 2022 European Commission (2022) https://health.ec.europa.eu/system/files/2023-02/2022_confidence_rep_en.pdf

[112] Ibid.



Source: Online Survey to the stakeholders

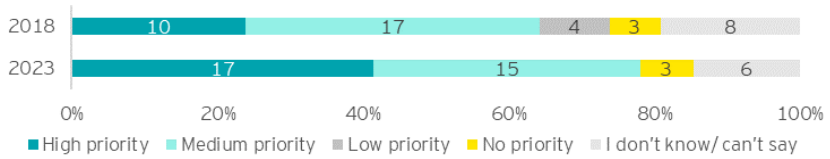
As a result, the need to address mis- and disinformation is still there but has evolved in priority and now requires enhanced collaboration and coordination for better dissemination of information, in coordination with other EU and international initiatives, and with a continued fight against disinformation on social media.

The difficulties identified in vaccinations and vaccination structures demonstrates the need for further action

Access to vaccination has been seen as a key focus at EU level, dating back to the 2006 Council Conclusions on common values and principles in European Health Systems[113] which highlighted the importance of ensuring equity of access to vaccination services regardless of social status, age, or geographical location. The importance of access to vaccination and vaccination structures has been identified by stakeholders both at national and EU level and those representing professionals (e.g. pharmacists) and civil society.

Actions of the Roadmap allowed to clarify several dimensions of difficulties in in terms of accessing vaccinations and vaccination structures, including physical barriers (such as long distance), cumbersome vaccination procedures, lack of awareness of the systems in place or less ability to interact with those systems due to illiteracy, language barriers, behavioural or cognitive bias, etc.

Figure 14 Stakeholders' perception of the priority level of the need "Difficulties in accessing vaccinations and vaccination structures" in 2018 and 2023 (n=42)



Source: Online Survey to the stakeholders

Initially ranked as a medium-priority need, addressing the difficulties in accessing vaccination structures has been identified by a large majority of stakeholders interviewed and surveyed as a priority as of today. 76% of survey respondents identified this as a priority, with 36% ranking access as a 'medium priority' and 40% ranking access as a 'high priority'. Interviews confirmed this evolution in terms of priority, but also helped to precise the scope of the difficulties that need to be tackled:

- The most frequently mentioned difficulties during interviews were those related to specific disadvantaged or vulnerable groups, for instance, the Roma and Traveller Community, as well as third-country nationals coming to EU Member States including those seeking international protection, such as displaced persons from Ukraine.
- Economic barriers were also identified as a persistent dimension of the need to address access difficulties. Most often pointed out by civil society organisations, the affordability of vaccination is still a need to be addressed to ensure a better access to vaccination. Some stakeholders advocated for a free-of-charge vaccination throughout the EU.

[113] Council Conclusions on common values and principles in European Health Systems, source: EUR-Lex - 52006XG0622(01) - EN - EUR-Lex (europa.eu)

- Distance from vaccination facilities as well as available time slots in vaccination facilities due to a stress on the number of health staff[114] also became more evident after COVID-19 pandemic that put a light on the need to possibly open the right to vaccinate to a larger range of healthcare workers, such as pharmacists. Overall, the need to address difficulties in accessing vaccination appears to be related to a need for a more community-level based vaccination facilities.

As a result, **the need to address vaccination access difficulties became more important**, but also **more specific** with the emphasis put on specific populations, affordability of vaccination and physical distance of facilities.

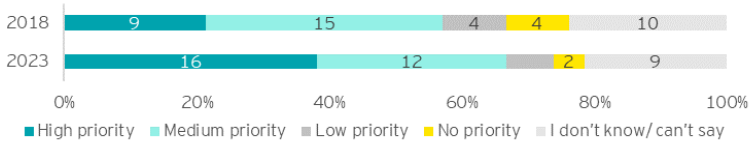
3.2.3 As the importance of data becomes more evident, the needs relating to access and sharing of health data continue to be of key importance

A persistent lack of access to and sharing of health data remains across borders for citizens, professional and national authorities, although achievements are acknowledged. As outlined under Question 1 above, the actions relating to data have been particularly relevant in contributing to the evolving policy landscape at EU level. The Commission 2019 Recommendation on a European Electronic Health Record Format[115] identified the positive impacts for healthcare professionals and citizens to access and share health data across the EU. Such exchange would (i) Improve the quality of care for patients; (ii) Diminish the cost of healthcare to citizens; (iii) Modernise healthcare systems; and (iv) Facilitate citizens' lives in cross-border situations.

Stakeholders interviewed for this Study identified the achievements that have occurred in relation to data sharing since the adoption of the Council Recommendation in 2018. The benefits of sharing health data across borders were seen through the COVID-19 pandemic through the creation of the EU Digital COVID certificate, and the proposal for EHDS Regulation.

However, the need for better access and sharing of health data persists, with stakeholders from all stakeholder groups interviewed indicating the need to further enhance access to and sharing of data. In the online survey, 38% of stakeholders considered this need as a high priority need as of today, 7 percentage points more than for year 2018[116].

Figure 15 Stakeholders' perception of the priority level of the need "Secure access and sharing of heath data across borders for citizens and professionals" in 2018 and 2023 (n=42)



Source: Online Survey to the stakeholders

The interviews undertaken showed that needs have increased in terms of ensuring that citizens and third-country nationals moving between EU Member States have access to their vaccination history. It was acknowledged by stakeholders that the creation of an EU Vaccination Card would be a way to address this need, though the technical and legal difficulties in establishing such a Card were also acknowledged by stakeholders. The use of an EU vaccination Card was also identified as a mean to better empower EU citizens with regard to the vaccination process and their ownership of their vaccination history.

Therefore, **the need still exists with more focus on concrete solutions**, e.g. an EU Vaccination Card, to finish the work undertaken through the EHDS, European Vaccination Information portal, and other Initiatives.

[114] This lack of health workforce is identified in the healthcare systems overall, source: Health-EU newsletter 250 - Focus (europa.eu)

[115] Commission Recommendation on a European Electronic Health Record Format', li

[116] Results from EY Online Survey. See Synopsis Report.

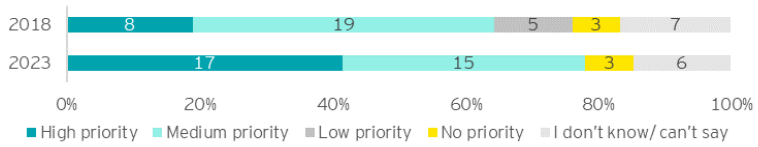
3.2.4 Suboptimal monitoring of vaccination coverage still needs to be addressed through the continued design of specific indicators

Enhanced monitoring was confirmed as a need by representatives of healthcare organisations, Member States and representatives from the vaccine industry interviewed. It was highlighted that further indicators should be defined in relation to uptake of vaccinations as well as vaccine hesitancy existing within the Member States.

Stakeholders from national authorities emphasised the importance of enhancing the information available on vaccination programmes of other Member States and enhancing knowledge-sharing in relation to vaccinations.

As result, the need has clearly evolved towards a more specific wish from national authorities to have more specific indicators with regard to vaccine uptake and coverage as well as to vaccination programmes themselves. Organisations representing the vaccine industry at national, EU and international level also indicated a shift in their perception of the priority of this need between 2018 and 2023, which can be linked to their will to contribute to better preparedness for emergencies and consolidating the vaccine R&D and manufacturing in the EU thanks to a better monitoring of vaccine need and quality across the EU.

Figure 16 Stakeholders' perception of the priority level of the need "Suboptimal monitoring of vaccinations" in 2018 and 2023 (n=42)



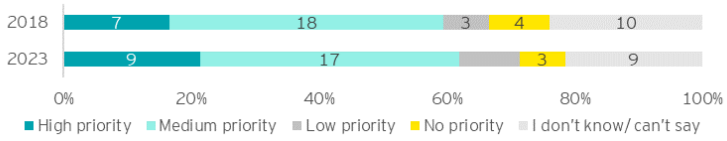
Source: Online Survey to the stakeholders

3.2.5 There is still a need to address the variation in vaccination programmes across the EU though there is acknowledgement that variations are inevitable within the EU model

Vaccination programmes differ from one Member State to another[117], in terms of (i) types of vaccines included in the programme (ii) vaccines manufacturers (iii) ages at which vaccines and boosters are recommended (iv) number of doses recommended for each vaccine (v) population (general of special groups only) for which each vaccine is recommended. These variations are caused by differences in the epidemiologic situation in each country; by differences in the way that countries make decisions and define goals; by capacity of the health system to add new vaccines; by cost; and by history and tradition[118].

While the variation in vaccination programmes was identified, interviews undertaken with stakeholder groups acknowledged that this remains a national competence, with these variations thus inherent to the structure in place within the EU. Indeed, this need is not identified as a priority by stakeholders, with 21% of respondents to the online survey considering that this need was a high priority need as of today, 4 percentage points more for year 2018.

Figure 17 Stakeholders' perception of the priority level of the need "Varying vaccination programmes across the EU" in 2018 and 2023 (n=42)



Source: Online Survey to the stakeholders

The Study identified the need to further enhance knowledge sharing and coordination between Member States in order to have the same support mechanisms in place to increase the vaccination rate while accepting that the

[117] Bernd Rechel et al., "The organization and delivery of vaccination services in the European Union", The European Observatory on Health Systems and Policies, 2018, p. 17; Vaccine Scheduler | ECDC (europa.eu)

[118] University of Oxford, Global Vaccination Schedules – General Information, last updated March 2022 (link)

variation in vaccination programmes across the EU Member States will continue to a certain extent, vaccination being national competence. EU Member States interviewed stated that information sharing and support for better cooperation and better convergence in terms of vaccination programme could not be replaced by a genuine core schedule produced at EU level, considering there might not be a "one-size-fit-all" solution for a vaccination programme to address national needs.

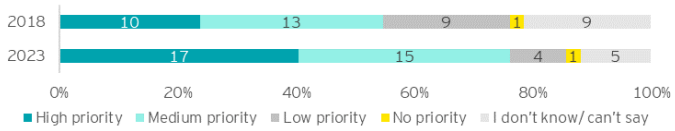
Lack of coordination between EU Member States and at international level in relation to vaccination programmes and preparedness is still a need to be addressed

While coordination between EU Member States and at international level through WHO initiatives for the European Regions or with Sub-Saharan Countries through R&D programmes has been observed, the interviews undertaken with national authorities as well as with European umbrella organisations, identified the need for further coordination as well as coherence in relation to the actions undertaken concerning vaccination programmes and policies.

Coordination between Member States was also observed and acknowledged as a success by a part of the national authorities interviewed. The use of joint procurement has been seen as the key tool for addressing preparedness within the Member States, with the deployment of joint procurement in relation to pandemic influenza vaccines considered as providing added value to Member States. The benefits of joint procurement have also been identified following COVID-19 through the joint procurement put in place in relation to the Monkeypox vaccination.

In relation to preparedness, the creation of HERA greatly contributed to address the need. However, interviews showed that there is still a constant need for better cooperation between Member States and at international level, by deploying specific actions relation to the cooperation for better vaccination programmes for preparedness for future crisis.

Figure 18 Stakeholders' perception of the priority level of the need "Sub-optimal global preparedness against vaccine-preventable diseases" in 2018 and 2023 (n=42)



Source: Online Survey to the stakeholders

As a result, **the need is persistent,** as coordination is an issue that needs to be continuously addressed through iterative actions (organising meetings, elaborating common action plan, defining same targets, etc.)

3.2.6 The need to address the risks of vaccine shortages has been put in the forefront of debates as a result of experience gained through the COVID-19 pandemic

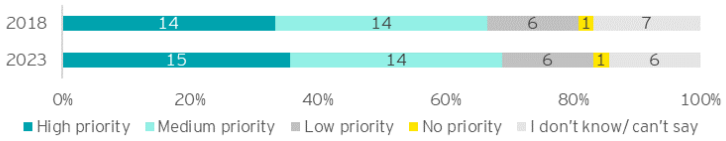
The Study conducted in 2019 by EU-JAV[119] found that the number of shortages or stockouts of vaccines remained stable between 2016 and 2018: 28 vaccine shortages/stockout events were identified in 2016, with the highest number in 2017 (33) before a decrease to 27 shortages in 2018. The vaccines most frequently involved in these shortages were Diphtheria-Tetanus-Pertussis (DTP) containing vaccines, Hepatitis B, Hepatitis A and BCG vaccines. The main causes of such shortages were interruptions in the supply chain due to quality issues as well as global shortages.

While the interviews found that Member States have not identified a significant risk in relation to vaccine shortages for 'common' vaccines, concerns were raised in interviews to ensure that the right actions are taken to address potential vaccine shortages moving forward. This means that the need to tackle shortages is still existing.

[119] Report-on-Vaccine-shortages-WP6-Task-6.1-FINAL-mod.pdf (eu-jav.com)

The establishment of HERA was also identified as positive by stakeholders at national level and those representing industry and HERA aims to guarantee sufficient preparedness and the establishment of a sufficient range of measures in case of another pandemic.

Figure 19 Stakeholders' perception of the priority level of the need "Risk of vaccine shortages" in 2018 and 2023 (n=42)



Source: Online Survey to the stakeholders

While the online survey indicated that this need's priority is rather stable, interviews showed that the need to address the risk of shortages evolved towards a need to better identify the risk of shortages between usual vaccines and new disease-related vaccine. This need for better identification should bring more specific actions on both areas.

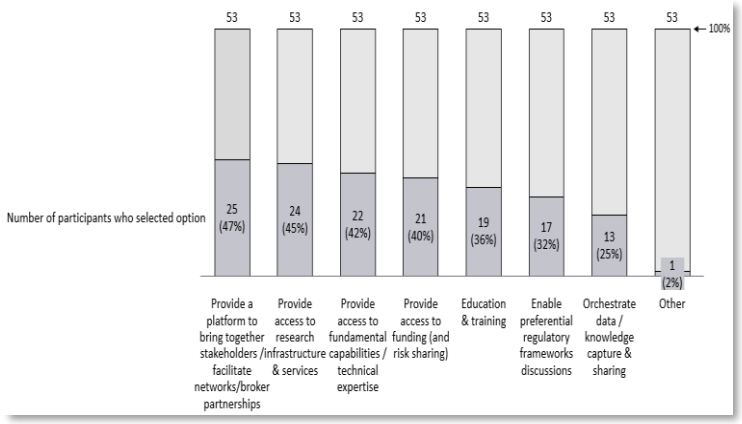
As a result, the need to address the risk of vaccines shortages has rather evolved to a need to better identify and scale the risk of shortages among the usual vaccines and the extraordinary vaccines related to new diseases.

The underdeveloped R&D landscape remains a need to be addressed, while guaranteeing coherence between the R&D projects funded by the EU

Research and development in vaccines is the first concrete step in addressing a public-health need, in order to successfully make available an effective and affordable product on the market. According to a survey of 53 vaccine R&D stakeholders[120] (universities, pharmaceutical companies, public institutions for the most part) conducted between October 2020 and June 2021 to identify "needs and gaps in current vaccine development programmes", R&D processes are however characterised by a large number of highly skilled, scientific- technical, and administrative stages, in an evolutive regulatory landscape, requiring financial and technical competencies.

Almost half of the respondents expressed the need for the system to "bring together stakeholders" (25 respondents), as well as provide access to infrastructure and services in research (24 respondents), and to fundamental capabilities and technical expertise (22 respondents). Therefore, vaccine R&D stakeholders push for support both in the technical and coordination areas.

Figure 20 Potential roles for a European vaccine infrastructure in R&D (2020-2021)

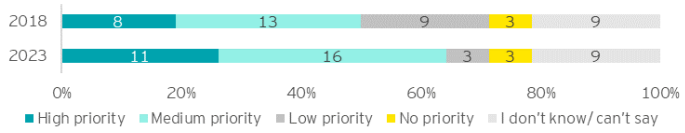


Source: Jungbluth et al., "A gaps-and-needs analysis of vaccine R&D in Europe: Recommendations to improve the research infrastructure"

[120] Jungbluth et al., "A gaps-and-needs analysis of vaccine R&D in Europe: Recommendations to improve the research infrastructure", Biologicals, Feb 2022, p. 16

During interviews, actions in relation to better cooperation between stakeholders have been considered as efficient and coherent with the need to address underdeveloped R&D landscape. Initiatives such as Vaccelerate have been for instance identified as relevant during the COVID-19 pandemic but also afterwards due to its ability to mobilise a network of R&D public stakeholders. However, one stakeholder also underlined that the mandate of Vaccelerate on Phase 2 and 3 of the clinical trials was too tight to be able to dynamise the network during the time of the funding.

Figure 21 Stakeholders' perception of the priority level of the need "Fragmented R&D landscape" in 2018 and 2023 (n=42)



Source: Online Survey to the stakeholders

As a result, the need still exists and requires to be addressed through more actions **to continuously develop the R&D landscape** including further streamlining of R&D efforts, namely in terms of coordination between stakeholders.

The manner in which the needs have evolved have also been impacted by the COVID-19 pandemic

The COVID-19 pandemic has provided both advantages and disadvantages in addressing the needs existing in relation to vaccination. The figure below summarises the positive and negative impacts identified through stakeholder consultation.

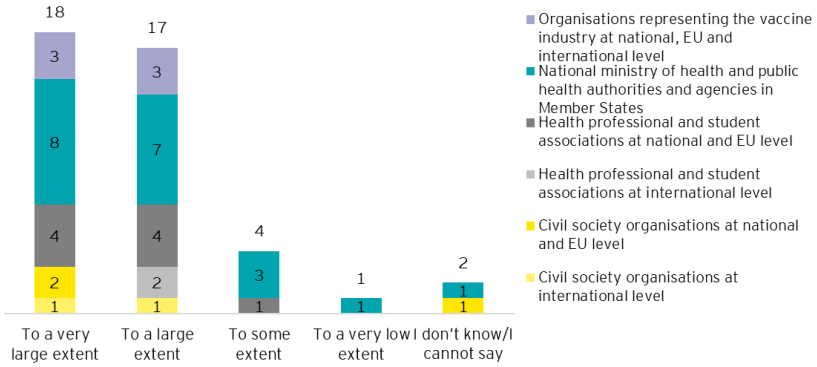
Figure 22 Impacts of COVID-19 on needs relating to vaccination

+	Positive Impacts
	- Greater investment and focus placed on public healthcare systems overall - Further emphasis placed on Health Policy at European and national level - Introduction of alternative vaccination centres in EU Member States - Increased focus on benefits of vaccination to combat new diseases

-	Negative Impacts
	- Increased mis and disinformation relating to the COVID-19 vaccine which has had a knock-on effect on vaccines in general - Vaccine hesitancy including increase of vaccine hesitancy for populations which were considered as 'pro-vaccines' prior to the Pandemic - Focus and prioritisation of specific vaccinations rather than focus on life-course approach - Reduced access to vaccinations proposed in national immunisation programmes due to reduced accessibility to schools, universities etc. - Fatigue of healthcare professionals due to COVID-19 pandemic

Overall, the stakeholder groups who perceived the most saliently the impact of the COVID-19 pandemic were organisations representing the vaccine industry at national, EU and international level.

Figure 23 Survey respondents' judgement on the questions "To what extent has the COVID-19 crisis had an impact on the needs existing in relation to vaccination?"



Source: Online Survey to the stakeholders

3.3 Q3: To what extent will the 27 actions remain relevant and address the needs still existing in the short to medium term (2- 5 years?)

When considering the relevance of the actions in the short to medium term, it is necessary to consider a number of different factors.

1. The extent to which the action, and the accompanying deliverables, will continue to be sustainable in relation to their outputs and impacts in the coming 2 to 5 years

2. The extent to which the action continues to be relevant to address needs existing and evolving

In order to be able to undertake this analysis, it is firstly necessary to consider the extent to which the actions have been completed since the adoption of the Roadmap in 2019. As previously mentioned, an overview of the 27 actions, with state of play as of June 2023, is available in Annex 7.

A mapping and analysis of the relevance of the actions in the short to medium term is presented in the sub-sections below.

Key findings

- In light of the analysis of the evolution of needs and taking into account the completion status of the different actions as well as their potential to be maintained and further developed, the Study found that approximately 75% of them will continue to be especially relevant in the short and medium term.
- In particular, the relevance of the actions relating to vaccine hesitancy and mis- and dis-information will continue to grow in the short and medium term.
- The remaining 25% of actions are still relevant to some extent, notably actions related to data and covered by the establishment of HERA.

3.3.1 Many of the actions and deliverables remain relevant in the short to medium term, though some will be outdated in the next two to five years

When considering the overall relevance of actions in the short to medium term, the findings of the Study under Questions 1 and 2 help to identify the overall relevance of actions to the needs existing both at the time of adoption of the Commission Roadmap and since 2018. Nevertheless, the extent to which the actions and the accompanying deliverables will stand the test of time, varies depending on the specific actions in place.

When examining the deliverables in the Commission Roadmap, it is clear that new deliverables need to be defined as practically all actions and deliverables have been completed. The relevance of the actions in the short to medium term must therefore be considered by assessing the extent to which the actions will continue to address

the evolving needs (as described under Question 2). The Table below presents an analysis of the manner in which the relevance of the actions is expected to evolve in the short to medium term.

It can be noted that no actions are categorised as having no relevance in the short to medium term. Which further highlights the initial relevance of the actions and objectives, and that they still continue to respond to a situation regarding vaccines which is still unresolved.

Table 2 Relevance of actions in short to medium term (Actions 1 to 6)

Action	Status	Relevance in short/medium term (2-5 years)
Action 1 – EU Vaccination Card	≈	The relevance of establishing a possible EU vaccination Card will **remain stable in the next 2 – 5 years.** In the online survey, around half of the respondents (n=25) considered this action as being highly relevant to enable the secure access and sharing of health data for citizens and professionals across the EU, which is a growing priority, although not among the most prioritised currently. Its relevance is also not expected to increase yet: it requires political discussion and cooperation between Member States, as current vaccination programmes are national competency.
Action 2 – Vaccine Confidence Report	+	The relevance of the Vaccine Confidence Report will **grow in importance in the next 2 – 5 years** as priority is placed on understanding the trends relating to vaccines. 68% of respondents to the Online Survey (n=17/25) found this action to be at least relevant. Indeed, the continued production of data related to confidence in vaccines is key to both establish a historicity between contextual developments and their correlation to vaccine confidence rates, to gain a measure of real changes in vaccine confidence over time, to put possible fluctuations (during health crises for example) into context, and to be able to make informed decisions based on up-to-date knowledge of EU citizens' main concerns.
Action 3 – Coalition for Vaccination	+	The relevance of the Coalition for Vaccination will **continue to increase** as focuses are placed on enhanced and coordinated cooperation between actors as well as on the fight against mis-and dis-information and vaccine hesitancy. During the past period, the Coalition was successfully set up and has been active in undertaking several communication campaigns towards health professionals, and over 75% of consulted stakeholders (25 exploitable responses) found it to be relevant. In the short to medium term, it will be relevant for the Coalition to maintain its activity and to amplify the reach of their actions, in order to valorise the work undertaken.
Action 4 – European Immunisation Week	+	The relevance of the European Immunisation Week will **increase** due to the rising importance that needs to be placed on communication in relation to vaccination. Already considered relevant by over 75% of respondents to the Online survey (n=19/25), and in interviews. In the next 2 – 5 years, much like other initiatives launched during the analysed period of the Roadmap, the challenges for the European Immunisation Week will be to amplify its reach in the short-term, and in the medium term to amplify the participation of EU institutions and Member States.
Action 5 – Identify barriers to access and support to increase access	+	Addressing barriers to access and support **will increase in relevance.** Indeed, the Action's title displays an ambition that has been highly recognised by stakeholders (42% of respondents to the online survey rated it as highly relevant, and almost 75% consider it to be at least relevant, 31 exploitable responses). This ambition has so far only been partially addressed in the completed deliverables. Significant progress has been made on the identification of barriers in specific sub-groups, the production of guidance to address their needs, and the dissemination of the produced knowledge – although communication on this diffusion is a continued challenge. Projects funded in 2020 also contribute to this action, although not directly identified as part of the deliverables. Continued focus is necessary to pursue and valorise the work done to actively reduce under-immunisation in in disadvantaged, isolated, and difficult to reach population groups. Furthermore, work remains to be done to further explore barriers to access and possible responses to these barriers, further contributing to the increasing relevance of this action.
Action 6 – Guidance on establishing Immunisation Information Systems for monitoring	≈	This action was focused on developing guidance on comprehensive Immunisation Information Systems to better monitor immunisation programmes. An overview of existing IIS (including reminder systems) and a state of the art in terms of what technical solutions exist to establish or enhance IIS were developed, with pilot platforms for monitoring. While some challenges remain in terms of diffusing the produced knowledge and inciting public authorities to utilise the platform, **the relevance of this Action has stabilised.**

Table 3 Relevance of Actions in short to medium term (Actions 7 to 13)

Action	Status	Relevance in short/medium term (2-5 years)
Action 7 – Guidance on Interoperability of Immunisation Information Systems	≈	Much like the previous action, Action 7 successfully established technical and legal guidance to overcome barriers impeding the interoperability of national immunisation systems. Keeping that knowledge up to date remains relevant in the context of the Commission Recommendation on a EU Health Record exchange format, making **the relevance of this Action stable in the short term.** In the medium term, this Action can also evolve towards more concrete steps towards the actual establishment of electronic health data exchange, as developing EU-wide monitoring related to vaccination is a rising need.
Action 8 – Funding Support for Research and Innovation	+	Already among the actions that stood out most to the stakeholders consulted through the Online Survey (half respondents considered Action 8 to be highly relevant to address the fragmented vaccine R&D landscape across the EU, and an additional 30% considered it to be relevant), the importance of funding support for research and innovation will **continue to increase in relevance** in order to stabilize existing programmes that have been set up through Horizon 2020 and Horizon Europe as well as during the COVID-19 pandemic, and to continue developing vaccine R&D. This is consistent with the longer-term perspective showcased in the Action from its beginning and in Horizon Europe's aims.
Action 9 – Strengthened Cooperation with International Actors and Initiatives	+	The need for enhanced cooperation with international actors and initiatives will remain relevant. The Global Vaccination Summit of 2019 was a step towards better interfacing of actors to coordinate forces and boost political commitment, which was recognised to be at least relevant by over 70% of respondents to the online survey (n=38). Continuing this event, further boosting partnerships, and continuing to fund research initiatives like GAVI (whose EU-funding has increased in the recent years following the Commission Recommendation), CEPI, GLoPID-R and JPIAMR will **continue to grow in relevance** and work remains to be done in that direction: the overall aim of Action 9 is wider than a single initiative.
Action 10 – Support for Member States to be Better Prepared	+	The need to support Member States to be better prepared **will remain relevant.** Initiatives undertaken between 2018 and 2023 (knowledge about vaccine shortages, guidelines on vaccine procurement and estimation, possibilities for joint mechanisms for joint procurement of vaccines, NITAG-networking, etc.) already contributed to fulfilling the Action's objectives, and the durability of NITAG networking is expected to hold under ECDC leadership. However, as EU-JAV highlighted, further actions can be developed to build on the existing outputs, although they depend on the involvement of European partners and Member States, and is to be fuelled by the Health Union dynamic and Member States impetus.
Action 11 – Counter misinformation and develop tools and guidance	+	Based on trends identified, this action will **continue to grow in relevance in the short to medium term**, especially to continue dealing with the fallout of the sharp surge in misinformation on the COVID-19 vaccines and its spill over effect to other vaccines. The need to fight mis-and-dis information is perceived by the surveyed stakeholders to be among the most priority needs, and Action 11 especially stood out to address it, with 77% of survey respondents (n=20/26) rating it as highly relevant. Although Action 11 is considered delivered, there is a continued need not only to update the knowledge produced on online vaccine misinformation but also to put into practice the guidance developed to fight against mis-and dis information, which is an ongoing endeavour.
Action 12 – Establish European Vaccination Information Sharing System	+	Greater information sharing relating to vaccines will **continue to increase in priority in the short to medium term.** Between 2018 and 2023, the technical, methodological feasibility of a European Vaccination Information Sharing system was studied and guidelines developed, and 82% of online survey respondents (n=38) consider this action to be at least relevant. However the Action is only partially completed: in a context where monitoring is still underdeveloped at EU level, qualitative and timely data, as well as concrete and usable platforms to share them, are still lacking to sustain operational and strategic decisions. Furthermore, the information shared on the European Vaccination Information Portal needs to be kept up to date and the notoriety of this tool to be amplified. Given all these factors, Action 12 **continues to remain highly relevant in the short and medium term** and can feature new deliverables to continue progressing towards these objectives.
Action 13 – Continuous monitoring of Benefits and Risks of Vaccines	+	The establishment of a Vaccine monitoring platform in 2022 contributed to providing a framework for independently funded studies on the benefits and risks of vaccines. Although the establishment of the platform has been completed, its sustainability and the amplification of the studies undertaken continue to be a challenge at short and medium term in order for it to effectively contribute to countering mis and dis information and vaccine hesitancy. The relevance of this Action, in light of the heightened need to provide trusted information to EU citizens, is thus **expected to increase**.

Table 4 Relevance of actions in the short to medium term (Actions 14-20)

Action	Status	Relevance in short/medium term (2-5 years)
Action 14 – Develop Common Methodologies to Assess Effectiveness of Vaccines	⊕	Based on National Competent Authority (NCA) viewpoint collection, the sharing of common methodologies of the monitoring of vaccines' effectiveness is high priority need: in 2023, 40% of stakeholders interviewed considered it as high priority need against 19% as of 2018. A first step has been undertaken towards developing common methodologies, with the ongoing dedicated study. The Action is still only partially completed, with dissemination being planned at the end of the study. **The Action will remain relevant** in the short term until completion, and in the medium term to broadcast the results and push towards taking guidance into account at Member State level and moving towards effective harmonisation.
Action 15 - Strengthen the effective application of Union rules on the protection of workers from risks related to exposure to biological agents at work	⊕	Strengthening access to vaccination in healthcare workers remains a salient need, and stakeholder's perception of the need to enhance access has increased between 2018 and 2023. The associated deliverable does not however focus specifically on Directive 2000/54/EC (healthcare workers' vaccination), which raises the relevance of further assessing the regulatory application of EU legal framework, and also to put forth concrete steps towards homogenisation. Therefore, the **relevance of this action, however specific, will continue to increase.**
Action 16 - Schoolnet and professionals' training on vaccinology	⊕	Enhanced training in schools and for professionals is a key priority identified for the coming years. Concerning the action, although the learning modules for healthcare providers to fight against mis and dis information was delivered, the Action is considered partially delayed in the Roadmap. Thus, at short and medium term, a need remains to (i) keep it up to date with potential new developments, (ii) boost its reach (only a few hundred participants so far) and (iii) make it more accessible to practitioners in their native languages. Moving forward, the relevance of this action **continues to be high.**
Action 17 - Develop a virtual warehouse on vaccines needs and stocks	⊕	The need to address the risk of vaccine shortages is considered by stakeholders in the online survey as one of the priority needs, and this assessment has remained stable for the year 2023. HERA's creation, which integrates vaccine stock monitoring responsibilities, further presses on the importance to address this need. This Action, with the work of EU-JAV, has established principles for vaccine demand and forecasting as well as a concept for a EU data warehouse, but concluded at the time that Member States saw it as relevant mainly for certain vaccines only. This was however conducted prior to the COVID-19 pandemic, which increased the priorities placed on forecasting demand and cooperating when it comes to stocks. The work of HERA, in continuity of the Action, It is therefore **relevant** in order to make progress before forgetting pandemic takeaways. The Institution's work on that topic can be still reported under Action 17.
Action 18 – Feasibility of Stockpiling	⊕	The inclusion of Action 18's purpose in the creation of HERA (increase stockpiling at EU level to address Member States' needs) continues to show how **this action's relevance remains high**, especially in the preparedness mode. During interviews, one stakeholder from EU DG also stressed the continued need to establish functional mechanisms for stockpiling and monitoring of stocks (snapshot or continuous monitoring) and the feasibility of sharing such data, and vaccine industry stakeholders saw a need to evolve physical stockpiling towards capacity reservation, especially for non-pandemic vaccines. Another stakeholder from Vaccine-advocate organisation underlined the need for a more readable and communicaable stockpiling strategy, paving the road for improvement in the next years.
Action 19 – Mechanism for exchange of vaccine supply during crisis between Member States	≈	This action is considered delivered with the creation of HERA, as the responsible EU body for structuring future vaccine supply mechanisms. HERA aims to support Member States in their supply, by namely finding out solutions to address Member States needs through better cooperation between Member States and good allocation of production according the demand. Improving the link between supply and demand is at the core of vaccine supply forecasting (i.e. preparedness) which makes the Action **relevant** as this need is considered to be important at short and medium term. For international organisations, the exchange of vaccines with countries from the Global South would constitute a higher priority, which could be considered in updates made to this Action.
Action 20 - Improve Vaccine Manufacturing	≈	By focussing on improving vaccine manufacturing in the short to medium term, its long term impacts shall be sustainable. This Action also now constitutes a structural responsibility of HERA (to address problems and difficulties related to vaccine production). Similarly to the previous actions, It is expected to have a stable relevance as part of HERA's new responsibilities, and the Institution's work on that topic can be still reported under Action 20

Table 5 Relevance of actions in the short to medium term (Actions 14-20)

Action	Status	Relevance in short/medium term (2-5 years)
Action 21 – Exploit the Possibilities of Joint Procurement of Vaccines	≈	The relevance of Actions relating to the Joint Procurement of vaccines shall stabilise, unless a Pandemic occurs in the short to medium term. It produced a joint procurement initiative for pandemic influenza vaccines between a manufacturing company and 15 EU Member States. Emergency joint procurement measures were considered to be successfully put into place during the COVID-19 pandemic and have been made durable under HERA: this **Action's relevance is therefore stable**
Action 22 – Support EU Officiel Medicine Control Laboratories	≈	The **relevance of this Action shall remain stable moving forward**, unless new challenges emerge concerning the testing and approval of vaccines that have not been covered during the 2019 meeting between the DG SANTE of the EU Commission with the EU Official Medicines Control Laboratories Network. Regular check-ins could be instituted, in order to make this action more sustainable.
Action 23 – Monitor Compliance with the Obligation of Continuous Supply of Medicines	≈	The **relevance of this Action shall remain stable** moving forward: a study has been undertaken and delivered to assess compliance with the obligation of continuous supply, and shown that it does not currently function well. Bettering the mechanisms, definitions and regulatory framework to ensure continuous supply of medicines is still relevant to need to prevent vaccine shortages. Further actions on that subject are however the responsibility of Member States, and the regular assessment of this work makes the **relevance of that specific action stable** in a European Roadmap.
Action 24 – Facilitate early Dialogue with Stakeholders to support authorisation of new vaccines	+	Actions to enhance dialogue with stakeholders shall continue to be a priority. The COVID-19 crisis showcased the importance of clarity and collaboration between researchers, industry and EU regulatory agencies to foster innovation and creation of new vaccines. Moving forward, continuing this dialogue is key in order to be able to readjust priorities in regards of shifting contexts and to create environments that are favourable to the development of new vaccines. This Action's relevance **therefore remains high.** As a responsibility of HERA and with the support of EMA, the Institutions' work on that topic can be still reported under Action 24.
Action 25 – Reinforce Partnerships and research Infrastructures	+	Ensuring partnerships and research infrastructures are enforced shall be a high priority in the short to medium term. Through the launch of VACCELERATE, the Action proved to be relevant to address the need of a better developed R&D Landscape by funding a network for clinical trials, with no previous equivalent. It is also useful for medium players of the pharmaceutical industry. The relevance of this action stood out to the stakeholders consulted in the online survey (highly relevant for 50% of respondents, n=30). As outlined by stakeholders from EU bodies and EU R&D organisation, sustainable funding is now needed in order to sustain the network, and other initiatives on different areas of expertise outside of clinical trials could be developed. This makes the Action's objective increasingly relevant in the short and medium term.
Action 26 – Seek Consensus on Unmet Population Needs and Vaccine Priorities to inform future vaccine research funding	+	Actions to address unmet population needs and vaccine priorities shall remain a high priority. The purpose of Action 26 was to establish collaboration between stakeholders to define and agree on a set of priorities and associated vaccines (including research), based on population needs. The work is considered completed in the Roadmap. About 75% of survey respondents saw this Action as being at least relevant for addressing both the need to help the research and development of vaccines, and to address uneven vaccination coverage rates. Based on interviews with stakeholders, this dialogue and subsequent prioritisation is still relevant, although some of them suggest that prioritisation of a subset of vaccines could also be broadened to a set of viral families that could become of interest in the future. One stakeholder from a vaccine advocate organisation also underlines the need to strengthen the focus on communities within the EU, but also at boarders of the EU, since virus can be cross boarders threats. Thus, this Action's **relevance is thus expected to increase** as the EU continues to push forth vaccine R&D
Action 27 – Consider investing in behavioural and social science on vaccine hesitancy determinants	+	As with Actions relating to research and innovation, there will be a **continued need** to invest in behavioural and social science. It is necessary to understand individual and collective behaviours in order to effectively combat vaccination hesitancy, which is foreseen as a highly important need to address in future years, according to stakeholders surveyed (57% rated it as highly priority need in 2018 and 2023, n=24 out of 42). Additionally, this Action could also address the need to reduce the barriers in vaccination structures access, a need of increasing importance (40% of respondents rated high priority need as of today, and 24% as of 2018), when barriers are related to some behavioural issues.

3.4 Q4: Which actions are expected to still be relevant in the long term (+10 years) and why?

When considering the extent to which actions will remain relevant in the long term (+10 years), the Study team undertook an analysis of the actions. In comparison to the ranking of priority under Question 3 above, it is anticipated that some of the actions shall stabilise in priority in the long term due to the effectiveness of actions that are foreseen to be undertaken in the short to medium term. This is the case, for example, in relation to actions relating to data access and interoperability which are expected to increase in impact over the coming years, particularly due to the ongoing work undertaken by the Commission in relation to the EHDS. While some actions are expected to stabilise in relation to their relevance, the Study team has identified certain actions that shall continue to be priorities in the long term. This is for example the case in relation to actions concerning communication and education and training which shall continue to be key issues in the long term, with new generations to be reached and trained. This can also be considered to be the case in relation to actions relating to Research and Innovation which will probably always be seen as a priority as innovation evolves. It can be noted that no actions are categorised as having no relevance in the long term, as the challenges underlying the situation in Europe regarding vaccines are expected to persist in the longer term.

The Tables below present an assessment of the manner in which the actions are expected to still be relevant in the long term.

Key findings

- In the longer term, the heightened relevance of around 50% of the actions is expected to stabilise, notably actions related to preparedness thanks to the establishment of HERA and to data and information sharing, as well as Action 2 "Vaccine Confidence Report" and Action 3 "Coalition for Vaccination" that are already well established.
- Depending on structural evolutions, in particular concerning political consensus and needs, some action's relevance may increase again: Action 3 to increase the access to vaccination, and the Actions 8, 9 with regard funding and cooperation. Also, Action 11 consisting in countering misinformation will continue to be highly relevant with the evolution in online information sharing.

Table 6 Relevance of actions in the long term (Actions 1 to 7)

Action	Status	Relevance in long term (10 years)
Action 1 – EU Vaccination Card	⊕	It is expected that the relevance of the EU Vaccination Card might increase in relevance moving forward due to continuous changing demographics and movement of EU citizens and third-country nationals, as well as the development of digital technology. Its implementation would be made also possible because of the development of the European immunisation information systems. Additionally, the last study published within the Roadmap showed the interest of EU citizens for such a card that could empower them in their relation to their health.
Action 2 – Vaccine Confidence Report	≈	In addition, the purpose of the Action is to provide updated information on the state of vaccine confidence of EU citizens. The need for updated information will be the same in 10 years. Very well welcomed by the National Authorities, this report will be still relevant at the same level, with the EU barometer monitoring Europeans' attitudes towards vaccination, as vaccine hesitancy will still be a need to address in 10 years. Specific guidance on countering vaccine hesitancy could be updated and shared once again in ten years to support the Member States in their fight, based on the main deliverable of the Action. If the action continues to be prioritised in the short to medium term, its relevance can be expected to stabilise in the longer term, once it is anchored in public policy practices.
Action 3 – Coalition for Vaccination	≈	The Coalition for Vaccination was established in 2019. If it follows its natural course of development with public support in the medium term, the relevance of sustaining the Coalition for Vaccination will be stable in the long term (10 years). The purpose of the Coalition will remain relevant in 10 years, as the Coalition for Vaccination has demonstrated its value to provide information to the public and the NCAs, who see information sharing as a key need to be continuously addressed.
Action 4 – European Immunisation Week	⊕	The relevance of the European Immunisation Week will continue to be of high priority due to the high priority need to enhance communication on a continuous basis in relation to vaccinations (71% of stakeholder surveyed rated combatting mis and disinformation as a high priority need in 2023). NCAs interviewed considered it as an useful tool, but, in the long term, it could be enhance by more coordination with the WHO for instance, and also more coordination between Member States when considering national calendars.
Action 5 – Barriers to access and support to increase access	⊕	In 10 years, sufficient actions will have been undertaken to address the main barriers, but not all barriers are identified so far, as the need has been recently addressed. Additionally, accessibility is one of the top priority areas of intervention identified by the European Commission for the following years. In addition, fighting against access to barriers will surely evolve towards more specific actions, although cost of getting vaccinated seems to remain a classic but elevant barrier to tackle,a according to a stakeholder representing parents at EU level. Therefore, the relevance of the action will still increase to finish the work undertaken so far.
Action 6 – Guidance on establishing Immunisation Information Systems for monitoring	≈	If effective immunisation information systems at a European scale are put in place, the relevance of this Action that aims to provide guidance to establish immunisation information systems will stabilise in the long term . Additionally, if such systems are implemented, this action will have to be redesigned to address possible challenges or problems of future existing information systems relating to immunisation.
Action 7 – Guidance on Interoperability of Immunisation Information Systems	≈	If interoperability is prioritised in the short to medium term, it is likely that the need to establish guidance on IIS interoperability will stabilise. Updates to this guidance with future technological developments will need to be regularly made to reflect the up-to-date state of the art, and in the event of effective linking of national IIS (or the establishment of an IIS at EU scale), the guidance will remain relevant to address possible arising issues.

Table 7 Relevance of actions in the long term (Actions 8 to 13)

Action	Status	Relevance in long term (10 years)
Action 8 – Funding Support for Research and Innovation		Funding of research and development shall continue to be a priority area in the next 10 years in order to guarantee research and innovation capacities on vaccines within the EU. As highlighted during the interviews and through the survey, the EU has accomplished several steps forwards in terms of funding, these recent years, with the creation of HERA, the creation of platforms such as VACCELERATE that contributed to better organising the use of funding as well as the mobilisation of funding. However, the stakeholders also underlined the relatively limited funding for vaccination in the EU compared to the United States and BARDA. They also mentioned the 7-year funding program as an challenge to build a robust and continuous R&D landscape, especially considering the tasks to undertake in order to prepare future health threats. Therefore the Action on funding will be increasingly relevant and should be continued.
Action 9 – Strengthened Cooperation with International Actors and Initiatives		Actions to guarantee the coherence of cooperation with international actions will remain a priority, as health is a global issue that deserves to be addressed in connection with other global initiatives. The COVID-19 pandemic has shown that viruses are cross-borders threats and require global response to fight them and not letting low- and middle- income countries aside, for instance countries in Africa. Stakeholders from International Non-Governmental organisation relating to vaccination interviewed underlined the necessity that the EU continues to support international initiatives to develop R&D on vaccines such as EVI, GAVI as well as the development of local productive capacities.
Action 10 – Support for Member States to be Better Prepared		Even if effective Actions are put in place with the development of HERA in the short to medium term to define better preparedness, the relevance of this Action will increase, since Preparedness is a major challenge for the long term and can be further developed by the European Commission. It will remain an important general issue related to the Preparedness of the European Union in the area of stockpiling, but also research and development to be prepared in case of emergency crisis. This will need to be monitored to identify future needs to address.
Action 11 – Counter misinformation and develop tools and guidance		Actions to address mis- and dis-information shall continue to be required in the long term with the evolution in online information sharing. The COVID-19 pandemic and the quick vaccine research and development period showed how much social media and digital environment are the first area of information sharing with the accompanied risk of mis- and dis-information. Action 11's relevance will therefore increase as the fight for a good and scientific evidence-based information sharing will occur on internet where it is difficult to react since the web is a large space of intervention. One EU Member State has already launched workshops to reflect on solutions for countermeasures in a large spread of mis and dis-information during a health crisis, such a digital task force for digital actions against mis- and disinformation spread.
Action 12 – Establish European Vaccination Information Sharing System		If effective efforts are made to enhance information sharing, the need for this Action on building digital information infrastructure will stabilise – Action 12 is not already completed. However the scope of the action is well defined and corresponds to a specific intervention to build digital infrastructure. Once realised, the objective of this Action will be completed and the relevance stabilised.
Action 13 – Continuous monitoring of Benefits and Risks of Vaccines		The monitoring of benefits and risks of vaccine shall continue to be of relevance in the long term as science evolves, new vaccines are created and a new generation needs to be informed. As shown by the COVID-19 pandemic, information on the quality of vaccine can contribute to sharing evidence-based information. This Action indirectly addresses the need to have a high quality information on vaccines' results and impacts on immunisation and global health state that can be used to counter disinformation for the benefit of EU citizens. It also indirectly addresses the issue of preparedness in monitoring the new innovative vaccines and their outputs, helping to enhance their impacts and estimate the level of preparedness of the EU. Therefore, the relevance of this Action will increase in the future 10 years as combatting vaccine hesitancy and preparing the EU for emergencies have been identified as key priorities for the future.

Table 8 Relevance of actions in the long term (Actions 14 to 20)

Action	Status	Relevance in the long term (10 years)
Action 14 – Develop Common Methodologies to Assess Effectiveness of Vaccines	≈	Following the forecasted developments and implementation of common methodologies to assess vaccine effectiveness, it can be expected that the relevance of this Action will stabilise and a new Action could be developed to foster the effective harmonisation of methodologies in EU Member States.
Action 15 - Strengthen the effective application of Union rules on the protection of workers from risks related to exposure to biological agents at work	≈	This Action is considered in the updated version of the Roadmap. It consisted in the evaluation of the implementation of the Directive 2000/54/EC accompanying the Commission's Communication on the EU strategic framework on health and safety at work 2021-2027. In ten years, relevance is hard to assess as the strategic framework may change after 2027. It will need to be reconsidered to see whether there is a need to strengthen the access to information for workers in relation to vaccination.
Action 16 - Schoolnet and professionals' training on vaccinology	+	This Action is considered as delayed, and therefore still need to be fully implemented. Training and education could continue to be support by relevant Actions moving forward due to the need to continue training of new professionals and students. However, in the long term, this Action shall be further developed taking account of the already full curriculum of healthcare students, as underlined by National authorities and healthcare professional representative associations.
Action 17 - Develop a virtual warehouse on vaccines needs and stocks	≈	This Action is considered delivered, partially due to the set-up of HERA. As the scope of the Action consisted in the realisation of a study on the possibility stockpiling the relevance of such action *per se* is considered stable when projected in future years. As said previously in Question 3, the relevance of the action now falls under the development of and the outputs of HERA in relation to stockpiling can be reported under Action 17.
Action 18 – Feasibility of Stockpiling	≈	This Action is considered delivered with the creation of HERA. In 10 years, it can be expected that the impacts of the creation of HERA will disseminate stockpiling mechanisms and push forward the development of stockpiling strategies at EU and Member State level. Additionally, as stockpiling is a key pillar of the preparedness of the EU, the Action will remain relevant at a stable level since the first purpose of the Action has been fulfilled but the general objective remains relevant.
Action 19 - Mechanism for exchange of vaccine supply during crisis between Member States	≈	The Action is considered delivered due to the set up of HERA. As underlined in the previous table related to Question 3, the scope of intervention of the Action remains relevant, and efforts should be continuously implemented to always support any possibilities in the exchange of vaccine supply between Member States in case of emergency. As a result, in the next 10 years if nothing changes, the relevance of the action will remain stable, without being a key priority.
Action 20 - Improve Vaccine Manufacturing	≈	This Action also now constitutes a structural responsibility of HERA (to address problems and difficulties related to vaccine production). At long term, the relevance of this Action will remain stable as its purpose relates to the continuous improvement of EU Vaccine Manufacturing in order to strengthen preparedness of the EU.

Table 9 Relevance of actions in the long term (Actions 21 to– 27)

Action	Status	Relevance in the long term (10 years)
Action 21 – Exploit the Possibilities of Joint Procurement of Vaccines	≈	Following the same reasoning as developed in Question 3, the relevance of Actions relating to the Joint Procurement of vaccines will likley stabilise in the long term, unless a pandemic occurs in the next ten years.
Action 22 – Support EU Official Medicine Control Laboratories	≈	In the long term, the relevance of this Action shall remain stable moving forward, unless new challenges emerge concerning the testing and approval of vaccines as mentioned in the response to Question 3.
Action 23 – Monitor Compliance with the Obligation of Continuous Supply of Medicines	≈	The relevance of this Action shall remain stable moving forward. The compliance of marketing autorisation holders to the obligation of continous supply of medicines is an issue to be continiously addressed, but without being a high priority need, as actions have already been undertaken.
Action 24 – Facilitate early Dialogue with Stakeholders to support authorisation of new vaccines	+	At short/medium, the first years following the COVID-19 pandemic will give the time to gain experience on managing emergency R&D and innovative solutions to boost R&D in case of health emergency crisis. In the long term, the next 5-10 years shall continue to give room and priority to enhancing the early dialogue with the R&D stakeholders. Additionally, this action would contribute to addressing the increasing priority need of sub-optimal global preparedness (40% considered it to be a high priority need as of 2018 and today), as productive and dynamic R&D sector is a key element to ensure preparedness for a possible next pandemic.
Action 25 – Reinforce Partnerships and research Infrastructures	+	In the long term, as this Action implies to align with the needs of the stakeholders and with external factors such as vaccine demand and health threats, ensuring that partnerships and research infrastructures are enforced shall continue to be a priority. Cooperation and support of the EU to research infrastructures are also among the most significant expectations of the stakeholders.
Action 26 – Seek Consensus on Unmet Population Needs and Vaccine Priorities to inform future vaccine research funding	+	In the long term, as demographics change, actions to address unmet population needs and vaccine priorities will remain a high priority through the continuous and better dialogue and collaboration between all stakeholders from researchers to vaccine industry and Member States in order for vaccination funding programmes to be adapted to current needs.
Action 27 – Consider investing in behavioural and social science on vaccine hesitancy determinants	+	In the long term, in addition to combatting vaccination hesitancy and lifting cognitive barriers to vaccination structures access, investing in behavioural and social science can contribute to reducing the uneven vaccination coverage rates. 53% of respondents to the online survey saw this action as highly relevant to address uneven vaccine coverage rates across the EU (and overall 84%, n=32/38). This Action's relevance in the long term is expected to be sustained, as social determinants are likely to evolve and shift current knowledge of behavioural factors to vaccine hesitancy. There is thus an ongoing relevance to continue researching vaccine hesitancy determinants to respond quickly to new developments.

While actions are considered as staying relevant in the long-term, the manner in which the actions are formulated and the stakeholders to be targeted will need to be fine-tuned moving forward. This is further analysed under Questions 8 and 9 below.

4 Findings relating to Coherence and Complementarity (Questions 5 – 7)

The Study aims to respond to the following questions in relation to coherence and complementary.

Study Questions	Q5. To what extent are the actions coherent and complementary to the other 27 actions? Q6. To what extent are the actions coherent and complementary to other Commission policy initiatives? Q7. To what extent are the actions coherent and complementary to policy initiatives undertaken at international level e.g. WHO?

Our approach to responding to the Study Questions

The Study Questions in relation to coherence concern both internal coherence (i.e. the coherence of the actions between themselves) as well as external coherence (i.e. the coherence of the Roadmap and actions with other policy initiatives). This has been undertaken through the examination of the objectives of the specific actions in order to identify synergies, complementarities and/or overlaps existing.

4.1 Q5: To what extent are the actions coherent and complementary to the other 26 actions?

When responding to this question, it is important to note that the Study team focuses on Actions 1 – 27 of the Commission Roadmap since Action 28 of the Roadmap relates to the present Study (see Section 1.2 above) .

Key findings

- Overall, the analysis of the 27 actions showed that the Roadmap is internally coherent, as all the 27 actions contribute to increasing the vaccination coverage rates across the EU, which is the primary need to be addressed through the Roadmap.
- The categorisation of the 27 actions showed that (i) several actions contribute in different ways to the same specific issues covered by the Roadmap, (ii) some actions can also contribute to several areas of interventions being therefore complementary in a more transversal way, (iii) complementarity between the 27 actions can be also assessed through the variety of stakeholders, from national authorities, researchers, and citizens, targeted by the actions

4.1.1 The 27 actions all aim to contribute to the primary goal of increasing vaccination coverage rates across the EU

The 27 actions of the Roadmap all aim to contribute to increasing the vaccination coverage rates across the EU. The actions can be grouped into sub-groups which pursue this aim through different means:

1. Actions to provide information to individuals, professionals and national authorities that aim to tackle vaccine hesitancy in line with the first pillar presented in the Commission Communication[121],

[121] European Commission COM(2018) 245 final, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, "Strengthened Cooperation against Vaccine Preventable Diseases", 26.4.2018. Source: EUR-Lex - 52018DC0245 - EN - EUR-Lex (europa.eu)

2. Actions to improve the conditions relating to research and trials for scientific and industry stakeholders, that contribute directly to the second pillar 'Sustainable vaccination policies in the EU' identified by the Commission Communication as a priority,

3. Actions to improve the purchase of vaccines for Member States, providing responses to meet the objective of having sustainable vaccination politics across the EU too (second pillar),

4. Actions to introduce innovative solutions for better data to monitor the needs of vaccines, vaccination rates and risks of vaccine shortages, contributing both to Pillar I and II.

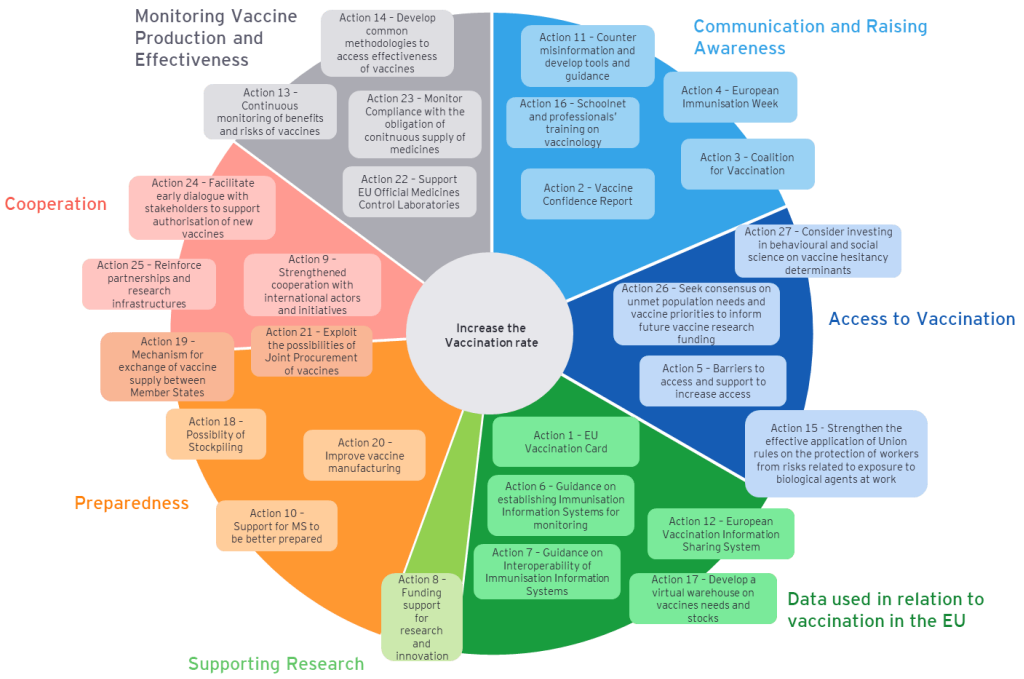
5. Actions to strengthen the cooperation between Member States, stakeholders of the EU vaccination eco-system (national authorities, regulatory agencies, laboratories, vaccine industry, and healthcare workers), as well as international initiatives, enabling the Roadmap to contribute to the Pillar III about EU coordination and contribution to global health.

However, actions are not specifically organised and identified within categories, with specific objectives and a list of related actions. The logical presentation of the individual actions can be questioned, since their simple organisation by number, rather than by category, leaves the Roadmap without a logical categorisation of the types of actions that have been defined. For instance, the first part of actions is a mix of actions relating to data and information systems (EU citizen's vaccination card feasibility study with **Action 1**, electronic immunisation Information system **Actions 6 and 7**) and actions relating the provision of information to individuals (**Action 3** with EU Coalition for Vaccination, Immunisation Week – **Action 4**), and national authorities (report on the State of Vaccine Confidence in the European Union – **Action 2**, identification of barriers to access vaccination and support interventions to increase the access at national level – **Action 5**). This lack of categorisation can be seen as providing a certain level of incoherence and inconsistency, and this was also identified by stakeholder groups consulted during the Study.

While no formal classification of actions exists in the Roadmap, a classification by seven areas of intervention can be defined: (i) Raising awareness; (ii) Access to vaccines; (iii) Use of data in relation to vaccination in the EU; (iv) Supporting Research; (v) Preparedness for future health threats; (vi) Cooperation inside the EU and internationally; (vi) Monitoring vaccine production and Effectiveness.

The classification, presented in the figure below, demonstrates the overall coherence which exists in relation to the actions and the manner in which specific actions are coherent with others presented within the Roadmap.

Figure 24 - Classification of the 27 Actions by areas of intervention



Source: Roadmap accompanying the Council Recommendation

4.1.2 Categorisation of actions within the Roadmap demonstrates the complementarity between actions

Among the 27 actions, complementarity between actions can be identified as several actions contribute in different ways to the same specific issues covered by the Roadmap. For instance, two key areas of intervention can provide clear examples relating to complementarity:

- **Increasing Awareness** regarding the importance of vaccination is a key need to be developed in the area of vaccination. This is tackled through several actions within the Roadmap. Some actions aim to contribute to improving access to information namely due to the Working group of healthcare professionals (for instance, **Action 3** with the establishment of the Coalition for Vaccination). The improvement of information can also be observed through ECDC involvement in the EU Immunisation Week (**Action 4**) to raise public awareness, as well as actions aimed at providing healthcare workers with materials and tools to combat vaccine hesitancy (**Action 2** with the report on Vaccine Confidence in the European Union, **Action 11** on countering online misinformation, and **Action 16** on e-learning about vaccination and vaccinology for professionals). These actions all coherently contribute in their way to strengthening public awareness and improving vaccination rates.

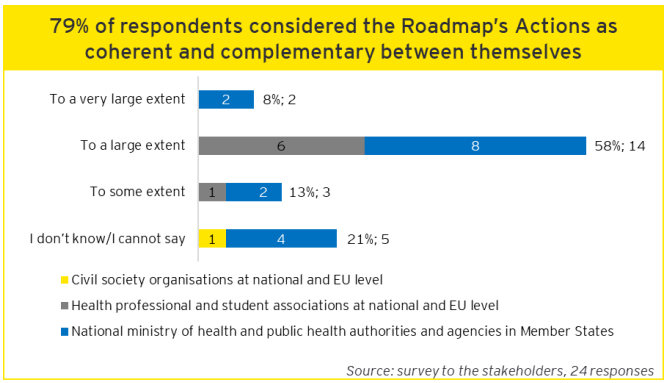
- With regard to **the use of data**, several actions of the Roadmap implicitly identify the use of data in relation to vaccination in the EU. A set of five actions were undertaken to make the best of the available and potential data on vaccine and vaccination in the EU Member States. **Action 1** on the EU citizen's Vaccination Card which is one of the key pillars of the better use of data, through its studying of existing systems, their interfacing, and the added value of citizens, **Action 6** on the guidance for the IIS in the Member States in coherence with **Action 7** working the possible interoperability of the IIS all contributed to achieve a better use of data that aims to increase the vaccination rate. **Action 17** also contribute to make the best use of data with the development of a virtual warehouse mapping the vaccine needs and stocks.

Actions can also contribute to several areas of interventions, being therefore complementary in a more transversal way. For instance, the Roadmap defines specific actions focusing on both 'Cooperation' (**Action 19**) and 'Preparedness' (**Action 21**). These actions contribute to helping Member States to be better prepared in case of a health-crisis situation with collaborating initiatives such as the exchange of vaccine supply between Member States and the joint procurement of vaccines. By presenting actions that apply on two areas of intervention, the Roadmap produces complementarities between actions. The complementarity of the actions in the Roadmap can also be observed through the contribution of actions in helping the vaccine industry and other stakeholder producers of vaccines (i.e. laboratories for prototypes and vaccine for essays) to have a clearer vision on efforts being undertaken in the making of vaccines, with a better collaboration between stakeholders. These actions comprise a panel of measures from supporting research and development (**Action 8** with funding programmes), as well as trials (**Action 25** that aims to reinforce partnerships and research infrastructures including for clinical trials), to actions contributing to improving the dialogue between developers, national authorities and regulators when putting innovative vaccines onto the market (**Action 24** on the facilitation of innovative vaccine authorisation).

Finally, **complementarity between the 27 actions can be also assessed through the variety of stakeholders, from national authorities, researchers, and citizens, targeted by the actions**. With this large panel of stakeholders, the Roadmap deploys a real comprehensive approach to vaccination. Varying stakeholder groups are targeted either directly or indirectly through specific actions within the Roadmap. Moreover, some actions focus directly on specific stakeholder groups. This is the case, for instance, in relation to **Action 26** which aims to focus on individuals within specific unmet needs in relation to vaccination as well as **Action 15** which focusses on workers in the workplace. A table assesses the complementarity in annex (Mapping table of the stakeholders concerned by the actions).

4.1.3 A more formal categorisation of the actions in the Roadmap could provide additional benefits

While the Study has identified internal coherence and complementarity between the actions of the Roadmap, the coherence of the actions is not easily perceived due to a lack of categorisation. The online survey launched for the Study found that overall, 79% of respondents to the survey considered that the 28 actions of the Roadmap were coherent and complementary, with 58% considering them to be 'to a large extent' and 8% considering this to be the case to a 'very large extent'. Overall, 21% of respondents could not assess the coherence and complementarity of the actions. The interviews undertaken to date for the Study have raised questions with regard to the *perceived coherence of actions***.** As outlined above, while many stakeholders were not fully informed of the specific individual actions of the Roadmap, those stakeholders that played a role in the implementation of specific actions (e.g. EU-JAV, Coalition for Vaccination) indicated that the overall coherence of actions between themselves was not clear, with overlaps perceived in some instances in relation to the actions.



Moving forward, when considering the manner in which the actions could be further fine-tuned, the categorisation of actions could be further considered by the Commission in order to provide a Roadmap for future policy initiatives that is more streamlined in its rationale and easier to communicate to stakeholders.

4.2 Q6: To what extent are the actions coherent and complementary to other Commission policy initiatives?

EU Policy initiatives relating to health have considerably evolved since the adoption of the Council Recommendation on vaccination in 2018. While the European Commission has been promoting vaccination through EU Health Strategies and Action Plans, a considerable shift has occurred since 2018, particularly in the wake of the COVID-19 pandemic. This has been particularly the case since the launch of the European Health Union[122] in 2020 by President von der Leyen in her State of the Union Speech[123]. The Study team undertook a comparative analysis of four main initiatives that appear to be the most relevant in the field of vaccination, in order to assess the coherence and the complementarity of the 27 actions of the Roadmap:

- The EU Health Union (hereafter 'EHU4')[124], as it is an umbrella project under which the Roadmap can have close initiatives;
- The EHDS[125], as data is one of the topics tackled in the Roadmap;
- The Europe's Beating Cancer Plan[126], as it is one of the main action plans recently issued;
- The Pharmaceutical Strategy for Europe[127], as vaccination and vaccine production is directly linked to initiatives relating to pharmaceutical action areas.
- The three last initiatives are also key pillars of the EHU[128]

[122] Source: European Health Union (europa.eu)
[123] Source: European Health Union (europa.eu)
[124] Source: European Health Union (europa.eu)
[125] COM(2022) 196, Communication from the Commission to the European Parliament and the Council, 03 March 2022: com_2022-196_en.pdf (europa.eu)
[126] Europe's Beating Cancer Plan (europa.eu)
[127] Pharmaceutical Strategy for Europe, 2020: pharma-strategy_report_en_0.pdf (europa.eu)
[128] European Health Union (europa.eu)

Key findings

- Overall, the Roadmap was found coherent and complementary to the EU initiatives analysed.
- With the European Health Union, the Commission Roadmap was found to propose a coherent rationale and complementary actions tackling different needs and different stakeholder groups than the EU Health Union.
- The Roadmap had specific actions contributing directly to the objectives of the EHDS, being coherent and complementary, in particular regarding Action 1 on the EU citizen's Vaccination Card.
- The Study's assessment found that the actions in the Roadmap were coherent with Europe's Beating Cancer Plan in relation to ensuring prevention of specific diseases through vaccination.
- Overall the complementarity Europe's Beating Cancer Plan is also identified for two reasons : (i) by acting for the improvement of vaccine coverage rates, that indirectly contributes to having more people vaccinated, which is complementary to the development of a specific vaccine against HPV cancer (ii) by raising the awareness of healthcare professionals and to help Member States to communicate.
- The actions under the Commission Roadmap are overall coherent and complementary with the Pharmaceutical Strategy for Europe, by proposing a different approach in line with the Pharmaceutical Strategy for Europe's objectives.

4.2.1 The overall rationale of the Commission Roadmap, as well as specific actions, are coherent with the European Health Union

The EHU launched in October 2020 in the wake of the COVID-19 pandemic, is a vast project that aims at better protecting the health of EU citizens, at equipping the EU and Member States to better prevent and address future pandemics, and at improving resilience of Europe's health Systems. Two years after the publication of the Council Recommendation on vaccination. the EHU came out with several key initiatives to: (i) address the serious cross-border threats to health; (ii) strengthen the ECDC with an additional network of EU reference laboratories on specific diseases, and the EMA with the possibility to monitor and mitigate shortages of medicines and to faster approve vaccines; (iii) establish HERA; (iv) build the EHDS; (v) establish the Pharmaceutical Strategy; the Europe's Beating Cancer Plan; (vi) establish the State of Health Preparedness; (vii) address Global Health Security.

The coherence between the Council Recommendation and Roadmap on vaccinations as well as the EU Health Union is evident as the actions are addressing the same needs of the EU Health Union. Launched two years later, the EU Health Union also addresses other general needs of high priority: Preparedness and the development of a data ecosystem to get full return on IT technology for EU health system. Although the Roadmap was issued in 2019, a series of actions were already addressing those needs, being therefore coherent with the EHU:

- For **better preparedness**, **Action 10** on the development of evidence-based tools and guidance for Member States to be better prepared to health crisis situations as well as **Action 18** on the possibility of vaccine stockpiling aimed to address the need for mitigating the risk of vaccine shortages and for optimal monitoring of stocks of vaccine, in order to be as much as possible prepared for the next health crisis.
- For **better use of data on vaccination** across the EU, a series of actions relating to the development of digital tools and data collection were on the agenda of the Roadmap in order to make the best of the innovative technologies available: **Action 6** on better monitoring through electronic IIS, **Action 7** on the interoperability of national IIS, **Action 12** on the establishment of a European Vaccination Information System (4 deliverables completed, one deliverable pending, one deliverable under completion).

When analysing the regular updates of the Roadmap completed with new actions, it is illuminating to see how coherent the Roadmap continued to be with the EHU. For instance, Action 17, launched in 2022 for a reflection on developing a virtual European Data Warehouse on vaccine needs and stocks, was able to address at the same time the needs relating to Preparedness to new possible pandemic or cross-border health threats and needs relating to the use of innovative technologies in order to increase the vaccination coverage in the EU.

4.2.2 The actions under the Commission Roadmap ensure complementarity with initiatives under the EU Health Union

The actions of the Roadmap are complementary to the EU Health Union. They tackle different needs and stakeholder groups than the EU Health Union. The first focus of the actions supporting the Council Recommendation is on citizens as well as healthcare professionals. These actions (2 with the report on confidence, 3 with Coalition for Vaccination, 4 with the Immunisation Week, 11 on combatting mis- and disinformation, 16 on healthcare workers training) by providing them with relevant and evidence-based information to fight mis-and disinformation as well as vaccine hesitancy, complement the approach of the EU Health Union that focuses more on research, industrial production, and the use of data by Member States. Further, actions that help to identify barriers to access to vaccination structure, or that contribute to vaccination missing opportunities contribute to enrich the approach of the EU health Union for vaccination (namely Actions 5 on barriers and 27 on behavioural and social individual factors that contributes to vaccine hesitancy).

The Roadmap also appears to be a real preparatory work for the EU Health Union, as several actions were launched in 2019 and were meant to reflect on the implementation of key initiatives of the European Health Union. For instance, **Action 18** that aimed at reflecting of the feasibility of physical stockpiling in coordination with vaccine industry stakeholders was launched in 2019 contributing to address the needs related to preparedness ("risk of shortages"). **Action 19** also contributed to offer Member States tools for better preparedness to future health crisis by reflecting on the possibility of vaccine exchange between Member States, in the same way as **Action 21** has focused on studying the possibility of Joint Procurement for Vaccines. All three actions were issued in 2019 and considered delivered with the creation of HERA that aimed at preparing EU Member States which was part of the key initiatives of the EU Health Union.

As a result, the Roadmap appears to be complementary to the EU Health Union, as it has provided a different approach to vaccination targeting more precisely citizens and healthcare workers as well as being a sort of preparatory work for the creation of the EU Health Union.

Stakeholders' contributions on coherence and complementarity of the 27 actions with the EU Health Union are presented in annex.

4.2.3 Specific actions of the Roadmap contribute directly to the objectives of the EHDS and are both coherent and complementary

The EHDS is a key initiative falling under the EU Health Union. The objectives of the EHDS are to: (i) empower individuals with increased digital access to and control of their electronic personal health data; (ii) support the free movement of people within the EU; (iii) foster a single market for electronic health record systems; (iv) provide a consistent, trustworthy, and efficient set-up for the use of health data for research, innovation, policy-making and regulatory activities.

The Roadmap accompanying the Council Recommendation appears to be coherent with the EHDS as specific actions of the Roadmap contribute to achieving the objectives of the EHDS. The Roadmap indeed contributed to reflecting on the possible empowerment of individuals in coherence with the EHDS initiative thanks to **Action 1** proposing the creation of an EU citizen's Vaccination Card. The project of the EU Vaccination Card aimed to help citizens to have a better access to their own health information in order for them to control their health data, to facilitate their free movement across the EU by having an electronic document that bring secure data across borders, as well as to have a better view on their needs of boosters and life-long vaccination programmes. In addition, by publishing a feasibility study on such a Vaccination Card[129] in 2022, the European Commission was aiming to support stakeholders including Member States in identifying the potential benefits of using such a card. Other actions were also directly contributing to the objective of fostering a single market of electronic health record systems and providing a trustful data ecosystem[130].

The main result in terms of complementarity to the EHDS associated with the Roadmap relates to Action 1 Deliverable 2 with the EU citizen's Vaccination Card proposal. After surveying 78,000 citizens on the practical

[129] Deliverable 1 "Feasibility Study for the Development of a Common EU Vaccination Card" – Action 1 EU Vaccination Card.

[130] These Actions are the followings: Action 6 with sharing guidance to Member States to establish a comprehensive electronic immunisation information system (IIS), Action 7 that was meant to develop guidance in order to overcome the legal and technical barriers impeding the interoperability of national IIS and Action 12 with the establishment of a European Vaccination Information Sharing Systems for Member States and EU institutions.

relevance and degree of welcoming of such a card (Deliverable 1), the Commission's proposal for a vaccination card for EU citizens (the second deliverable of Action 1) was incorporated in the Regulation proposal for the establishment of the EHDS[131] issued in May 2022, in order to address the challenges relating to electronic health data access and sharing. Through Action 1, the Roadmap complemented the establishment of the EHDS by proposing a concrete measure (the EU vaccination card) that contributed to making a step forward in the direction of a common EU health information data space.

Stakeholders' contributions on coherence and complementarity of the 27 actions with the EHDS are presented in annex.

4.2.4 The actions in the Roadmap are coherent with Europe's Beating Cancer Plan in relation to ensuring prevention of specific diseases through vaccination

Europe's Beating Cancer Plan was presented in 2020, as a new EU Approach to cancer prevention, treatment, and care. It aims at tackling the entire disease pathway, from prevention to quality of life of cancer patients and survivors. As part of the four key-action areas of the Beating Cancer Action Plan, prevention is directly related to vaccination and therefore makes bridges with the Council Recommendation on Vaccination. Among specific objectives mentioned in the Plan, improvement of the Human papillomaviruses vaccination coverage of girls and boys is identified as key "to prevent cancers caused by infections. The goal set in the Cancer Plan's objective is to vaccinate at least 90% of the EU target population of girls and to significantly increase the vaccination of boys by 2030"[132]. In the Cancer Plan, the Commission also commits to present a proposal for a Council Recommendation on vaccine-preventable cancers, focused on supporting Member States in increasing the uptake of vaccination against to contribute to help address cancer risks associated with Human papillomaviruses and Hepatitis B.

As the Europe's Beating Cancer Plan is a holistic approach to fight against cancer across Europe, the links with the Roadmap accompanying the Council Recommendation on vaccination are limited to the part on prevention which is tackled in General Objective 3 "Saving Lives through Sustainable Cancer Prevention", as well as in General Objective 5 "Ensuring High Standards in Cancer Care".

The overall coherence between the Commission Roadmap on vaccination and Europe's Beating Cancer Plan can be seen in relation to the joint need of both instruments to increase the vaccination rate, with the Beating Cancer Plan focussing on increasing the vaccination rate in relation to Human papillomaviruses and Hepatitis B vaccination. The actions within the Commission Roadmap, relating to better information and better access to relevant information (**Actions 2, 3, 4, 11, and 16**), and barrier-free access to vaccines for all (**Actions 5 and 27**) including people with specific health needs that are not met yet, aimed at contributing to increase the overall vaccination rate in the EU.

With regard to innovation, the Roadmap appears to be also coherent with the Europe's Beating Cancer Plan, as it contributed to supporting innovation through **Action 24** for instance. This action followed the purpose to reflect on setting earlier dialogue with developers, national policy makers and regulators to work on authorization of innovative vaccines. Since COVID-19 pandemic was considered as a leap forward in terms of innovation as regards vaccine thanks to mRNA technology[133], the Cancer Plan foresees this technology as a possible new way

[131] COM(2022) 197 final Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space, available at https://eur-lex.europa.eu/resource.html?uri=cellar:dbfd8974-cb79-11ec-b6f4-01aa75ed71a1.0001.02/DOC_1&format=PDF.
Deliverable 2 of the Roadmap "Commission proposal for a common vaccination card/passport for EU citizens" was considered delivered with the publication of the Regulation on the EHDS.

[132] Action 4 and Flagship 3 « Saving Lives through Sustainable Cancer Prevention"; Source: eu_cancer-plan_en_0.pdf (europa.eu)

[133] Definition of mRNA: "mRNA (messenger Ribonucleic acid) is the molecule that direct cells in the body to make proteins. It can be used to make vaccines to prevent or treat". Source: Europe's Beating Cancer Plan.

to personalised vaccination[134]. Supporting any kind of innovation with regards to vaccination, the Roadmap is coherent with this pathway foreseen by the Beating Cancer Plan.

4.2.5 Overall complementarity Europe's Beating Cancer Plan is also identified

The actions undertaken through the Roadmap are generally complementary to the Europe's Beating Cancer Plan for two reasons:

1. The Roadmap proposed a series of actions that directly contribute to providing Member States with guidance as well as tools to ensure a better monitoring of vaccination coverage. This effort put into better monitoring aims to help Member States reaching out to specific people that will need to get vaccinated. Indirectly, such effort contributes to having more people vaccinated, which is complementary to the development of a specific vaccine against HPV cancer – such initiative that was not presented in the Beating Cancer Plan;

2. In parallel, the Roadmap proposed several actions to raise the awareness of healthcare professionals as well as to help Member States to communicate which were not included in the Beating Cancer Plan as well. For instance, **Action 2** with the publication of a report on the State of Vaccine Confidence in the European Union covers the confidence in the HPV vaccine which can contribute to help policy makers and healthcare professional to have a clear view on the vaccine hesitancy for this vaccine and apply tailor-made countermeasure to increase the vaccination rate.

Stakeholders' contributions on coherence and complementarity of the 27 actions with Europe's Beating Cancer Plan are presented in annex.

4.2.6 The actions under the Commission Roadmap are overall aligned and coherent with the Pharmaceutical Strategy for Europe

The Pharmaceutical Strategy for Europe, proposed in 2020, aimed to create a future-proof regulatory framework and to support industry in promoting research and technologies to meet patients' therapeutic needs while addressing market failures as well. Launched during the COVID-19 pandemic, it also aimed to consider the need to address future emergency health threats. As a patient-centred strategy, it aimed to ensure the quality and the safety of medicines, including vaccines. It also aimed to boost the sector's global competitiveness. This strategic plan was designed to mobilise the whole value-chain of the pharmaceutical industry, from producers of patented medicines to distributions and wholesalers. Finally, it also aimed to contribute to Europe's Beating Cancer Plan.

The coherence of the Roadmap and its actions is perceived with this Pharmaceutical Strategy for Europe through outputs of specific actions that are aligned with the objectives of the Pharmaceutical Strategy for Europe 2020. These objectives are the followings: (i) "Delivering for patients: fulfilling unmet medical needs and ensuring accessibility and affordability of medicines"; (ii) "Supporting a competitive and innovative European pharmaceutical industry"; (iii) "Enhancing resilience: diversified and secure supply chains; environmentally sustainable pharmaceuticals; crisis preparedness and response mechanisms"; (iv) "Ensuring a strong EU voice globally".

With **Action 26** that foresaw to "seek consensus on unmet population needs and agreed priorities for vaccines that can be used to inform future vaccine research funding programmes at national and EU level", the Roadmap is greatly coherent with the first objective that considers addressing unmet needs as a priority for patients, but also with the second objective that relates to supporting industry in competition with non-EU players and with innovation. Action 26 aimed at setting up a roadmap to establish a consensus on unmet needs and their priorities by EU JAV. This roadmap for reaching consensus consisted in establishing a list of needs, a list of EU vaccine research priorities on vaccines for unmet medical protection needs as well as report on a proposal for shared funding mechanisms. These deliverables were able to identify unmet needs and help to address them by

[134] « It [support from new and existing research infrastructures to researchers working on personalised cancer treatments] will also include support to further explore and develop the area of therapeutic and personalised cancer vaccination, which has taken a massive leap forward with the recent approval of mRNA-based vaccines for COVID-19 showing that this new technology is ready for wider deployment. Patients with advanced melanoma, and head and neck cancers have for example already successfully been treated with mRNA technology »; Source: eu_cancer-plan_en_0.pdf (europa.eu) p. 18 of the report Europe's Beating Cancer Plan.

supporting the research with funding mechanisms support, which is coherent with the objectives 1 and 2 of the Pharmaceutical Strategy for Europe.

In addition, **Action 8** of the Roadmap is also coherent with the objective to support the EU pharmaceutical industry in the area of research and innovation through EU framework programmes. This action aimed to link projects with available funding of Horizon 2020 and Horizon Europe. With Horizon 2020 COVID-19-related vaccination R&D projects were funded. For instance, Vaccelerate was awarded with €12 million to set up a platform connecting all European vaccine development stakeholders. Existing laboratories were also funded: BioN Tech (EU support to frontier research and applied collaborative research between academia and industry), CureVac (support for covid vaccine development, but also inducement prize in 2014).

In terms of provision of security in the supply chain and of preparedness in case of emergency which relates to the Objective 3 of the Pharmaceutical Strategy, the Roadmap also provided coherent actions. For instance, **Action 24** is coherent with the third objective of the Pharmaceutical Strategy, as it aimed to facilitate early dialogue, namely in case of emergency, with developers, national policy makers and regulators in order to support the authorisation of innovative vaccine.

Finally, the Roadmap also offers coherence with the Pharmaceutical Strategy for Europe in the area of the preparedness and measures in case of new Health crisis with the actions considered delivered with the creation of HERA, such as **Action 20** that aimed to ensure the security and continuity of the supply chain and as action 17 that proposed to reflect on the possibility of developing a data warehouse to monitor the stockpiling and needs of vaccines across Member States.

The Roadmap accompanying the Council Recommendation is also complementary with the Pharmaceutical Strategy, as it proposed a series of actions to intervene on different areas of initiatives. The **complementarity is mostly perceived through the first objective of the Strategy**. Tackling the matter of accessing medicines and vaccines for patients, the Pharmaceutical Strategy focused on affordability attempting to address the need for transparency, better pricing, and reimbursement. The Roadmap rather tackled other types of barriers through **Action 5** with the identification of barriers related to disadvantaged and socially excluded groups, as well as with **Action 27** that proposed to invest in behavioural and social science research in order to identify specific social and behavioural barriers that hamper the access to vaccination.

Besides, the Roadmap is also complementary to the Pharmaceutical Strategy for Europe as it proposed a different approach to contribute to achieve similar objectives. The Flagship initiatives of the Pharmaceutical Strategy set up for the Vaccine Industry mostly relied on revisions of legal frameworks. For instance, it proposed to "revise the legislation on medicines for children and rare diseases to improve the therapeutic landscape and address unmet needs", while **Action 26** of the Roadmap focussed on the organisation of collaboration between stakeholders to establish a consensual list of needs and then to launch R&D or manufacturing of vaccines. This focus on helping vaccination stakeholders to better collaborate (earlier, deeper, and continuously) goes also with better R&D and facilitated entrance into the market for new vaccines. For instance, actions that consisted to ensure a better exchange of data on the vaccination rate, immunisation programmes and vaccines needs embedded in the Roadmap (**Action 6, Action 7 and Action 17**) are complementary to flagship initiatives on competitiveness of the Strategy as they contributed to the same objective by (i) providing soft knowledge for Member States to establish information systems on immunization, (ii) guidance to overcome legal and technical barriers impeding the interoperability of national IIS, or (iii) by considering developing a virtual European Data Warehouse on vaccine needs.

Stakeholders' contributions on coherence and complementarity of the 27 actions with the Pharmaceutical Strategy for Europe are presented in annex.

4.3 Q7: To what extent are the actions coherent and complementary to policy initiatives undertaken at international level?

Vaccination is a public health matter that is tackled also at international level. Initiatives cover a wide range of policy areas, from vaccination programmes to strengthening research and advisory institutions to help Member States to increase their vaccination rates, as well as through general guidelines and objectives relating to Health in general.

This Study focusses on two main initiatives undertaken at international level: (i) the Global Vaccine Action Plan (2015-2020) and its declination European Vaccine Action Plan (2015-2020)[135]; (ii) European Immunisation Agenda 2030[136].

Key findings

- Coherence is observed between the Roadmap and the WHO European Vaccine Action Plan (2015-2020), as both initiatives aimed to address the same needs (e.g. mis- and dis-information) through similar actions
- Complementarity was also found with the WHO European Vaccine Action Plan, as the Roadmap presented several actions that were a step forward of the primary objective of the WHO initiative. It also proposed a complementary approach to strengthening vaccination at EU level by targeting the supply chain and the healthcare workers, as well as EU Member States.
- The Roadmap was found coherent with the WHO European Immunisation Agenda 2030 (EIA 2030) as it aimed at addressing the same needs. It was also found complementary as it targeted different types of stakeholders, other than decision-makers, national and subnational leaders and national authorities, and ministries targeted by the WHO initiative.

4.3.1 Overall coherence and complementarity are observed between the Roadmap and the WHO European Vaccine Action Plan (2015-2020)

The Global Vaccine Action Plan (2015-2020), endorsed by the 65th World Health Assembly, was translated by the European WHO Office into the European Vaccine Action Plan (2015-2020) (EVAP). Its general objective is to address the specific needs and challenges relating to immunisation and serve a vision of a European Region "*free of vaccine-preventable diseases, where all countries provide equitable access to high-quality, safe, affordable vaccines and immunisation services throughout the life course"*. This Action plan had Five Objectives: (i) make all European Countries commit to immunisation as a priority; (ii) ensure that European individuals understand the value of vaccination; (iii) ensure that vaccination benefits are extended to all people through specific and innovative strategies; (iv) ensure that strong immunisation systems are a full part of the health systems; (v) ensure that immunisation programmes have sustainable access to predictable funding and high-quality supply.

The Roadmap is coherent with the WHO European Vaccine Action Plan 2015-2020 (EVAP), as it aimed at addressing the same needs through similar objectives. First, both initiatives were built to contribute to the fight against mis- and disinformation by ensuring an accurate level of information to individuals on the benefits of vaccines and vaccination, either through awareness campaigns or through better skilled and trained healthcare workers (priority action area 3 of Objective 4 of the EVAP). Both initiatives are also coherent because they encompassed measures to address all individuals' needs, specifically the ones of marginalised communities and minorities, either with studies to identify social barriers that contribute to vaccine hesitancy or with studies to list the needs that have to be addressed specifically for vulnerable populations (Priority action area 1, Objective 3). Another key priority that both initiatives have identified and targeted in their action plan is the use and contribution of data in increasing vaccination rates. As EVAP, the Roadmap undertook an action on electronic immunisation registration either through the EHDS or the EU Vaccination Card, that makes it coherent with the WHO initiative. Further, the Roadmap also set up actions to improve and strengthen monitoring with regard to vaccination rates and the quality of vaccines, as did the EVAP with priority action area 2 of Objective 4. Finally, the actions of the Roadmap were also coherent with the action plan on vaccination of WHO as they also aim to make vaccines cheaper through joint procurement, higher dynamic competition with greater medium players thanks to EU-funded platforms such as Vaccelerate – issues that were also tackled within the WHO initiative through the priority action area 2, objective 5.

The Roadmap was complementary to the European Vaccination Action Plan 2015-2020, as several of its actions were a step forward of the primary objective of the WHO initiative. For instance, EVAP had the objective to ensure that all countries of the region commit to immunisation as a priority. The indicator was the presence of a NITAG. The Roadmap undertook actions to strengthen the coordination and the collaboration between EU Member States' NITAGs (**Action 9**), completing this EVAP's first objective of the European Vaccine Action Plan by making not

[135] European Vaccine Action Plan 2015-2020 (who.int)

[136] The European Immunization Agenda 2030 (who.int)

only a commitment at national level but also setting up an action to bring out more coordination and collaboration between these groups.

The Roadmap of 28 actions proposed a complementary approach to strengthening vaccination at EU level in comparison to what were identified in the EVAP 2015-2020. The Roadmap targeted rather the supply chain and the healthcare workers, as well as EU Member States while EVAP was more focused on Member States themselves and their leaders and decision-makers. Indeed, EVAP proposed in its first objective to attempt to make decision-makers of countries of the European region enhancing vaccination as a high-priority matter in public policy. The Roadmap accompanying the Council Recommendation was rather built to help Member States either in informing individuals and healthcare worker or in developing and purchasing vaccine.

As a result, the Roadmap is coherent and complementary with the EVAP as the actions pursed to achieve the same objectives, with similar actions, but with complementary added values such as the more developed and specific actions as well as complementing focus on healthcare workers and vaccine industry.

Overall, stakeholders' contributions on coherence and complementarity of the 27 actions with the WHO initiatives are presented in annex.

4.3.2 The actions of the Roadmap are also coherent with the evolving policy landscape set out in the WHO European Immunisation Agenda 2030

The European Immunisation Agenda 2030, set by the European Programme of Work 2020-2025 "United Action for Better Health in Europe" as one of the Europe's flagship initiatives for immunisation, provides a strategic way forward for Europe. It is built on the achievements and lessons learned from implementation of the European Vaccine Action Plan 2015-2020. The EIA 2030 have seven Strategic priorities: (i) work in "partnership and to coordinate with other [countries'] health programmes leveraging their respective capacities to strengthen the delivery of primary health care"; (ii) "ensure that national leader advocate for and demonstrate their commitment to immunisation programmes, and immunisation is valued and actively sought by all people"; (iii) "ensure that immunisation coverage is high, and all individuals have equitable access to and adequately utilise all vaccines in national immunisation schedules"; (iv) "ensure that all people benefit from recommended immunisations throughout the life course"; (v) "ensure rapid detection and response to vaccine-preventable disease outbreaks and sustain immunisation programmes during emergencies"; (vi) "ensure all countries have appropriate and sustainable supply and financing for immunisation programmes"; (vii) "ensure operational research is used to increase the reach of immunisation programmes and ensure impactful innovations are rapidly made available to all countries and communities".

The Roadmap and the 28 actions are coherent with the WHO European Immunisation Agenda 2030 (EIA 2030) as the Roadmap aims at addressing the same needs: inequal vaccination coverage across EU Member States, fighting against mis- and disinformation, combatting vaccine hesitancy, and making the best of new technologies related to data to improve coverage vaccination rates. With the Roadmap, the need to address suboptimal vaccination coverage is mostly made by actions with indirect effects either through better monitoring, with better use of data, with better information, or by fighting against mis- and disinformation or still by identifying barriers that imped vulnerable groups to be vaccinated – contributing to vaccine hesitancy.

Therefore, through different segmentation and internal organisation of the set of actions, the Roadmap and the EIA 2030 have actions that are coherent. The issues related to suboptimal vaccination coverage tackled through actions related to Strategic Priorities 3 and 4 of the EIA 2030, are addressed within the Roadmap more indirectly with a set of actions that aims at combating mis and disinformation (e.g. **Action 11**), at finding factors of vaccine hesitancy (Actions 5 & 27) or at building consensus on specific unmet needs of vulnerable people to be address with vaccination. To increase vaccination coverage, the Roadmap attempts with **Action 26** for instance to strengthen vaccination on a life-long perspective like the European Immunisation Agenda 2030. The Roadmap also foresaw actions to address issues relating to appropriate and sustainable supply of vaccines and by supporting the funding of vaccine research and development, which is aligned with the Strategic Priorities 6 and 7 of the European immunisation Agenda 2030. Besides, with regard to the need for preparedness in case of future health threat and pandemic, the Roadmap is also aligned with the EIA 2030 as it also encompasses actions that aims to address the need for preparedness (Actions 10, 17 and 18 for shortages, 19 for instance).

The Roadmap is complementary with this WHO initiative, because it targets through the actions different types of stakeholders. Through the 28 actions, the Roadmap focuses on healthcare workers, national authorities, scientists, and researchers in the field of vaccination as well as vaccine industry. By targeting these types of stakeholders, the Roadmap seems to rather attempt to provide practical and specific solutions to existing issues for these stakeholders rather than generic actions and seems to be more oriented to (i) the supply chain and (ii) the people on the field that vaccine. The WHO Initiative has another focus, mainly on decision-makers, national

and subnational leaders and national authorities, and ministries. EIA 2030 also proposes to help Member States, political leadership, and decision-makers to strengthen governance and management of immunisation programmes (Strategic Priority 1) and to ensure their full commit to immunisation programmes (Strategic Priority 2). By choosing these targets, the WHO Agenda has a more generic list of actions that would need to be tailored and declined by stakeholders on the ground to correspond to the national context of needs.

The Roadmap also develops a complementary approach to the European Immunisation Agenda 2030. Indeed, the Roadmap gives Member States guidelines and supports initiatives in collaboration with healthcare workers or industry, while EIA 2030 relates more to a list of high-level actions that should be undertaken by countries on the ground.

5 Findings relating to Further Development of the Roadmap and its actions (Questions 8 – 9)

The following sub-Sections present the findings relating to the future development of highly relevant actions in the long term as well as the possible synergies between them and EU initiatives.

5.1 Q8: Which actions, that are expected to still be relevant in the longer term (+10 years), can be further developed to build on possible synergies/avoid duplication with other Commission policy initiatives in health?

As outlined under Section 4 above, a number of actions have been identified as increasingly relevant in the longer term (+10 years). To ensure the maximum impact when developing these actions and future deliverables, it is necessary to consider the manner in which synergies can be created in line with other Commission policy initiatives in health and at large and to identify any risks of duplication. This is outlined in turn below.

Key findings

- Moving forward, a categorisation of the actions included in the Roadmap would be useful to ensure a better development of the actions. The Study proposed 7 areas of intervention, where actions can be categorised.
- Further development of the Roadmap should take advantage of the policies in Health sector and other sectors to work on data, communication, access to vaccination, funding support of research and innovation, cooperation, preparedness, and monitoring vaccine production and effectiveness

5.1.1 The actions that are expected to still be relevant in the longer term can be categorised into specific groups to ensure a better development

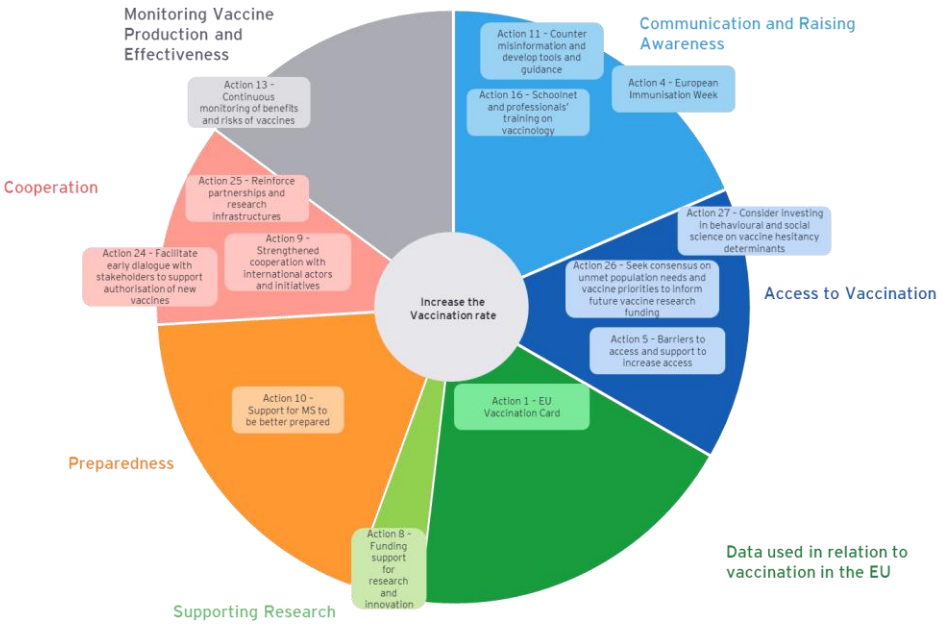
As outlined under Question 4 above, a number of actions will be increasingly relevant in the longer term. Nevertheless, through the analysis undertaken by the Study team, a key finding of the Study is that there is a lack of knowledge by stakeholders relating to the specific actions and deliverables falling under the Roadmap.

A key cause of this lack of knowledge appears to be the manner in which the specific actions are drafted within the Roadmap. The absence of categorisation of the actions do not permit stakeholders to monitor specific actions of interest to them.

The Study team identifies, therefore, the merit in further categorising actions. The Study proposes the following categorisation of actions: : (i) Communication and Raising Awareness; (ii) Access to Vaccination; (iii) Data used in relation to Vaccination in the EU; (iv) Supporting Research; (v) Preparedness; (vi) Cooperation; (vii) Monitoring Vaccine Production and Effectiveness

These seven areas of intervention all directly or indirectly contribute to increasing the vaccination rate (in the centre of the figure).

Figure 25 - Categorisation of the Actions by areas of intervention



5.1.2 For the Further Development of the Roadmap, synergies and alignment could be sought across EU Health initiatives as well as through a cross-sector perspective

The Table below presents an overview of the EU policies that should be considered in relation to the relevant actions of high priority in the long term, and with which the actions could be articulated to ensure further development.

Table 10 - Overview table of the potential link between the future Roadmap and EU initiatives

Category	Actions	EU Health Union	Eu Health Data Space	Beating Cancer Plan	Pharmaceutical Strategy	EU4Health	EU Digital Strategy	EU Social Policies
Data	Action 1: Vaccination Card		X				X	
Communication and Raising Awareness	Action 4 - European Immunisation Week	X		X				
Access to Vaccination	Action 5 - Barriers to access and support to increase access	X						X
Supporting Research	Action 8 - Funding Support for Research and Innovation	X		X	X	X		
Cooperation	Action 9 - Strengthened Cooperation with International Actors and Initiatives	X		X	X			
Preparedness	Action 10 - Support for Member States to be Better Prepared	X						
Communication and Raising Awareness	Action 11 - Counter misinformation and develop tools and guidance	X		X				
Monitoring Vaccine Production and Effectiveness	Action 13 - Continuous monitoring of Benefits and Risks of Vaccines	X		X	X			
Communication and Raising Awareness	Action 16 - Schoolnet and professionals' training on vaccinology			X				
Cooperation	Action 24 - Facilitate early Dialogue with Stakeholders to support authorisation of new vaccines	X			X			
Cooperation	Action 25 - Reinforce Partnerships and research Infrastructures	X		X	X			
Access to Vaccination	Action 26 - Seek Consensus on Unmet Population Needs and Vaccine Priorities to inform future vaccine research funding			X	X			
Access to Vaccination	Action 27 - Consider investing in behavioural and social science on vaccine hesitancy determinants							X

Within the vast portfolio of EU strategies and programmes, synergies could be sought with the Roadmap relating to vaccination, since the actions tackle a wide range of challenges from communication to accessibility to all, through health R&D as well as digital innovation. Indeed, in addition to four key EU policy initiatives identified by the Study team in Question 6, other initiatives have been considered as relevant to build further development of the Roadmap in the long term. These EU Initiatives concern:

- **The Funding of Health (EU4Health)** – the challenges of R&D relate to the financing of innovative research (continuously financing and selecting successful research projects), to the acceleration of R&D activities in case of crisis as well as to addressing not only mainstream need of vaccine but also supporting research programmes for unmet population needs. The search for synergies and articulation with a wider funding related to umbrella initiatives is a worthful way to amplify the complementarity and impacts of the key-priority actions for the future (+10 years).
- **The Funding of Digital Innovation (EU4Digital)** – The current Roadmap undertook a series of actions that contributed to the overall digital development of the EU. Within its scope of action, further developments of actions should be considered in line with the EU Digital Strategy. This is a relevant initiative with which to build on actions as access to digital goods and information is one of the key pillars of the strategy.
- **Social Initiatives (EaSI and Green Paper for EU Ageing**) – The Roadmap brought a series of actions in relation to inclusivity, promoting research of vaccine for unmet population needs, works, and studies on concrete and behavioural barriers as well as lifelong vaccination perspective. Synergies could be found between the Roadmap organised by the DG SANTE with social initiatives such as EaSI and EU ageing initiatives.

5.1.3 While no duplication is identified, the further development of the Roadmap should take advantage of the policies in the Health sector and other sectors by co-building actions

In relation to **data**, actions relating to the sharing of data through a form of vaccination card will continue to be a relevant issue moving forward. When considering the sharing of data, the future actions that can be foreseen should be considered particularly in the context of the work currently being undertaken in relation to the EHDS. The EHDS aims to create a common space where natural persons can easily control their electronic health data. In the context of the EHDS, it was foreseen that additional services may be needed in addition to those provided under the MyHealth@EU including in relation to 'support for vaccination card functionalities, including the exchange of information on vaccination plans or verification of vaccination certificates or other health-related activities. Future actions relating to the exchange of data on vaccines both to ensure citizens' ease of access to their own personal data as well as ease of access in exchanging health data between EU Member States should be considered in line with the work undertaken under the EHDS in order to guarantee synergies. With this in mind, it may be necessary to consider what other types of deliverables could be considered moving forward in order to further advance reflections on the manner in which vaccine data can be optimized through the EHDS. To guarantee taking full advantage of all EU initiatives, the actions that would be further undertaken under the Roadmap should also take into account the EU Digital Strategy that is fully aligned with the aim of **Action 1**, with its ambition to transform the health and care sector with digital tools to empower citizens and build an EU person-centred healthcare[137]. Among activities already launched, further developments should consider the eHealth Digital Service Infrastructure that aims to deliver cross-border services (patient summaries and ePrescriptions)[138] to activate potential synergies in the building of an EU vaccination card.

With regard to **communication**, actions relating to providing citizens with scientific based information on immunisation to counter mis- and disinformation as well as relevant training on vaccination for healthcare workers could first seek for synergies with another Health-related initiative already launched: Europe 's Beating Cancer Plan. It identified vaccines as a leverage to protect people from cancer, due to the vaccine against human papillomaviruses, against Hepatitis B and Hepatitis C. The synergies could be of a form of a provision of information with regards to the immunisation rate, the effects of new vaccines, and the update of the research and development process, either during the Immunisation Week and on the internet or by completing pharmacist and general practitioner students' curricula by a module on vaccination and vaccine-preventable cancers. The Umbrella Initiative EU Health Union should also be mobilised to find synergies with the future Roadmap, especially

[137] Source: Infographics of Digital Health and Care - eHealth | Shaping Europe's digital future (europa.eu)

[138] Support European Commission – Actions "Secure access and exchange of health data" : Infographic Digital Health and Care in the EU | Shaping Europe's digital future (europa.eu)

when it comes to ageing and life-course perspective vaccination. Synergies could be built to more communicate on adult and elderly vaccination for instance.

In relation to the **access to vaccination**, synergies can be designed with policies that aim to act on concrete accessibility and the vaccine provision for people that belong to population with unmet needs in terms of vaccine research and development. Further actions continuing the purpose of **Action 5** on barriers and **Action 27** on behavioural and cognitive vaccine hesitancy determinants could be articulated with EU Social Policies such as the Action Plan for Social Rights[139] within its section on social protection and inclusion where the challenge of inclusivity could be linked to the future actions of the Roadmap that would aim to address all people's needs in terms of vaccination. With regard to further actions on accessibility to innovative vaccines, synergies could likely be found with the Europe's Beating Cancer Plan as well as the Pharmaceutical Strategic Plan in working on actions to ensure that unmet population needs are addressed through R&D programmes with a form of a consensus to take advantage of a focused R&D landscape working on the same list of vaccines.

Actions of the Roadmap relating to the **funding support of research and innovation** will continue to be highly relevant in the next 10 years, particularly **Action 8**. In order to amplify the potential impact of the future actions, it appears necessary to create synergies with already existing initiatives that can address vaccine R&D. Initiatives have been only identified in the area of Health, with the Europe's Beating Cancer Plan and the Pharmaceutical Strategies, which both placed the R&D as a key pillar of the development of solutions to combat and prevent cancer and to enhance pharmaceutical sector across the EU. In terms of concrete funding, the synergies could be built with funding actions more directly related to the next EU4Health programme (after 2028-2035).

Cooperation is also a key area of intervention where future actions should strengthen the relationships and the work with the stakeholders of the vaccine landscape at EU and international levels, between EU bodies and industries as well as research institutions and international organisations. Synergies should be primarily sought through the development of common programmes, for instance with the priority of the Beating Cancer Plan and the Pharmaceutical Strategic Plan. Based on the alignment of the needs to meet, the future Roadmap could undertake actions in articulation with both Plans and directly mentioning them in the document presenting the overall Roadmap. Overall, the future actions in continuation of Actions 9, 24 and 25 should more explicitly refer and coordinate with the EU Health Union to ensure that synergies with actions of the Umbrella initiative could be amplified.

Regarding **preparedness**, **Action 5** that aims to help Member States to be prepared for new health crisis will continue to be relevant in the future. As work has been done since the COVID-19 pandemic, this action should be updated and refined moving forward. In this process of further development of the EC Support to Member States with regard to preparedness, synergies should be built based on the work undertaken under the EU Health Union project to specifically build in collaboration with Member States actions that specifically target key dimensions of the preparedness (R&D, stockpiling, development of emergency measures, local production of vaccines, etc.).

Finally, when it comes to **monitoring vaccine production and effectiveness**, **Action 13** will remain highly relevant in future years, as it will contribute to ensuring data of high quality relating to innovative vaccines that can help to combat vaccine hesitancy as well as to enhance innovation and development landscape in the EU. With this in mind, the future actions following the same purpose should be specifically designed in articulation with the Beating Cancer Plan as well as the Pharmaceutical Strategic Plan to support these plans in having a good level of information on the development of new innovative vaccines in their area of intervention as well as to build capacities in informing the populations on new vaccine-preventable cancer for instance. In addition, the future actions should be particularly designed to contribute to providing data on the quality of innovative vaccines for any EU bodies that work on preparedness against pandemic.

5.2 Q9: What could be the enablers and barriers for such further development?

A number of **enablers and barriers** have been identified which can impact the development and implementation of actions relating to vaccination in the coming years. When considering the enablers and barriers, the Study team has identified five categories: (i) Financial (ii) Human (iii) Political (iv) Health (v) Innovation. These

[139] Source: The European Pillar of Social Rights Action Plan - Employment, Social Affairs & Inclusion - European Commission (europa.eu)

categories have been identified as enablers and/or barriers which can impact further development of actions moving forward.

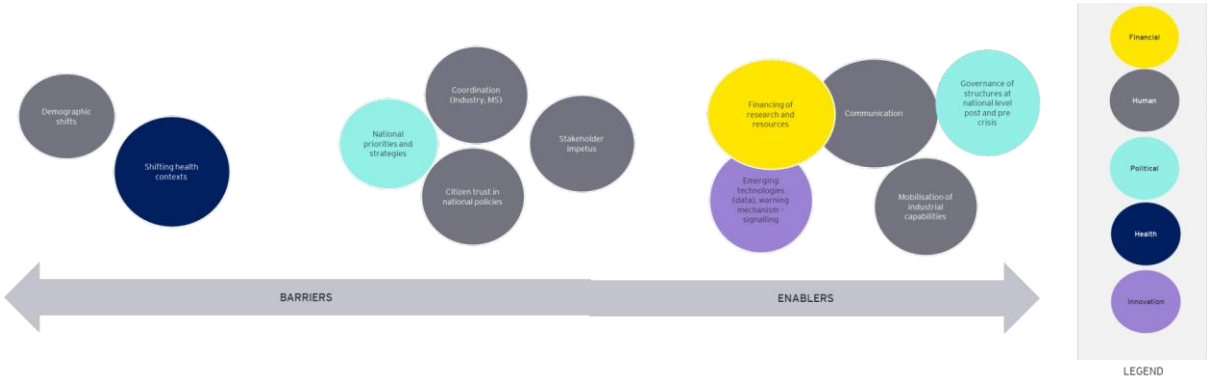
Key findings

Key enablers for further development of actions focus on funding, communication, mobilisation of industrial capabilities, emerging technologies, and governance structures, and will contribute to ensuring the correct development and implementation of actions in relation to vaccination throughout the EU.

Certain factors can be identified both as enablers and barriers to the development of future actions: citizen trust in national policies and strategies, stakeholder impetus, coordination and national priorities and strategies.

The demographic shifts and the shifting health contexts have been identified as key barriers to future development of actions.

Figure 26 Overview of enablers and barriers for further development of Actions



In relation to the enablers and barriers identified, the Table below summarises the manner in which they contribute to the Categories of actions that have been identified by the Study as of relevance in the long term.

Table 11 Enablers and barriers for developing key actions in the long term

	Financing	Communication	Emerging Technologies	Governance of structures	Mobilisation of industrial capabilities	National priorities and strategies	Coordination	Citizen trust	Stakeholder impetus	Demographic shifts	Shifting health contexts
Action 1: Vaccination Card		x	x			x		x	x	x	x
Action 4: European Immunisation Week	x	x				x		x	x		
Action 5: Barriers to access and support to increase access	x	x		x		x				x	
Action 8: Funding support for R&I	x	x		x		x	x		x		
Action 9: Strengthened cooperation with international actors		x					x				
Action 10: Support for MS to be better prepared				x	x		x				x
Action 11: Counter misinformation	x	x				x		x			
Action 13: Monitoring benefits and risks of vaccinations	x	x	x			x				x	
Action 16: Training	x	x				x			x		
Action 24: Facilitate early dialogue with stakeholders		x									
Action 25: Reinforce partnerships and research infrastructures	x	x					x		x		
Action 26: Seek consensus on unmet population needs		x				x	x	x	x	x	
Action 27: Consider investing in behavioural and social science	x	x				x			x	x	

5.2.1 Key enablers for further development of actions which focus on financial, human, political and innovative factors

As outlined in the responses to previous questions of this Study, a number of enablers are key to guarantee the correct development and implementation of actions in relation to vaccination throughout the EU.

Funding

The allocation of proper financial resources for actions at national and EU level is identified as a primary enabler for the success of actions relating to vaccination moving forward. The interviews undertaken with all groups of stakeholders for this Study identified the necessity to ensure adequate funding is in place in order to guarantee that appropriate resources are implemented. When considering funding, this can take numerous forms. Funding is a key enabler, for instance, in relation to enhancing research and development in relation to vaccinations as well as research in relation to social and behavioural insights concerning vaccination. In addition, funding can be identified as a key enabler at national level for Member States in order to facilitate specific issues such as (i) access (ii) communication (iii) training of healthcare practitioners.

When considering the manner in which funding enables the correct development of actions, it is important to note that specific considerations also need to be taken into account in relation to funding to ensure that the financial support provided to specific actions is coherent. This can be considered, for example, in relation to research and development projects financed at EU level. While financing is a key enabler to enhancing research and development and ensure that the EU as a whole is leading in research in relation to vaccines, it is important to also consider the overall coherence of this funding. This was identified by stakeholders from civil society organisations and healthcare professionals participating in EU funding projects that indicated the current lack of coherence that can exist in projects financed by the EU.

Communication

The Study has identified the key role Communication plays in enabling the success of actions relating to the promotion of vaccination and addressing challenges relating to vaccination throughout the EU. A coherent approach needs to be implemented for Communication to add the value that is required to combat specific needs through dedicated actions such as addressing vaccine hesitancy, mis and disinformation and knowledge on vaccines. When considering the manner in which Communication can enable the further development of actions, it is important for Communication to be integrated horizontally for all actions to be deployed further.

Mobilisation of industrial capabilities

The COVID-19 pandemic has demonstrated the importance of ensuring that the EU has the ability to mobilise industrial capabilities needed to address future challenges, including future pandemics. The mobilisation of industrial capabilities is a vital enabler to guarantee success of actions relating to preparedness moving forward. By guaranteeing that the right industrial resources are in place, which can be adapted in an agile manner, both at times of crisis and at times where the status quo prevails, the success of actions relating to vaccine preparedness are enhanced.

Emerging Technologies

As outlined in academic research[140] digitalization provides significant potential in improving the uptake of vaccination. Research undertaken in 10 European countries (Germany, Greece, Italy, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, United Kingdom) demonstrate a variation in relation to the level of digital technologies currently deployed within vaccination services. Some countries have started developing eHealth strategies while others have put in place robust programmes to deploy digital tools through institutional websites, educational videos and electronic immunisation records.

The adaptation of emerging technologies to all Member States is a key enabler to ensuring the success of actions developed, moving forward. The role emerging technologies can play in the area of healthcare was also confirmed in the Commission's Green Paper on ageing which outlined that 'the large-scale introduction of social and technological innovation such as e-health, mobile health […] could substantially improve the efficiency of health

[140] The use of digital technologies to support vaccination programmes in Europe: State of the Art and Best Practices from Experts' Interviews available at The Use of Digital Technologies to Support Vaccination Programmes in Europe: State of the Art and Best Practices from Experts' Interviews - PMC (nih.gov)

and long-term care systems'[141]. Technology can also improve **access** to healthcare in rural and peripheral areas and for older populations. Moreover, the use of warning systems through the optimisation of data can permit a more rapid and effective response to emerging crises.

The exploitation of emerging technologies is thus a key enabler to the development of actions moving forward to guarantee the modernisation of these actions tackling vaccination.

Governance of structures

Ensuring appropriate governance is put in place for structures addressing vaccination was identified as a key enabler for success during the COVID-19 pandemic. By guarantee clear governance, with identified resources available, guaranteed the success of tackling the COVID-19 pandemic, with the existence of clear governance structures stronger in certain countries both within the EU and abroad.

Guaranteeing strong governance is thus a key enabler for all actions that will be developed moving forward, in order to ensure that a key 'implementer' for actions is identified to carry the actions and guarantee their success.

5.2.2 In some instances, certain factors can be identified both as enablers and barriers to the development of future actions

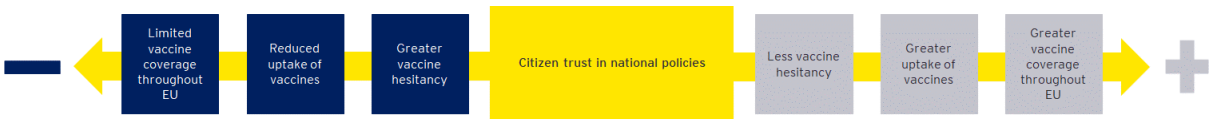
When considering the enablers and barriers to the further development of actions, the Study has identified a number of factors which can be considered as both enablers and barriers to the development of future actions. These factors are primarily human factors, as further described below.

Citizen trust in national policies and strategies

The trust of EU citizens in national policies and strategies implemented in relation to vaccination can either enable the development and success of future actions or act as barriers to their success.

The recent OECD Trust in Government Survey identified an equal split between those who trust and distrust governments, with just over 4 out of 10 people indicating high or moderately high trust in their national government. When considering health crises, the Trust Survey identified the role a clear government strategy can have on trust, particularly in times of crisis. Disadvantaged groups have a lower level of trust in governments, with people with financial concerns less likely to trust the government. In relation to vaccinations, and the success of actions moving forward, it is necessary to consider the factors which play a role in trust in governments for disadvantaged groups.

Figure 27 The impact of Citizen trust in national policies and strategies for vaccination



As outlined in the Figure above, citizen trust in national policies can either act as an enabler or barrier to further actions being developed in relation to vaccination. Where trust is low, this can lead to greater vaccine hesitancy, a reduced uptake of vaccines and thus limited vaccine coverage throughout the EU. In contrast, where trust is high, this leads to less vaccine hesitancy and thus a greater uptake of vaccines.

The role citizen's trust plays in the success of future actions must therefore be considered as key for future success.

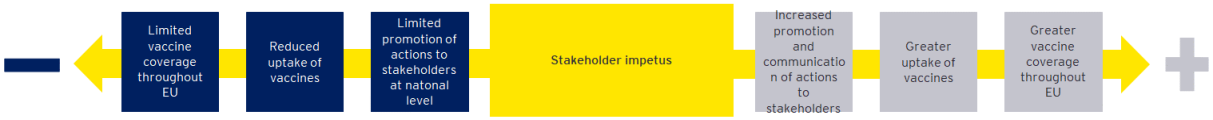
Stakeholder impetus

The role of key stakeholders (civil society, healthcare professionals) and their wish for change is a key enabler or barrier to the development of actions in relation to Vaccination. Due to the ecosystem of stakeholders in place in the area of vaccination, the 'ownership' felt by stakeholders in being involved in the implementation of specific actions is key to guarantee success in relation to vaccination moving forward. As with citizen trust in national

[141] Commission Green Paper on Ageing: Fostering solidarity and responsibility between generations COM(2021) of January 1, 2021 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52021DC0050

policies and strategies, stakeholder impetus can shift the balance from a barrier to an enabler, as presented in the figure below.

Figure 28 Enablers and barriers associated with stakeholder impetus



Coordination

Coordination between actors, at EU, national and international level including coordination between different stakeholder groups, such as coordination between national and EU agencies and industry, can also be considered as a key enabler or barrier to the success of future actions. As outlined in the Study, better coordination has been acknowledged as vital to guarantee greater impact, with a coordinated approach ensuring that actions are better leveraged.

Where coordination is strong, the actions developed in relation to vaccination can reach their maximum impact and thus have a positive effect on vaccine coverage throughout the EU overall. This can be seen, for instance, in relation to the COVID-19 pandemic where enhanced coordination ensured a more rapid response at a time of crisis. Nevertheless, where coordination is weak, a fragmented approach will be observed in relation to the implementation of specific actions moving forward, leading to less synergies and thus limited impact.

National priorities and strategies

The national priorities and strategies that shall be put in place over the next years shall either contribute as an enabler or a barrier to the implementation of actions in relation to vaccination. A move towards a more streamlined vaccination programme throughout the EU Member States, removing inequalities and divergences existing, would contribute to better accelerating the actions to be taken to lead to the ultimate objective of increasing the vaccine coverage rate throughout the EU Member States and having a better level of health protection of citizens throughout the EU. Nevertheless, if further divergences continue to exist in relation to vaccination programmes and actions, such divergence shall act as a barrier to further development in this area.

5.2.3 Two factors that are difficult to control have been identified as key barriers to future development of actions

When considering the future development of actions, the Study has identified two key barriers which can have an impact on the future impact of actions moving forward.

Demographic shifts

As outlined in the European Commission 2023 report on the impact of demographic change[142] demographic change 'has a powerful impact on our […] welfare and health systems'. While demographic changes bring benefits, with people living longer and healthier lives, these changes also require policies and strategies to be agile and adapted to the shifts in demography.

In relation to the impact of demographic changes on strategies relating to vaccination, this can be seen both in relation to the EU's ageing population as well as change in demographics due to increase migration.

In relation to the ageing population, demography has been put high on the policy agenda by the European Commission, through the publication of the first report on the impact of demographic change in 2020. As outlined in the Green Paper on ageing, 'the older you get, the higher the chance of illness or disability'. The demographic changes and the presence of older patients will increase the need for healthcare and other care or support services. Where demographic changes are not appropriately considered in future policies relating to vaccination, this can create an obstacle to successful actions moving forward.

Regarding demographic shifts due to migration, the COVID-19 pandemic demonstrated the challenges faced when attempting to implement a vaccination programme for migrants. A Joint Guidance Note on equitable access

[142] SWD(2023) 21 final Commission Staff Working Document – The impact of demographic change – in a changing environment

to COVID-19 Vaccines for all, published by the Council of Europe, outlined the types of measures that needed to be taken in order to ensure the uptake of vaccination for this population group. This includes developing coordinate strategies and mechanisms of cooperation, provide targeted outreach and information. Research has also been undertaken to examine the national approaches to the vaccination of recently arrived migrants in Europe.[143] This Research found that there is a need for further emphasis on ensuring migrant-specific guidance and reducing the variations in policies existing throughout the EU in relation to approaches to vaccination for migrants. The challenges brought by demographic shifts relating to migration were also identified by the Study through interviews undertaken with national authorities that identified key challenges in ensuring their vaccination programmes were agile to new populations entering their Member States.

While demographic shifts should be considered as positive, it can be identified as a barrier to the success of future actions if sufficient consideration is not made to ensure that actions implemented by Member States are adaptable to such demographic changes.

Shifting Health Contexts

The European Commission 2023 report on the impact of demographic change[144] highlighted the impact the COVID-19 pandemic had on demonstrating the vulnerability of economies to health-related shocks. While the Study identified both advantages and disadvantages to the COVID-19 pandemic, with considerable lessons learnt identified, shifting health contexts as well as the emergence of future pandemics can be identified as a real barrier to development of actions moving forward.

While enabling factors, identified above, can combat future challenges that may emerge, the uncertainty and lack of timeline regarding future health crises can still be considered as the key barrier to success of actions in the long term.

6 Conclusion

The objective of this Study was to identify the manner in which the actions in the Roadmap responded to the needs identified in 2018, and the extent to which they are still and will continue to be relevant, coherent, and complementary with other related policy initiatives.

The Study has identified the overall relevance of the actions set out in the Roadmap. This assessment was conducted at the level of the deliverables and supported by the collection of stakeholders' viewpoints. It found that **all actions have been relevant to some extent to address the needs identified.** It highlighted that actions undertaken at EU level to combat vaccine hesitancy and mis- and dis-information have particularly been relevant. Additionally, the assessment showed that by tackling the needs with multiple angles (e.g. vaccine hesitancy addressed through the development of studies and guidance, the education of healthcare workers, the production of reliable data etc), the Roadmap succeeded in addressing the needs. **In terms of relevance of the needs**, the Study's assessment of the needs' evolution found that most needs are still relevant. However, some needs stood out more than others reflecting the inevitable shifts in perception linked to the COVID-19 pandemic. **In particular, issues relating to mis-and dis-information and vaccine hesitancy have become high priority needs to be addressed**. Some lesser-prioritised needs in 2018 also increased in priority, such as preparedness and the production and aggregation of data. In light of this analysis and taking into account the completion status of the different actions as well as their potential to be maintained and further developed, **the Study found that approximately 75% of them will continue to be especially relevant in the short and medium term**. The remaining 25% are still relevant to some extent, although without needing to be prioritised as much. **In the longer term, the heightened relevance of around 50% of the actions is expected to also stabilise**. Depending on structural evolutions, in particular concerning political consensus and needs, some action's relevance may however increase again.

In relation to internal coherence of the Roadmap's actions, the Study overall found the actions were complementary to each other, identifying no salient overlap between the actions themselves. An initial thematic categorisation of the actions, which did not exist previously, was necessary to undertake in order to bring clarity

[143] National approaches to the vaccination of recently arrived migrants in Europe: A comparative policy analysis across 32 European countries; Sofanne J Ravensbergen, Laura B Nellums, Sally Hargreaves, Jon S Friedland

[144] Commission 2023 Report on the Impact of Demographic Change. https://commission.europa.eu/system/files/2023-01/Demography_report_2022_0.pdf

on the Roadmap's organisation. **Concerning external policy initiatives within the EU, the Study found the Roadmap to be complementary and relevant**. This assessment was done via a comparative analysis of the Roadmap, with a focus on the four main initiatives that appear to be the most relevant in the field of immunisation (EHU, EHDS, Europe's Beating Cancer Plan, and Pharmaceutical Strategy for Europe) and a triangulation with stakeholders' views. The same methodology was applied to policy initiatives at global level (Q7), which found that the Roadmap is overall coherent with WHO's main initiatives (Global Vaccine Action Plan and its European declination, the European immunisation Agenda). Interviews with stakeholders at global level further confirmed this absence of misalignment and overlap.

Regarding the further development of highly relevant actions in the long-term, the Study identified 13 actions that should be prioritised for development in the long-term (10+ years). A clear recommendation identified by the Study is to ensure a categorisation of the actions to be pursued in order to guarantee clarity for stakeholders and coherence and complementarity with developing policy initiatives at EU level.

Finally, several enablers and barriers have been identified that would support the development of the Roadmap. Funding for research and development, for behavioural research, for access, communication and training can boost the correct development of actions. **Communication is also key** both to promote the benefits and safety of vaccines, and to ensure internal coherence and visibility of what is being done across the EU. A **focus on emerging technologies and eHealth services also holds potential** in improving the uptake of vaccination and could also support the Roadmap in a transverse manner. Furthermore, additional enablers can become barriers, such as the citizen trust in national policies and strategies, which could either boost vaccine uptake and confidence if high, or further amplify hesitancy and mis-and dis-information if low. Similarly, stakeholder impetus and national priorities and strategies can boost EU actions if aligned with a vision for harmonised efforts but can also be factors of decreased relevance for actions aimed at overall alignment if there are too many divergences in terms of policies as well as priority setting. Finally, demographic shifts and shifting health contexts can bring down the uptake and impact of the Roadmap's actions.

7 Annexes

7.1 Annex 1: Mapping table of the stakeholders concerned by the actions

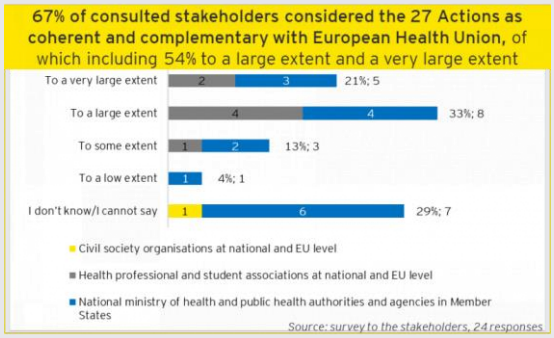
Figure 29- Mapping table of the stakeholders concerned by the actions

Actions / Stakeholders	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
National Authorities	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓		✓	✓			
EU Institutions		✓				✓	✓	✓	✓			✓	✓	✓			✓	✓		✓	✓	✓	✓	✓	✓		
International Institutions									✓																✓		
Vaccine Industry	✓					✓	✓	✓				✓	✓	✓				✓		✓			✓	✓		✓	
Health Professionals	✓	✓	✓	✓		✓	✓				✓	✓				✓											
Researchers	✓					✓	✓	✓	✓			✓	✓	✓										✓	✓	✓	
Citizens, including Workers	✓			✓	✓	✓	✓				✓	✓			✓												✓

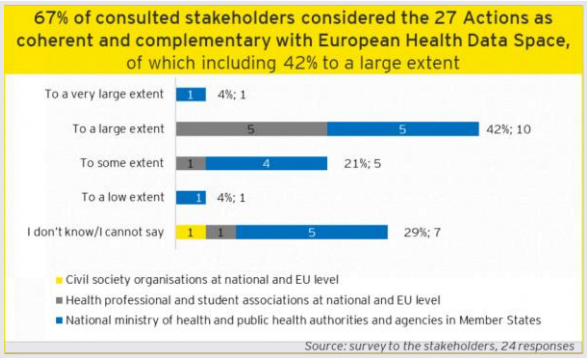
Source: EY Analysis

7.2 Annex 2: Analysis of the stakeholders' contribution with regard to coherence and complementarity of the 27 actions with other EU and global initiatives

Coherence and Complementarity of the 27 actions with the EU Health Union perceived by the stakeholders



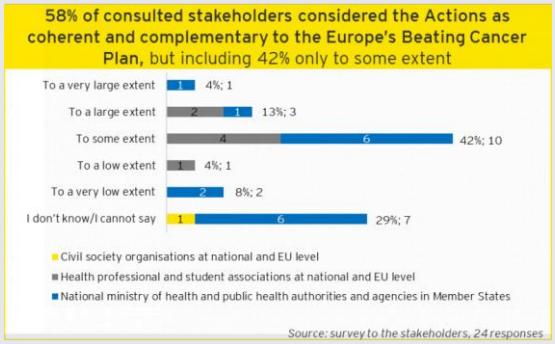
Overall, 67% respondents (n=16 out 26 responses) to the Survey considered that the 27 actions of the Roadmap are coherent and complementary to the European Health Union. Among them, 33% considered the actions as coherent and complementary to a large extent (n=8), 21% of them to a very large extent (n=5), and 13% respondents considered to some extent only (n=3). Only one respondent considered the actions relevant and complementary but to a low extent. Among respondents, 29% could not assess the coherence and complementarity of the 27 actions (n=7).



Coherence and Complementarity of the 27 actions with the EHDS perceived by the stakeholders

Overall, 67% respondents (n=16 out 24 responses) to the Survey considered that the 27 actions of the Roadmap are coherent and complementary with the EHDS. Among them, 42% considered the actions as coherent and complementary to a large extent (n=10), 4% of them to a very large extent (n=1), and 21% respondents considered to some extent only (n=5). Only one respondent considered the actions relevant and complementary but to a low extent. Among respondents, 29% could not assess the coherence and complementarity of the 27 actions (n=7).

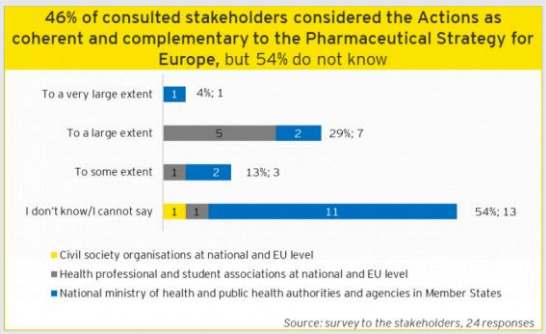
Coherence and Complementarity of the 27 actions with Europe's Beating Cancer Plan perceived by the stakeholders



Overall, 58% respondents to the Survey consider that the actions contained in the Roadmap are coherent and complementary to the Europe's Beating Cancer Plan. However, among them, they mostly consider that they are coherent to some extent only (42%, n=10 out of 23), while 13% and 4% of respondents considered the Roadmap as coherent and complementary to a large or a very large extent (resp. n=3 and n=1). The other significant share of respondents could not assess the coherence and complementarity with the Europe's Beating Cancer plan (n=7, representing 329%).

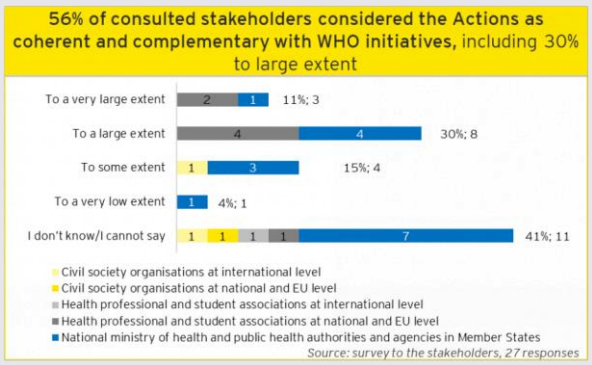
These results confirm the coherence and the complementarity of the Roadmap with this EU Initiative, but it also puts a light on the difficulty for stakeholder to understand both initiatives, and to identify possible synergies between them.

Coherence and Complementarity of the 27 actions with the Pharmaceutical Strategy for Europe perceived by the stakeholders



46% respondents considered that the actions are overall coherent and complementary with the Pharmaceutical Strategy for Europe (n=11 out of 24), that is also in line with the above assessment. However, a majority of respondents (54%, n=13) could not tell the extent to what they considered the actions coherent and complementary to the Strategy. Again, most of the respondents seem to be unable to consider both actions in connection to one another and to identify possible synergies.

Coherence and Complementarity of the 27 actions with WHO initiatives perceived by stakeholders



Overall, 56% respondents to the Survey considered that the 28 actions of the Roadmap are coherent and complementary with the WHO Initiatives European Vaccine Action Plan 2015-2020 and the European Immunisation Agenda 2030. Among them, 30% considered the actions as coherent and complementary to a large extent (n=8, out of 27 respondents) and 11% of them to a very large extent (n=3). 15% of respondents considered the actions to be coherent and complementary to some extent only (n=4). Other key findings are that 41% of respondents could not assess the coherence and the complementarity of the Roadmap with the WHO initiative (n=11).

Study on the coherence, complementarity, and continued relevance of actions in the Council Recommendation on strengthened cooperation against vaccine-preventable diseases in view of possible similar policy initiatives in the future

7.3 Annex 3: Documentary sources

7.3.1 EU documents

Council Recommendation on seasonal influenza vaccination, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:348:0071:0072:EN:PDF

European Parliament resolution of 19 April 2018 on vaccine hesitancy and the drop in vaccination rates in Europe (2017/2951(RSP)) https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52018IP0188

Commission Communication to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - Strengthened Cooperation against Vaccine Preventable Diseases https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2018%3A245%3AFIN

Council Recommendation of 7 December 2018 on strengthened cooperation against vaccine-preventable diseases (2018/C 466/01) https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX:32018H1228(01)

European Parliament resolution of 19 April 2018 on vaccine hesitancy and the drop in vaccination rates in Europe (2017/2951(RSP)), source: EUR-Lex - 52018IP0188 - EN - EUR-Lex (europa.eu)

Commission Recommendation on a European Electronic Health Record exchange format (C(2019)800) of 6 February 2019. Accessed at: Recommendation on a European Electronic Health Record exchange format (europa.eu)

Commission Communication to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, 2020. Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0724&from=EN

Council Conclusions on common values and principles in European Health Systems, source: EUR-Lex - 52006XG0622(01) - EN - EUR-Lex (europa.eu)

COM(2022) 196, Communication from the Commission to the European Parliament and the Council, 03 March 2022: https://health.ec.europa.eu/system/files/2022-05/com_2022-196_en.pdf

COM(2022) 197 final Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space, available at https://eur-lex.europa.eu/resource.html?uri=cellar:dbfd8974-cb79-11ec-b6f4-01aa75ed71a1.0001.02/DOC_1&format=PDF

Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022R0123

EU COM 2021/576, Communication, Introducing HERA, the European Health Emergency Preparedness and Response Authority, the Next Step Forwards Completing the European Health Union

EU COM 2020/0322 'Proposal for a Regulation of the European Parliament and of the Council on Serious Cross-Border Threats to Health and Repealing Decision

COMMISSION STAFF WORKING DOCUMENT Accompanying the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of Regions EU strategic framework on health and safety at work 2021-2027 Occupational safety and health in a changing world of work EUR-Lex - 52021SC0148 - EN - EUR-Lex (europa.eu)

7.3.2 EU institutions and agencies

ECDC. Monthly measles and rubella monitoring report, January 2018, https://ecdc.europa.eu/sites/portal/files/documents/Monthly%20measles%20and%20rubella%20monitoring%20report%20-%20JAN%202018.pdf

ECDC, Designing and implementing an immunisation information system, Technical Report. Nov 2018 A handbook for those involved in the design, implementation, or management of immunization information systems https://ec.europa.eu/health/sites/default/files/vaccination/docs/10actions_en.pdf

ECDC. Proposal AF53-07 EU/EEA NITAG collaboration to ECDC Advisory Forum May 15 – 16 2018. Proposal to establish a system for EU/EEA NITAG (or equivalent expert committee) collaboration for the sharing and generation of scientific evidence on EU vaccines and immunization practice. Minutes of the Advisory Forum 53rd Meeting, Stockholm, 15-16 May 2018

ECDC Countering online vaccine misinformation in the EU/EEA https://www.ecdc.europa.eu/en/news-events/ecdc-launches-report-countering-online-vaccine-misinformation-eueea

Vaccination schedules for individual European countries and specific age groups (europa.eu)

https://www.ecdc.europa.eu/en/about-us/partnerships-and-networks/national-immunisation-technical-advisory-groups-nitag

https://health.ec.europa.eu/system/files/2023-02/2022_confidence_rep_en.pdf

https://health.ec.europa.eu/system/files/2022-11/2020_confidence_rep_en.pdf

https://health.ec.europa.eu/system/files/2018-11/2018_vaccine_confidence_en_0.pdf

https://www.ecdc.europa.eu/en/news-events/ecdc-launches-e-learning-course-how-address-online-vaccination-misinformation

https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space_en

European Health, and Digital Executive Agency, Provision of Opinions and recommendations for an EU citizen's vaccination card. Annex 2, Design and testing of three dual templates, 2022.

Handbook on designing and implementing an immunisation information system (europa.eu)

European Commission, 2019. Memo - Framework contracts for pandemic influenza vaccines ev_20190328_memo_en_0.pdf (europa.eu)

Factsheet on the European Health Emergency preparedness and Response Authority (HERA) (europa.eu)

Ad-hoc technical meeting under the Pharmaceutical Committee on shortages of medicines, 25 May 2018 (europa.eu)

European Commission, 2018. Paper on the obligation of continuous supply to tackle the problem of shortages of medicines ev_20180525_rd01_en_0.pdf (europa.eu)

Health-EU newsletter 250 https://health.ec.europa.eu/other-pages/basic-page/health-eu-newsletter-250-focus_en

European Vaccination Information Portal https://vaccination-info.eu/en

European Health Union, https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/promoting-our-european-way-life/european-health-union_en

Europe's Beating Cancer Plan (europa.eu)

Pharmaceutical Strategy For Europe, 2020 https://health.ec.europa.eu/system/files/2021-02/pharma-strategy_report_en_0.pdf

Infographics of Digital Health and Care - eHealth | Shaping Europe's digital future (europa.eu)

Support European Commission – Actions "Secure access and exchange of health data" : Infographic Digital Health and Care in the EU | Shaping Europe's digital future (europa.eu)

European Commission The European Pillar of Social Rights Action Plan - Employment, Social Affairs & Inclusion - European Commission (europa.eu) https://ec.europa.eu/social/main.jsp?catId=1607&langId=en

EMA https://www.ema.europa.eu/en/news/ecdc-ema-collaborate-vaccine-safety-effectiveness-monitoring-studies

EMA, Darwin EU project https://www.ema.europa.eu/en/about-us/how-we-work/big-data/data-analysis-real-world-interrogation-network-darwin-eu

7.3.3 Organisations and networks at EU level

Communication Materials | IMMUNION (coalitionforvaccination.com)

Press release of September 2019 from the Standing Committee of European Doctors https://www.cpme.eu/api/documents/adopted/2019/PR_Coalition.For_.Vaccination.12.09.2019.pdf

Coalition for Vaccination (2023). Press release of 17th January 2023 – European healthcare professionals unite for the future of vaccination https://coalitionforvaccination.com/assets/content/attachments/PressRelease_CfV_Conference.pdf

EU-JAV https://eujav-platform.com/

EU-JAV (2022). Guidelines on procedures to estimate vaccine needs and procurement in EU. Accessed at: link

https://eu-jav.com/the-project/wp6/

http://eu-jav.com/wp-content/uploads/2019/10/Report-on-Vaccine-shortages-WP6-Task-6.1-FINAL-mod.pdf

The Vaccine Confidence Project https://www.vaccineconfidence.org/

https://research-and-innovation.ec.europa.eu/research-area/health/coronavirus/vaccines_en

7.3.4 International Organisations

WHO, 2022. Immunization coverage. Retrieved from Who.int website: https://www.who.int/en/news-room/fact-sheets/detail/immunization-coverage

http://www.euro.who.int/en/media-centre/sections/press-releases/2018/europe-observes-a-4-fold-increase-in-measles-cases-in-2017-compared-to-previous-year

Global Vaccination Summit (who.int)

WHO/UNICEF, 2016, Estimates of National Immunization Coverage http://www.who.int/immunization/monitoring_surveillance/who-immuniz.pdf?ua=1

https://www.who.int/news-room/spotlight/ten-threats-to-global-health-in-2019

WHO Available HPV vaccination through national vaccination programmes free of charge - European Health Information Gateway (who.int)

WHO, European Vaccine Action Plan 2015-2020 European Vaccine Action Plan 2015-2020 (who.int).

WHO, The European Immunization Agenda 2030 https://www.who.int/europe/initiatives/the-european-immunization-agenda-2030

WHO, Clinical trials. https://www.who.int/health-topics/clinical-trials#tab=tab_1

WHO, https://www.who.int/initiatives/the-global-vaccine-safety-initiative

GloPID-R, "Meeting Report: Reaching out – a Meeting to Advance Clinical Research Preparedness for Infectious Disease Outbreaks

7.3.5 Studies and academic publications

Larson HJ, Jarrett C, Eckersberger E, Smith D, Paterson P. Understanding vaccine hesitancy around vaccines and vaccination from a global perspective: A systematic review of published literature, 2007–2012. 2014. Vaccine. 32: 2150-2159

Under-vaccinated groups in Europe and their beliefs, attitudes and reasons for non-vaccination; two systematic reviews https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-018-5103-8

Vaccine hesitancy in health-care providers in Western countries: a narrative review https://doi.org/10.1080/14760584.2022.2056026

Larson HJ, de Figueiredo A, Xiahong Z, Schulz WS, Verger P, Johnston IG, Cook AR, Jones NS. The State of Vaccine Confidence 2016: Global Insights Through a 67-Country Survey. EBioMedicine. 2016 Oct;12:295-301. doi: 10.1016/j.ebiom.2016.08.042. Epub 2016 Sep 13. PMID: 27658738; PMCID: PMC5078590 accessed at link

Buble, T (2022), Report on interoperability of IIS in the EU area. Croatian Institute of Public Health.

Emborg HD (2021), Report on reminder systems. Statens Serum Institut

Blomquist & Andersson (2018). Report on feasibility study for future coordinated cross-border vaccination campaign in EU and non-EU countries. Public Health Agency of Sweden.

https://www.nivel.nl/en/project/study-guidance-methodologies-assess-performance-vaccination-programmes

Bernd Rechel et al., "The organization and delivery of vaccination services in the European Union", The European Observatory on Health Systems and Policies, 2018, p. 17

University of Oxford, Global Vaccination Schedules – General Information Global Vaccination Schedules | Vaccine Knowledge Project (ox.ac.uk)

Jungbluth et al., "A gaps-and-needs analysis of vaccine R&D in Europe: Recommendations to improve the research infrastructure", Biologicals, Feb 2022, p. 16

Fierce Pharma, World has huge unmet vaccine needs https://www.fiercepharma.com/infectious-diseases/world-has-huge-unmet-vaccine-needs

L. Sigfrid, 2020 "Addressing challenges for Clinical Rearch Responses to Emerging Epidemics and Pandemics: a scoping review", BMC Medicine

M. Pasté et. al. Addressing vaccine supply challenges in Europe: Expert industry perspective and recommendations, Health Policy, Volume 126, Issue 1, 2022 https://doi.org/10.1016/j.healthpol.2021.11.006

Miranda-García, Maria Auxiliadora and Hoffelner, Marcus and Stoll, Hagen and Ruhaltinger, Dörte and Cichutek, Klaus and Siedler, Anette and Bekeredjian-Ding, Isabelle, A 5-year look-back at the notification and management of vaccine supply shortages in Germany, Eurosurveillance, 27, 2100167 (2022) https://doi.org/10.2807/1560-7917.ES.2022.27.17.2100167

De Weerdt E, Simoens S, Casteels M, Huys I. Toward a European definition for a drug shortage: a qualitative study. Front Pharmacol. 2015 Oct 30;6:253. doi: 10.3389/fphar.2015.00253 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4626567/

Arianna Maviglia, Elvis Bitar, Jelena Schmidt, Philippe Winters, Sander de Souza, & Timo Clemens. (2023). Human Papillomavirus vaccines: Call for a European change to tackle current and future shortages. *South Eastern European Journal of Public Health*, 19–37. https://doi.org/10.56801/seejph.vi.368

7.4 Annex 4: Targeted Interviews Undertaken

Table 12 - List of interviews

Country/Region	Stakeholder group	Organisation	Date	Status
Worldwide	International Organisation	The International Vaccine Institute	14/03/2023	Completed
Germany	National Authority	Federal Ministry of Health - Paul-Ehrlich-Institute. Committee for Medicinal Products for Human Use ('CHMP')	14/03/2023	Completed

Country/Region	Stakeholder group	Organisation	Date	Status
Estonia	National Authority	Health Board - Department of communicable diseases	15/03/2023	Completed
Ireland	National Authority	Health Services Executive - National Immunisation Office (NIO)	16/03/2023	Completed
EU	Civil Society Organisation	European Network and People's Health Movement	17/03/2023	Completed
EU	Civil Society Organisation	EuroHealthNet	17/03/2023	Completed
EU	Civil Society Organisation	European Parents' Association	21/03/2023	Completed
EU	Civil Society Organisation	European Forum for Vaccine Vigilance	21/03/2023	Completed
EU	EU Institution	DG GROW - Unit F.3, Agro-food, retail, and health	24/03/2023	Completed
Croatia	National Authority	Croatian Institute of Public Health - Division for epidemiology of communicable diseases / Department for Immunisation	24/03/2023	Completed
EU	Healthcare professional and student association	EFN	27/03/2023	Completed
Germany	Vaccines industry	VFA	27/03/2023	Completed
EU	Civil Society Organisation	European Patients' Forum	28/03/2023	Completed
EU	Healthcare professional and student association	European Public Health Alliance (EPHA)	28/03/2023	Completed
Belgium	National Authority	Vlaams Agentschap Zorg en Gezondheid (EU-JAV) - Department of Prevention	29/03/2023	Completed
EU	Healthcare professional and	PGEU	30/03/2023	Completed

Country/Region	Stakeholder group	Organisation	Date	Status
	student association			
EU	Civil Society Organisation	Active Citizenship Network	31/03/2023	Completed
EU	Healthcare professional and student association	CPME	03/04/2023	Completed
EU	Civil Society Organisation	European Public Health Association (EUPHA)	04/04/2023	Completed
EU	EU Institution	DG RTD - Unit D.1, Combatting diseases	05/04/2023	Completed
Czech Republic	National Authority	Ministry of Health - Protection and public health support section	05/04/2023	Completed
Sweden	National Authority	Public Health Agency of Sweden (EU JAV)	06/04/2023	Completed
Germany	Civil Society Organisation	Vaccine Safety Initiative	07/04/2023	Completed
Sweden	National Authority	Swedish Work Environment Authority	17/04/2023	Completed
France	Vaccine Industry	Sanofi	19/04/2023	Completed
Netherlands	National Authority	Ministry of Health, Welfare and Support - RIVM Centre for Infectious Diseases	21/04/2023	Completed
Spain	National Authority	Ministry of Health, Social Services and Equity - Direccion General de Cartera Comun de Servicios del SNS y Farmacia	25/04/2023	Completed
EU	Vaccine industry	Vaccines Europe	25/01/2023	
France	Vaccine Industry	Valneva SE	02/05/2023	Completed
EU	EU Institution	DG SANTE - Unit A3	03/05/2023	Completed
EU	EU Institution	Vaccelerate	03/05/2023	Completed
Germany & Worldwide	International Organisation	Deutsche Stiftung Weltbevöolkerung (German Foundation for World Population)	03/05/2023	Completed
EU	EU Institution	HERA	04/05/2023	Completed
Germany	Vaccine Industry	Biontech	05/05/2023	Completed
EU	EU Institution	HERA	10/05/2023	Completed

Country/Region	Stakeholder group	Organisation	Date	Status
Cyprus	National Authority	Ministry of Health	11/05/2023	Completed
EU	EU Institution	EMA	16/05/2023	Completed
Worldwide	International Organisation	TBVI	22/05/2023	Completed
EU	EU Institution	EMA	23/05/2023	Completed
Worldwide	International Organisation	IAVI	26/05/2023	Completed
Worldwide	International Organisation	GAVI	02/06/2023	Completed
Worldwide	International Organisation	EVI	15/05/2023	Completed
Worldwide	International Organisation	CEPI	08/06/2023	Completed
Worldwide	International Organisation	EDCTP	15/06/2023	Completed

7.5 Annex 5: Interview Guides

Study on the coherence, complementarity, and continued relevance of actions in the Council Recommendation on strengthened cooperation against vaccine-preventable diseases in view of possible similar policy initiatives in the future

Targeted Interview

Topic Guide for Member States

EY has been mandated by DG SANTE of the European Commission to undertake a Study on the coherence, complementarity, and continued relevance of actions in the Council Recommendation on strengthened cooperation against vaccine-preventable diseases in view of possible similar policy initiatives in the future. The study aims to support the European Commission in assessing (i) the relevance of each of the 28 actions in the "vaccination roadmap, taking the COVID-19 pandemic into account and (ii) the coherence and complementarity with other related policy initiative, as well as in (iii) providing the Commission with a set of recommendations on how the most relevant actions could be further developed and made sustainable to remain relevant on a longer term.

The aim of the interviews is to collect your views and opinions related to the relevance, coherence and complementarity of the actions already implemented as well as to identify new needs to be addressed by potential actions in short or longer term (2-5 / +10 years) in the framework of the Council Recommendation and Commission Roadmap.

This interview guide provides indicative questions that are aimed to frame the interview. It also provides a table where a targeted number of actions of the Council Recommendations to be discussed is listed. The questions are phrased in a general manner and apply to the actions and Needs in the table.

Respondents may not consider themselves in a position to respond to all questions. The interviews will be anonymised.

Introduction

- Q1. Please introduce yourself and your experience relating to vaccines and the implementation of the Council Recommendation and subsequent Commission Roadmap.
- Prompt. Among the actions presented in the table below, have you been related to any of them? Have you been related to any other actions of the Council Recommendation?

Relevance of the actions regarding the needs identified so far

- Q2. In your opinion, based on the table below, are the needs identified in 2018 still relevant in 2023?
- Q3. In your opinion, what are the most/least relevant needs in 2023? What are the reasons? Have some needs gained further importance or prioritisation in your Member State?
- Q4. In your opinion, have any new needs emerged that had not been identified in 2018? Are there any specific external factors which have triggered the emergence of unanticipated needs?
- Q5. In your opinion, have the actions identified in the table below addressed the needs identified in 2018? Have any needs not been addressed or insufficiently addressed by these actions?
- Q6. Regarding the needs relating to communication and vaccination hesitancy, do you consider that this need has been sufficiently covered? Have you perceived any evolution in the implementation of actions to tackle vaccine hesitancy?
- Q7. Regarding the need to improve and facilitate the procedures related to clinical research and trials on vaccines, do you consider that this need has been sufficiently covered? Are there specifics dimensions of the issue that still needs to be covered? Have you perceived any evolution in the implementation of actions to tackle this issue?
- Q8. Regarding preparedness, anticipation, and prevention against future pandemics, do you consider that this need has been sufficiently addressed? Do you identify areas of improvement?
- Q9. Regarding strategic autonomy, do you consider that this need has been sufficiently addressed by the Council Recommendation's actions? What areas of improvement do you identify?

Coherence and Complementarity

- Q10. In terms of coherence between actions, to what extent are all 28 actions coherent with each other? Do you identify similarities or inconsistencies between the 28 actions with each other? Do you identify any overlaps between action in terms of achieving the objectives of the Council Recommendation?
- Q11. In your opinion, to what extent are the actions coherent with other EU policy initiatives?
- Q12. At international level, to what extent are the actions coherent with other international policy initiatives in the field of vaccination? Prompt: if yes, could you name any of the international policy initiatives related?

Prospective

- Q13. In your opinion, in the short term (2-5 years), would you think that the current needs will still be relevant? Prompt: Same question, in the long term (+10 years).
- Q14. In your opinion, in the short term (2-5 years) what would be the future needs to be addressed in the next years?
- Q15. What kind of actions would be required to address such needs? Prompt: Same question, in the long term (10 years).
- Q16. In your opinion, in the long term (+10 years) which actions could be developed to build on possible synergies or avoid duplication with Commission policy initiatives? Prompt: Same question in relation with international policy initiatives.
- Q17. In your opinion, what factors could play in favour of further development of those actions at EU level?

Thank you for your cooperation.

Actions	Needs
Action 1 - Examine the feasibility of developing a common vaccination card/ passport for EU citizens (that takes into account potentially different national vaccination schedules and), that is compatible with electronic immunisation information systems and recognised for use across borders, without duplicating work at national level	➢ Secure access and sharing of heath data across borders for citizens and professionals ➢ Lack of interoperability between MS with regards to electronic health records ➢ Mis and disinformation / lack of accurate information

Action 3 - Convene a Coalition for Vaccination to bring together European associations of healthcare workers as well as relevant students' associations in the field, to commit to delivering accurate information to the public, combating myths and exchanging best practices	➢ Vaccination hesitancy including for healthcare workers ➢ Mis and disinformation / lack of accurate information
Action 4 - Strengthen the impact of the annual European Immunisation Week by hosting an EU public awareness initiative and supporting Member States' own activities	➢ Vaccination hesitancy including for healthcare workers ➢ Mis and disinformation/ lack of accurate information
Action 5 - Identify barriers to access and support interventions to increase acess to vaccination for disadvantaged and socially excluded groups, inclucing by promoting health mediators and grassroots community networks, in line with national recommendations	➢ Vaccination hesitancy including for healthcare workers

Action 7 - Develop guidance to overcome the legal and technical barriers impeding the interoperability of national immunisation information systems, having due regard to rules on personal data protection, as set out in the Commission Communication on enabling the digital transformation of health and care in the Digital Single Market, empowering citizens and building a healthier society.	➢ Lack of interoperability between MS with regard to electronic health records ➢ Secure access and sharing of heath data across borders for citizens and professionals ➢ Suboptimal monitoring of vaccination ➢ Varying vaccination programmes across the EU

Actions	Needs
Action 9 - Strengthen existing partnerships and collaboration with international actors and initiatives, such as the WHO and its Strategic Advisory Group of Experts on Immunization (SAGE), the European Technical Advisory Group of Experts on Immunization (ETAGE), the Global Health Security Initiative and Agenda processes (Global Health Security Initiative, Global Health Security Agenda), Unicef and financing and research initiatives like Gavi, CEPI, GloPID-R and JPIAMR (the Joint Programming Initiative on Antimicrobial Resistance).	➢ Sub-optimal global and coordinated preparedness & resilience against vaccine-preventable epidemics, including cross-border threats
Action 10 - Develop evidence-based tools and guidance at EU level in order to support countries to anticipate, pre-empt or respond to crisis situations	➢ Sub-optimal global and coordinated preparedness & resilience against vaccine-preventable epidemics, including cross-border threats
Action 11 - Counter online vaccine misinformation and develop evidence-based information tools and guidance to support Member States in responding to vaccine hesitancy, in line with the Commission Communication on tackling online disinformation	➢ Mis and disinformation/ lack of accurate information
Action 12 - Establish a European Vaccination Information Sharing system	➢ Secure access and sharing of heath data across borders for citizens and professionals
Action 13 - Continuously monitor the benefits and risks of vaccines and vaccinations, at EU level, including through post-marketing surveillance studies	➢ Suboptimal monitoring of vaccination
Action 14 - Work towards developing common methodologies and strengthen the capacities to assess the relative effectiveness of vaccines and vaccination programmes	➢ Varying vaccination programmes across the EU
Action 15 - Strengthen the effective application of Union rules on the protection of workers from risks related to exposure to biological agents at work, as laid down in Directive 2000/54/EC and Council Directive 2010/32/EU, taking into account national competences, in particular by supporting continuing education of healthcare workers, monitoring their immunisation status and actively offering vaccination where necessary, to ensure adecuate levels of patient and healthcare-workers' safety	➢ Vaccination hesitancy including for healthcare workers
Action 16 - Provide evidence and data, including through the European Schoolnet, to support Member States' efforts to strengthen the aspects related to vaccinology and immunisation in their national medical curricula and postgraduate education	➢ Vaccination hesitancy including for healthcare workers
Action 17 - Consider developing a virtual European data warehouse on vaccine needs and, if applicable, offerable stocks, to facilitate the voluntary exchange of information on available supplies, possible surpluses and global shortages of essential vaccines	➢ Varying vaccination programmes across the EU ➢ Risk of vaccine shortages / Suboptimal monitoring of stocks ➢ Sub-optimal global and coordinated preparedness & resilience against vaccine-preventable epidemics, including cross-border threats
Action 18 - Explore feasibility of physical stockpiling and engage in a dialogue with vaccine producing companies on a mechanism to facilitate the stockpiling and availability of vaccines in case of outbreaks, taking into account global shortages of essential vaccines	➢ Risk of vaccine shortages / Suboptimal monitoring of stocks ➢ Sub-optimal global and coordinated preparedness & resilience against vaccine-preventable epidemics, including cross-border threats
Action 19 - Consider developing a concept for a mechanism for exchanging vaccine supplies from one Member State to another in case of an outbreak, improving the links between supply and demand for vaccines	➢ Risk of vaccine shortages / Suboptimal monitoring of stocks ➢ Sub-optimal global and coordinated preparedness & resilience against vaccine-preventable epidemics, including cross-border threats

Actions	Needs
Action 21 - Exploit the possibilities of joint procurement of vaccines or antitoxins to be used in cases of pandemics, unexpected outbreaks and in case of small vaccine demand (small number of cases or very specific populations to be covered)	➢ Risk of vaccine shortages / Suboptimal monitoring of stocks ➢ Sub-optimal global and coordinated preparedness & resilience against vaccine-preventable epidemics, including cross-border threats
Action 22 - Monitor compliance with the obligation of continuous supply of medicines placed on marketing authorisation holders (Article 81 of Directive 2001/83/EC) and explore ways to enhance compliance with that obligation	➢ Risk of vaccine shortages / Suboptimal monitoring of stocks ➢ Sub-optimal global and coordinated preparedness & resilience against vaccine-preventable epidemics, including cross-border threats
Action 25 - Reinforce existing partnerships and research infrastructures, and establish new ones, including for clinical trials	➢ Weak, fragmented & uncompetitive vaccine R&D landscape
Action 26 - Seek consensus on unmet population needs and agreed priorities for vaccines that can be used to inform future vaccine research funding programmes at national and EU level, including leveraging the advantages of the Coalition for Epidemic Preparedness Innovations (CEPI) and the Global Research Collaboration for Infectious diseases Preparedness (GloPID-R)	➢ Varrying vaccination programmes across the EU ➢ Weak, fragmented & uncompetitive vaccine R&D landscape
Action 27 - Consider investing in behavioural and social science research on the determinants of vaccine hesitancy across different subgroups of the population and healthcare workers	➢ Vaccination hesitancy including for healthcare workers

7.6 Annex 6: Survey Questionnaire

Dear Madam, dear Sir,

EY Consulting has been mandated by DG SANTE of the European Commission to undertake a Study on the coherence, complementarity, and continued relevance of actions in Council Recommendation of 7 December 2018 on strengthened cooperation against vaccine-preventable diseases (2018/C 466/01) in view of possible similar policy initiatives in the future. You can find the Accreditation Letter from DG SANTE here.

This Study aims to support the European Commission in assessing (i) the relevance of each of the 28 actions in the vaccination roadmap, taking the COVID-19 pandemic into account, (ii) the coherence and complementarity with other related policy initiatives, as well as in (iii) providing the Commission with a set of recommendations on how the most relevant actions could be further developed and made sustainable to remain relevant on a longer term

The purpose of this questionnaire is to **gather your views relating to the relevance and coherence of the actions and deliverables of the Council Recommendation**. The questionnaire is divided into five main parts. Following the Introduction (Part 1), Part 2 is dedicated to the "Relevance of Actions" of the 2018 Council Recommendation and accompanying Commission Roadmap. Part 3 concerns the "Coherence and Complementarity" of the actions between themselves and regarding other EU and international policy initiatives. Part 4 relates to "Prospective & Further developments". The questionnaire ends with three final open questions (Part 5)

During the survey, you will be asked to express your views on the relevance of specific actions falling under the 2018 Council Recommendation. It is important to note that in some cases, you will be asked to express your views on actions that address multiple needs.

As the main stakeholders dealing with vaccination issues at national, EU and international levels, your participation to this study is essential to the relevance of our conclusions and recommendations.

The information collected will be anonymised for processing and will be used in the form of aggregates. In addition, they will be systemically cross-referenced with data from the documentary review and interviews. Due to the particular care that we take in the anonymisation of data, we invite you to answer this questionnaire in a free and transparent manner.

The questionnaire has been adapted according to your profile: the answer you give to certain questions automatically and exclusively directs you to the most relevant questions.

Study on the coherence, complementarity, and continued relevance of actions in the Council Recommendation on strengthened cooperation against vaccine-preventable diseases in view of possible similar policy initiatives in the future

This questionnaire should not take more than 20 minutes of your time.

We would like to thank you for taking the time to answer these questions. Your contribution is essential to future policy thinking on vaccination across the EU, and to the reliability of our analyses.

In the event of a problem or if you have any questions regarding the questionnaire, you can contact us at the following address: paul.marie.roth@fr.ey.com and caroline.gentilhomme@fr.ey.com.

You can find the Privacy Statement for the questionnaire and the website cookies in the next page.

This questionnaire is accompanied by a Privacy Statement. This privacy statement explains the reason for the processing of your personal data, the way we collect, handle, and ensure protection of all personal data provided, how that information is used and what rights you have in relation to your personal data. We invite you to read it carefully. In line with the privacy notice, the contributions will be published in an aggregated form, but your personal data will not be published unless you give specific consent (see question below).

Privacy Statement: DG SANTE - "Vaccines" Survey - Privacy Statement

Q6 I have read the Privacy Statement and I would like to proceed in the survey

- o Yes (1)
- o No (2)

Q135 Do you agree with your personal data being published by the European Commission?

- o Yes, I agree (1)
- o No, I do not agree (2)

You have chosen not to consent to the EY Terms and Conditions.

Your response to this survey is invaluable in assisting EY to deliver products and services that continually meet your needs and the growing needs of our business. To accept the EY Terms and Conditions and to access the survey, please select **"Yes".**

By not accepting, you will not be able to proceed with the survey. Click "Next" to end your survey session.

If you have any objections regarding the processing of your personal data as described in the privacy statement, you cannot continue with the survey. For this reason, you can contact SANTE-CONSULT-B4@ec.europa.eu

I - Introduction

Q1. Please select the Member State from which you are from (Select 'EU' for EU Associations):

▼ Austria (1) ... EU (28)

Q2. What type of organisation do you work for?

- o National ministry of health and public health authorities and agencies in Member States (1)
- o Civil society organisations at national and EU level (2)
- o Civil society organisations at international level (3)
- o Health professional and student associations at national and EU level (4)
- o Health professional and student associations at international level (5)

o Organisations representing the vaccine industry at national, EU and international level (6)

Q3. Please provide us with the name of the EU Organisation/ National Association/ Business that you represent:

_____

Q4. Please rate your knowledge of the Council Recommendation on strengthened cooperation against vaccine-related diseases:

- o Very good (1)
- o Good (2)
- o Satisfactory (3)
- o Poor (4)
- o Very poor (5)
- o None (6)

Q5. Please rate your knowledge of the Commission's Roadmap on Vaccinations:

- o Very good (1)
- o Good (2)
- o Satisfactory (3)
- o Poor (4)
- o Very poor (5)
- o None (6)

II - Relevance of Actions in relation to strengthened cooperation against vaccine related diseases

Q6. At the time of adoption of the Council Recommendation in 2018, can you please rate the priority level of the following needs existing:

	No priority (1)	Low priority (2)	Medium priority (3)	High priority (4)	I don't know/ Can't say (5)
Unbalanced vaccine coverage rates across the EU (1)	o	o	o	o	o
Mis and disinformation/lack of accurate information on vaccines (2)	o	o	o	o	o
Vaccination hesitancy including for healthcare workers (3)	o	o	o	o	o
Suboptimal monitoring of vaccinations (4)	o	o	o	o	o
Difficulties in accessing	o	o	o	o	o

vaccinations and vaccination structures (5)					
Secure access and sharing of heath data across borders for citizens and professionals (6)	0	0	0	0	0
Suboptimal funding of vaccination programmes (7)	0	0	0	0	0
Lack of focus on vaccination in a life course perspective (8)	0	0	0	0	0
Varying vaccination programmes across the EU (9)	0	0	0	0	0
Lack of interoperability between MS with regards to electronic health records (10)	0	0	0	0	0
Fragmented vaccine R&D landscape (11)	0	0	0	0	0
Risk of vaccine shortages (12)	0	0	0	0	0
Sub-optimal global preparedness against vaccine-preventable diseases (13)	0	0	0	0	0

Q7. How would you rate the needs identified in 2018, <u>as of today</u>?

	No priority (1)	Low priority (2)	Medium priority (3)	High priority (4)	I don't know/ Can't say (5)
Unbalanced vaccine coverage rates across the EU (1)	0	0	0	0	0
Mis and disinformation/lack of accurate information on vaccines (2)	0	0	0	0	0
Vaccination hesitancy including for healthcare workers (3)	0	0	0	0	0
Suboptimal monitoring of vaccinations (4)	0	0	0	0	0
Difficulties in accessing vaccinations and vaccination structures (5)	0	0	0	0	0
Secure access and sharing of heath data across borders for citizens and professionals (6)	0	0	0	0	0

Suboptimal funding of vaccination programmes (7)	0	0	0	0	0
Lack of focus on vaccination in a life course perspective (8)	0	0	0	0	0
Varying vaccination programmes across the EU (9)	0	0	0	0	0
Lack of interoperability between MS with regards to electronic health records (10)	0	0	0	0	0
Fragmented vaccine R&D landscape (11)	0	0	0	0	0
Risk of vaccine shortages (12)	0	0	0	0	0
Sub-optimal global preparedness against vaccine-preventable diseases (13)	0	0	0	0	0

Q8. To what extent has the COVID-19 crisis had an impact on the needs existing in relation to vaccination?

- 0 To a very large extent (1)
- 0 To a large extent (2)
- 0 To some extent (3)
- 0 To a low extent (4)
- 0 To a very low extent (5)
- 0 I don’t know/I cannot say (6)

Q9. In addition to these needs existing in 2018, can you identify other needs that have emerged since then?

_____

II. 1 - Actions to address unbalanced vaccine coverage rates

Q10. Can you please rank the relevance of the 2018 Council Recommendation roadmap actions below that aimed to address unbalanced vaccine coverage rates across the EU?

	Not relevant (1)	Slightly relevant (2)	Relevant (3)	Highly relevant (4)	I don’t know/I cannot say (5)
Action 1: Examine the feasibility of developing a common vaccination card for EU citizens (1)	0	0	0	0	0

Action 8: Continue to support research and innovation for the development of safe and effective new vaccines, and the optimisation of existing vaccines (2)	0	0	0	0	0
Action 9: Strengthen existing partnerships and collaboration with international actors and initiatives (3)	0	0	0	0	0
Action 12: Establish a European Vaccination Information Sharing system (4)	0	0	0	0	0
Action 22: Support the EU Official Medicines Control Laboratories network and its work to ensure that vaccines placed on the EU market are of high quality (5)	0	0	0	0	0
Action 23: Monitor compliance with the obligation of continuous supply of medicines placed on marketing authorisation holders (6)	0	0	0	0	0
Action 26: Seek consensus on unmet population needs and agreed priorities for vaccines that can be used to inform future vaccine research funding programmes at national and EU level (7)	0	0	0	0	0
Action 27: Consider investing in behavioural and social science research on the determinants of vaccine hesitancy across different subgroups of the population and healthcare workers (8)	0	0	0	0	0

Q11. Have you identified any other action that appears relevant to address this need?

_____

II. 2 - Actions to address mis and disinformation and lack of accurate information on vaccines

Q12. Can you please rank the relevance of the 2018 Council Recommendation roadmap actions below that aimed to address mis and disinformation / lack of accurate information on vaccines across the EU?

	Not relevant (1)	Slightly relevant (2)	Relevant (3)	Highly relevant (4)	I don't know/I cannot say (5)
Action 1: Examine the feasibility of developing a common vaccination card for EU citizens (1)	0	0	0	0	0
Action 2: Produce on a regular basis a report on the State of Vaccine Confidence in the EU (2)	0	0	0	0	0
Action 3: Convene a Coalition for Vaccination to bring together European associations of healthcare workers as well as relevant students' associations (3)	0	0	0	0	0
Action 4: Strengthen the impact of the annual European Immunisation Week (4)	0	0	0	0	0
Action 11: Counter online vaccine misinformation and develop evidence-based information tools and guidance to support Member States (5)	0	0	0	0	0

Q13. Have you identified any other action that appears relevant to address this need?

II. 3 - Actions to address vaccination hesitancy, including for healthcare workers

Q14. Can you please rank the relevance of the 2018 Council Recommendation roadmap actions below that

aimed to address vaccination hesitancy, including for healthcare workers across the EU?

	Not relevant (1)	Slightly relevant (2)	Relevant (3)	Highly relevant (4)	I don't know/I cannot say (5)
Action 2: Produce on a regular basis a report on the State of Vaccine Confidence in the EU (1)	0	0	0	0	0
Action 3: Convene a Coalition for Vaccination to bring together European associations of healthcare workers as well as relevant students' associations (2)	0	0	0	0	0
Action 4: Strengthen the impact of the annual European Immunisation Week (3)	0	0	0	0	0
Action 5: Identify barriers to access and support interventions to increase access to vaccination for disadvantaged and socially excluded groups (4)	0	0	0	0	0
Action 15: Strengthen the effective application of Union rules on the protection of workers from risks related to exposure to biological agents at work, in particular by supporting continuing education of healthcare workers, monitoring their immunisation status and actively offering vaccination where necessary (5)	0	0	0	0	0
Action 16: Provide evidence and data to support Member States' efforts to strengthen the aspects related to vaccinology and	0	0	0	0	0

immunisation in their national medical curricula and postgraduate education (6)					
Action 27: Consider investing in behavioural and social science research on the determinants of vaccine hesitancy across different subgroups of the population and healthcare workers (7)	0	0	0	0	0

Q15. Have you identified any other action that appears relevant to address this need?

_____

II. 4 - Actions to address the suboptimal monitoring of vaccinations across the EU

Q16. Can you please indicate the relevance of the 2018 Council Recommendation roadmap actions below that aimed to address suboptimal monitoring of vaccinations across the EU?

	Not relevant (1)	Slightly relevant (2)	Relevant (3)	Highly relevant (4)	I don't know/I cannot say (5)
Action 1: Examine the feasibility of developing a common vaccination card for EU citizens (1)	0	0	0	0	0
Action 6: Develop EU guidance for establishing comprehensive electronic immunization information systems (2)	0	0	0	0	0
Action 7: Develop guidance to overcome the legal and technical barriers impeding the interoperability of national immunisation information systems (3)	0	0	0	0	0
Action 9 : Strengthen existing partnerships and	0	0	0	0	0

collaboration with international actors and initiatives (4)	

Q17. Have you identified any other action that appears relevant to address this need?

_____

II. 5 - Actions to address the difficulties in accessing vaccinations and vaccination structures across the EU

Q18. Can you please indicate the relevance of the 2018 Council Recommendation roadmap actions below that aimed to address suboptimal monitoring of vaccinations across the EU?

	Not relevant (1)	Slightly relevant (2)	Relevant (3)	Highly relevant (4)	I don't know/I cannot say (5)
Action 5: Identify barriers to access and support interventions to increase access to vaccination for disadvantaged and socially excluded groups (1)	0	0	0	0	0
Action 26: Seek consensus on unmet population needs and agreed priorities for vaccines that can be used to inform future vaccine research funding programmes at national and EU level (2)	0	0	0	0	0
Action 27: Consider investing in behavioural and social science research on the determinants of vaccine hesitancy across different subgroups of the population and healthcare workers (3)	0	0	0	0	0

Q19. Have you identified any other action that appears relevant to address this need?

_____

II. 6 - Actions to address suboptimal funding of vaccination programmes

Q20. Can you please rank the relevance of the 2018 Council Recommendation roadmap actions below that aimed to address the suboptimal funding of vaccination programmes across the EU?

	Not relevant (1)	Slightly relevant (2)	Relevant (3)	Highly relevant (4)	I don't know/I cannot say (5)
Action 8: Continue to support research and innovation for the development of safe and effective new vaccines, and the optimisation of existing vaccines (1)	0	0	0	0	0
Action 26: Seek consensus on unmet population needs and agreed priorities for vaccines that can be used to inform future vaccine research funding programmes at national and EU level (2)	0	0	0	0	0

Q21. Have you identified any other action that appears relevant to address this need?

_____

II. 7 - Actions to secure access and sharing of health data across borders for citizens and professionals

Q22. Can you please rank the relevance of the 2018 Council Recommendation roadmap actions below that aimed to secure access and sharing of heath data across borders for citizens and professionals across the EU?

	Not relevant (1)	Slightly relevant (2)	Relevant (3)	Highly relevant (4)	I don't know/I cannot say (5)
Action 1: Examine the feasibility of developing a common vaccination card for EU citizens (1)	0	0	0	0	0
Action 7: Develop guidance	0	0	0	0	0

to overcome the legal and technical barriers impeding the interoperability of national immunisation information systems (2)					
Action 12: Establish a European Vaccination Information Sharing system (3)	o	o	o	o	o

Q23. Have you identified any other action that appears relevant to address this need?

_____

II. 8 - Actions to address the lack of focus on vaccination in a life course perspective across the EU

Q24. Can you please rank the relevance of the 2018 Council Recommendation roadmap actions below that aimed to address the lack of focus on vaccination in a life course perspective across the EU?

	Not relevant (1)	Slightly relevant (2)	Relevant (3)	Highly relevant (4)	I don't know/I cannot say (5)
Action 26: Seek consensus on unmet population needs and agreed priorities for vaccines that can be used to inform future vaccine research funding programmes at national and EU level (1)	o	o	o	o	o
Action 27: Consider investing in behavioural and social science research on the determinants of vaccine hesitancy across different subgroups of the population and healthcare workers (2)	o	o	o	o	o

Q25 25. Have you identified any other action that appears relevant to address this need?

_____

II. 9 - Actions to address the diversity of vaccination programmes across the EU

Q26. Can you please rank the relevance of the 2018 Council Recommendation roadmap actions below that aimed to address the diversity of vaccination programmes across the EU?

	Not relevant (1)	Slightly relevant (2)	Relevant (3)	Highly relevant (4)	I don't know/I cannot say (5)
Action 6: Develop EU guidance for establishing comprehensive electronic immunization information systems (1)	0	0	0	0	0
Action 7: Develop guidance to overcome the legal and technical barriers impeding the interoperability of national immunisation information systems (2)	0	0	0	0	0
Action 12: Establish a European Vaccination Information Sharing system (3)	0	0	0	0	0
Acton 14: Work towards developing common methodologies and strengthen the capacities to assess the relative effectiveness of vaccines and vaccination programmes (4)	0	0	0	0	0
Action 17: Consider developing a virtual European data warehouse on vaccine needs and, if applicable, offerable stocks (5)	0	0	0	0	0
Action 26: Seek consensus on unmet population needs and agreed priorities for vaccines that can be used to inform future vaccine research funding programmes at national and	0	0	0	0	0

EU level (6)	

Q27. Have you identified any other action that appears relevant to address this need?

_____

II. 10 - Actions to address the lack of interoperability between Member States with regards to electronic health records

Q28. Can you please rank the relevance of the 2018 Council Recommendation roadmap actions below that aimed to address the lack of interoperability between Member States with regards to electronic health records?

	Not relevant (1)	Slightly relevant (2)	Relevant (3)	Highly relevant (4)	I don't know/I cannot say (5)
Action 1: Examine the feasibility of developing a common vaccination card for EU citizens (1)	0	0	0	0	0
Action 6: Develop EU guidance for establishing comprehensive electronic immunization information systems (2)	0	0	0	0	0
Action 7: Develop guidance to overcome the legal and technical barriers impeding the interoperability of national immunisation information systems (3)	0	0	0	0	0

Q29. Have you identified any other action that appears relevant to address this need?

_____

II. 11 - Actions to address the fragmented vaccine R&D landscape across the EU

Q30. Can you please rank the relevance of the 2018 Council Recommendation roadmap actions below that aimed to address the fragmented vaccine R&D landscape across the EU?

	Not relevant (1)	Slightly relevant (2)	Relevant (3)	Highly relevant (4)	I don't know/I cannot say

					(5)
Action 8: Continue to support research and innovation for the development of safe and effective new vaccines, and the optimisation of existing vaccines (1)	0	0	0	0	0
Action 24: Consider facilitating –together with EMA- early dialogue with developers, national policy-makers and regulators in order to support the authorisation of innovative vaccines, including for emerging health threats (2)	0	0	0	0	0
Action 25: Reinforce existing partnerships and research infrastructures, and establish new ones, including for clinical trials (3)	0	0	0	0	0
Action 26: Seek consensus on unmet population needs and agreed priorities for vaccines that can be used to inform future vaccine research funding programmes at national and EU level (4)	0	0	0	0	0

Q31. Have you identified any other action that appears relevant to address this need?

_____

II. 12 - Actions to address risk of vaccine shortages

Q32. Can you please rank the relevance of the 2018 Council Recommendation roadmap actions below that aimed to address the risk of vaccine shortages across the EU?

	Not relevant (1)	Slightly relevant (2)	Relevant (3)	Highly relevant (4)	I don't know/I cannot say (5)

Action 17: Consider developing a virtual European data warehouse on vaccine needs and, if applicable, offerable stocks (1)	0	0	0	0	0
Action 18: Explore feasibility of physical stockpiling and engage in a dialogue with vaccine producing companies on a mechanism to facilitate the stockpiling and availability of vaccines in case of outbreaks (2)	0	0	0	0	0
Action 19: Consider developing a concept for a mechanism for exchanging vaccine supplies from one Member State to another in case of an outbreak (3)	0	0	0	0	0
Action 20: Consider possibilities for improving EU manufacturing capacity, ensuring continuity of supply and ensuring diversity of suppliers (4)	0	0	0	0	0
Action 21: Exploit the possibilities of joint procurement of vaccines or antitoxins to be used in cases of pandemics, unexpected outbreaks and in case of small vaccine demand (5)	0	0	0	0	0
Action 23: Monitor compliance with the obligation of continuous supply of medicines placed on marketing authorisation holders (6)	0	0	0	0	0
Action 24: Consider facilitating –together with	0	0	0	0	0

EMA- early dialogue with developers, national policy-makers and regulators in order to support the authorisation of innovative vaccines, including for emerging health threats (7)	

Q33. Have you identified any other action that appears relevant to address this need?

_____

II. 13 - Actions to address the sub-optimal global preparedness against vaccine preventable diseases across the EU

Q34. Can you please rank the relevance of the 2018 Council Recommendation roadmap actions below that aimed to address the sub-optimal global preparedness against vaccine-preventable diseases across the EU?

	Not relevant (1)	Slightly relevant (2)	Relevant (3)	Highly relevant (4)	I don't know/I cannot say (5)
Action 9: Strengthen existing partnerships and collaboration with international actors and initiatives (1)	0	0	0	0	0
Action 10 - Develop evidence-based tools and guidance at EU level in order to support countries to anticipate, pre-empt or respond to crisis situations (2)	0	0	0	0	0
Acton 14: Work towards developing common methodologies and strengthen the capacities to assess the relative effectiveness of vaccines and vaccination programmes (3)	0	0	0	0	0
Action 17: Consider developing a virtual European data warehouse on vaccine needs and, if	0	0	0	0	0

applicable, offerable stocks (4)					
Action 20: Consider possibilities for improving EU manufacturing capacity, ensuring continuity of supply and ensuring diversity of suppliers (5)	0	0	0	0	0
Action 21: Exploit the possibilities of joint procurement of vaccines or antitoxins to be used in cases of pandemics, unexpected outbreaks and in case of small vaccine demand (6)	0	0	0	0	0
Action 23: Monitor compliance with the obligation of continuous supply of medicines placed on marketing authorisation holders (7)	0	0	0	0	0
Action 26: Seek consensus on unmet population needs and agreed priorities for vaccines that can be used to inform future vaccine research funding programmes at national and EU level (8)	0	0	0	0	0

Q35. Have you identified any other action that appears relevant to address this need?

_____

III - Coherence and Complementarity

Q36. In your opinion, to what extent are the 28 actions coherent between themselves and ensure synergies and complementarity?

- 0 To a very large extent (1)
- 0 To a large extent (2)
- 0 To some extent (3)
- 0 To a low extent (4)
- 0 To a very low extent (5)
- 0 I don’t know/I cannot say (6)

Q41 Please complete the box below if you wish to illustrate with examples of synergies or divergences.

_____

Q37. In your opinion, to what extent are the 28 actions in line and complementary to the 2020 *Pharmaceutical Strategy for Europe*?

- o To a very large extent (1)
- o To a large extent (2)
- o To some extent (3)
- o To a low extent (4)
- o To a very low extent (5)
- o I don't know/I cannot say (6)

Q43 Please complete the box below if you wish to illustrate with examples of synergies or divergences.

_____

Q38. In your opinion, to what extent are the 28 actions in line and complementary to the establishment of the Europe's *Beating Cancer Plan*?

- o To a very large extent (1)
- o To a large extent (2)
- o To some extent (3)
- o To a low extent (4)
- o To a very low extent (5)
- o I don't know/I cannot say (6)

Q45 Please complete the box below if you wish to illustrate with examples of synergies or divergences.

_____

Q39. In your opinion, to what extent are the 28 actions in line and complementary to the establishment of the European Health Union?

- o To a very large extent (1)
- o To a large extent (2)
- o To some extent (3)
- o To a low extent (4)
- o To a very low extent (5)
- o I don't know/I cannot say (6)

Q47 Please complete the box below if you wish to illustrate with examples of synergies or divergences.

_____

Q40. In your opinion, to what extent are the 28 actions in line and complementary to the establishment of the European Health Data Space, and especially with the 2022 Commission policy initiative *A European Health Data Space: harnessing the power of health data for people, patients, and innovation*?

- o To a very large extent (1)
- o To a large extent (2)
- o To some extent (3)

- To a low extent (4)
- To a very low extent (5)
- I don't know/I cannot say (6)

Q49 Please complete the box below if you wish to illustrate with examples of synergies or divergences.

_____

Q41. In your opinion, to what extent are the 28 actions in line and complementary to the conclusions of the Conference on Vaccination hold in Prague in November 2022 under the Czech Presidency of the EU?

- To a very large extent (1)
- To a large extent (2)
- To some extent (3)
- To a low extent (4)
- To a very low extent (5)
- I don't know/I cannot say (6)

Q51 Please complete the box below if you wish to illustrate with examples of synergies or divergences.

_____

Q42. In your opinion, to what extent are the 28 actions in line and complementary to the establishment of WHO *European Vaccine Action Plan 2015–2020* and *European Immunization Agenda 2030*?

- To a very large extent (1)
- To a large extent (2)
- To some extent (3)
- To a low extent (4)
- To a very low extent (5)
- I don't know/I cannot say (6)

Q53 Please complete the box below if you wish to illustrate with examples of synergies or divergences.

_____

Q43. In your opinion, to what extent are the 28 actions in line and complementary to the conclusions of the Global Vaccination Summit, organised under EU leadership and in cooperation with WHO?

- To a very large extent (1)
- To a large extent (2)
- To some extent (3)
- To a low extent (4)
- To a very low extent (5)
- I don't know/I cannot say (6)

Q55 Please complete the box below if you wish to illustrate with examples of synergies or divergences.

IV - Prospective & Further developments

IV.1 - Prospective & Further developments - Preparedness

Q44. In relation to preparedness, how would you rate the preparedness of the EU when facing public health

crisis?

- o Very good (1)
- o Good (2)
- o Satisfactory (3)
- o Poor (4)
- o Very poor (5)
- o I don't know/I cannot say (6)

Q45. In relation to preparedness in the face of crisis, to what extent do you agree with the following statements:

	Strongly agree (1)	Agree (2)	Disagree (3)	Strongly disagree (4)	I don't know/I cannot say (5)
The EU and its Member States are sufficiently equipped to face crisis situations (1)	o	o	o	o	o
Evidence-based tools and guidance at EU level are available to support Member States to anticipate, pre-empt and respond to crisis situations (2)	o	o	o	o	o

Q58 If you disagree with the following statements, can you please provide an explanation why.

_____

Q46. In relation to the deployment of tools to improve preparedness, to what extent do you agree with the following statements:

	Strongly agree (1)	Agree (2)	Disagree (3)	Strongly disagree (4)	I don't know/I cannot say (5)
The ECDC has successfully increased cooperation at EU level when it comes to preparedness (1)	o	o	o	o	o

A resilient and comprehensive electronic immunization information system has been deployed (via the European Vaccination Information Sharing System) (2)	0	0	0	0	0
Persistent legal and technical barriers are impeding the interoperability of national immunization information systems (3)	0	0	0	0	0

Q60 If you disagree with the following statements, can you please provide an explanation why.

_____

IV.2 - Prospective & Further developments - Clinical Research

Q47. In relation to clinical research, how would you rate the level of autonomy at EU level and at Member States' level in terms of clinical research?

- 0 Very good (1)
- 0 Good (2)
- 0 Satisfactory (3)
- 0 Poor (4)
- 0 Very poor (5)
- 0 I don't know/I cannot say (6)

Q48. In relation to clinical research, to what extent do you agree with the following statements:

	Strongly agree (1)	Agree (2)	Disagree (3)	Strongly disagree (4)	I don't know/I cannot say (5)
Research and innovation for the development of new vaccines in the EU is satisfactory (1)	0	0	0	0	0
The number of research infrastructures within the EU is satisfactory (2)	0	0	0	0	0
The EU intervention to simplify procedures and facilitate trials and clinical	0	0	0	0	0

research is helpful (3)					
"Vaccelerate", a clinical research network for the coordination and conduct of COVID-19 vaccine trials, funded by HERA Incubator, is a helpful tool to better coordinate EU stakeholders in vaccines' trials (4)	0	0	0	0	0
Covid-19 revealed tremendous amount of duplication of investigations on the same interventions (5)	0	0	0	0	0
The number of small trials in the EU is rising and should be more coordinated (6)	0	0	0	0	0
Current trials in the EU under-represent important population subgroups (7)	0	0	0	0	0
More transparency on clinical trials should be ensured to the public (8)	0	0	0	0	0

IV. 3 - Prospective & Further developments - Communication

Q49. In your opinion, to what extent do disinformation, misinformation and lack of communication have an impact on vaccination hesitancy?

- 0 To a very large extent (1)
- 0 To a large extent (2)
- 0 To some extent (3)
- 0 To a low extent (4)
- 0 To a very low extent (5)
- 0 I don't know/I cannot say (6)

Q50. In relation to dis and misinformation, to what extent do you agree with the following statements:

	Strongly agree (1)	Agree (2)	Disagree (3)	Strongly disagree (4)	I don't know/I cannot say (5)
Conspiracy theories have	0	0	0	0	0

increased during the COVID-19 pandemic (1)					
The level of dis and misinformation during the COVID-19 pandemic has remained equal but protestors against vaccination have become more vocal (2)	o	o	o	o	o
Online vaccine misinformation is being effectively tackled (through social media, search engine optimization and specialised media) (3)	o	o	o	o	o
The issue of dis and misinformation is effectively tackled at EU level via adequate tools and appropriate relays (doctors, pharmacists and other health care professionals) (4)	o	o	o	o	o
Post marketing surveillance studies effectively enable to monitor the safety, effectiveness and the impact of vaccination (5)	o	o	o	o	o

Q65 If you disagree with the following statements, can you please provide an explanation why.

_____

Q51. In relation to communication means and tools, to what extent do you agree with the following statements:

	Strongly agree (1)	Agree (2)	Disagree (3)	Strongly disagree (4)	I don't know/I cannot say (5)
To reach a large spectrum of the population (in a life-long perspective), different	o	o	o	o	o

means of communication are adequately deployed (1)					
The deployment of a common European reminder system would increase vaccination cover rates (2)	o	o	o	o	o
The different channels of information and communication concerning vaccination are streamlined and easily reachable (3)	o	o	o	o	o
The European Medicament Agency (EMA) is a key player when it comes to communication and general recommendations on vaccination (4)	o	o	o	o	o
Easy to digest materials on vaccination, up to date knowledge (5)	o	o	o	o	o

Q67 If you disagree with the following statements, can you please provide an explanation why.
_____

Q52. In relation to vaccination among healthcare professionnals, to what extent do you agree with the following statements:

	Strongly agree (1)	Agree (2)	Disagree (3)	Strongly disagree (4)	I don't know/I cannot say (5)
Vaccination hesitancy among health professionals has been tackled through effective communication (1)	o	o	o	o	o
Healthcare professionals benefit from up-to-date and easy-to-digest materials on vaccination (2)	o	o	o	o	o
Healthcare professionals are in position to provide clear	o	o	o	o	o

and up-to-date communicate on vaccination thanks to continuous training (3)	

Q69 If you disagree with the following statements, can you please provide an explanation why.

_____

IV. 4 - Prospective & Further developments - Strategic Autonomy

Q53. In your opinion, how would you rate the European Union's vaccine sovereignty and autonomy?

- o Very good (1)
- o Good (2)
- o Satisfactory (3)
- o Poor (4)
- o Very poor (5)
- o I don't know/I cannot say (6)

Q54. In relation to strategic autonomy, to what extent do you agree with the following statements:

	Strongly agree (1)	Agree (2)	Disagree (3)	Strongly disagree (4)	I don't know/I cannot say (5)
The EU's strategic autonomy depends on the existence, on the EU soil, of a strong vaccine industry (1)	o	o	o	o	o
The links between the vaccine industry and EU institutions should be reinforced (2)	o	o	o	o	o
There is a critical need for a much closer, much integrated and more strategic public-private partnership (3)	o	o	o	o	o

Q72 If you disagree with the following statements, can you please provide an explanation why.

_____

Q55. In relation to supply chain, to what extent do you agree with the following statements:

	Strongly agree (1)	Agree (2)	Disagree (3)	Strongly disagree (4)	I don't know/I cannot say (5)
The vaccine supply chain at EU level ensures optimal exchange of information on available supplies, surpluses and global shortages (1)	0	0	0	0	0
The creation of data warehouses / datacenter to monitor the offerable stocks of vaccines at EU level would strengthen the EU's strategic autonomy (2)	0	0	0	0	0
Supply chain optimization will improve vaccine transfers between Member States (3)	0	0	0	0	0

Q74 If you disagree with the following statements, can you please provide an explanation why.

_____

IV. 5 - Prospective & Further developments - Further development

Q56. In your opinion, which action should be put at the top of the agenda as of today?

_____

Q57. What would be the 3 additional actions you foresee critical the 5 to 10 years ahead?

_____

V - Final Questions

Q58. Do you have any additional comments or suggestions you would like to make?

_____

Q59. Do you have any data or documentation that would be of interest for the Study?

_____

Q60. Would you agree to be contacted by a member of the Study team to discuss further issues related to this Questionnaire?

_____

Q61. If so, can you specify your email address in the box? Your email will not circulate publicly and will be used

by the Study team at professional ends only, with regard to this study.

7.7 Annex 7: Overview Table of the 27 Actions

The following table reflects the situation by June 2023 and is based on the public Roadmap (the updated version from July 2022) as well as an unpublished internal Roadmap that was made available to the Study team at the beginning of its work and later updates.

Action	Status of their deliverables	Year of Beginning	Year of End
Action 1 – EU Vaccination Card	Delivered	2019	2023
Action 2 – Vaccine Confidence report	Delivered	2018	2021
Action 3 – Coalition for Vaccination	Delivered	2019	2022
Action 4 – European Immunisation Week	Delivered	2019	Onwards 2019
Action 5 – Barriers to access and support to increase access	Delivered	2018	2021
Action 6 – Guidance on establishing Immunisation Information Systems for monitoring	Delivered	2018	2021
Action 7 – Guidance on Interoperability of Immunisation Information Systems	Delivered	2021	2022
Action 8 – Funding Support for Research and Innovation	Delivered	2019	2022
Action 9 – Strengthened Cooperation with International Actors and Initiatives	Delivered	2019	2019
Action 10 – Support for Member States to be Better Prepared	Delivered	2018	2021
Action 11 – Counter misinformation and develop tools and guidance	Delivered	2018	Onwards 2018
Action 12 – Establish European	Partially Delivered	2018	-

Action	Status of their deliverables	Year of Beginning	Year of End
Vaccination Information Sharing System			
Action 13 – Continuous monitoring of Benefits and Risks of Vaccines	Delivered	2018	2020
Action 14 – Work towards developing common methodologies and strengthen the capacities to assess the relative effectiveness of vaccines and vaccination programmes	Delivered. Being carried out under EU4Health AWP 2021.	2018	2021
Action 15 - Strengthen the effective application of Union rules on the protection of workers from risks related to exposure to biological agents at work	Delivered	2019	2019
Action 16 - Schoolnet and professionals' training on vaccinology	Delayed	2019	-
Action 17 - Develop a virtual warehouse on vaccines needs and stocks	Considered DELIVERED due to the set-up of DG HERA	2018	2022
Action 18 – Possibility of Stockpiling	Considered DELIVERED due to the set-up of DG HERA	2019	2021
Action 19 - Mechanism for exchange of vaccine supply between Member States	Considered DELIVERED due to the set-up of DG HERA	2019	2021
Action 20 - Improve Vaccine Manufacturing	Considered DELIVERED due to the set-up of DG HERA	2019	2019
Action 21 – Exploit the Possibilities of Joint Procurement of Vaccines	Delivered	2019	2019

Action	Status of their deliverables	Year of Beginning	Year of End
Action 22 – Support EU Official Medicine Control Laboratories	Delivered	2019	2019
Action 23 – Monitor Compliance with the Obligation of Continuous Supply of Medicines	Delivered	2019	2019
Action 24 – Facilitate early Dialogue with Stakeholders to support authorisation of new vaccines	Considered DELIVERED due to the set-up of DG HERA	2019	2022
Action 25 – Reinforce Partnerships and research Infrastructures	Delivered	2020	2022
Action 26 – Seek Consensus on Unmet Population Needs and Vaccine Priorities to inform future vaccine research funding	Delivered	2018	2022
Action 27 – Consider investing in behavioural and social science on vaccine hesitancy determinants	Delivered	2019	2022

EW-05-23-380-EN-N

Publications Office
of the European Union