The set-up of guidelines in support of ePrescription interoperability

Final Report

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ABSTRACT

Directive 2011/24/EU "on the application of patients' rights in cross-border healthcare" stipulates the "Recognition of prescriptions issued in another Member State" for dispensation across the Union. Furthermore, "the Commission shall adopt guidelines supporting the Member States in developing the interoperability of ePrescriptions." The study drafted such guide-lines as a base for further political process.

Initially, it analysed the present status of ePrescription in Member States, identified good practice, and assessed the feasibility of drafting detailed guideline beneficial for moving to-wards a single market for prescription drugs. Close cooperation was established with the "epSOS Smart Open Services for European Patients" project and national experts to validate outcomes.

The potential benefits and costs from ePrescribing are summarised, and initial estimates of marginal costs for readiness clusters of Member States when establishing cross-border ePrescribing services presented. Based on a novel four domain, three level interoperability concept, principal requirements for data exchange are discussed, open versus proprietary standards explored, and still pending policy and technical challenges identified. A comprehensive ePrescription draft Guideline Proposal is complemented by a detailed roadmap for action steps to be undertaken at both the European and Member State levels when indeed introducing Union-wide ePrescription services for all people.

EXECUTIVE SUMMARY

Background and context

The recent European Union Directive 2011/24/EU of 9 March 2011 "on the application of patients' rights in cross-border healthcare" stipulates in Article 11 the "Recognition of prescriptions issued in another Member State" for dispensation in any other Member State. Article 11 2. states that "the Commission shall adopt" (b) "guidelines supporting the Member States in developing the interoperability of ePrescriptions" without prejudice to national rules.

In order to develop and formulate such guidelines, the Directorate General for Health and Consumers' Executive Agency for Health and Consumers (EAHC) awarded a contract to empirica Communication and Technology Research to produce draft guidelines on interoperable ePrescriptions.

In the first phase of the study, empirica and its partners explored in a feasibility analysis the political eHealth and ePrescribing context across the Union. The present status of ePrescription in Member States was researched, good practice identified, and the feasibility of such guidelines was explored as well as the level of detail which may be appropriate to achieve the objectives of the cross-border directive and of moving towards a single market for prescription drugs. Close cooperation was established with experts from "epSOS Smart Open Services for European Patients" - a 25 country project which designs, builds and pilots a cross-border eService infrastructure that demonstrates interoperability between electronic patient record systems across participating countries, focusing on ePatient Summaries and ePrescriptions.

ePrescription interoperability as a European health policy priority

The immediate motivation for the setting up of interoperability guidelines stems from the directive on patients rights in cross-border healthcare. It is complemented by the European Commission implementing directive 2012/52/EU of 20 December 2012 which lays down measures to facilitate the recognition of medical prescriptions issued in another Member State. It defines a minimum obligatory set of elements any European prescription must contain, regardless of the medium used (paper or electronic prescription).

An Implementing Committee on cross-border healthcare was created by the patients' rights directive Article 16 1.; "it is consisting of representatives of the Member States and chaired by the Commission representative." With respect to eHealth aspects, it is complemented by voluntary "eHealth Network." According to Article 14 1. "the Union shall support and facilitate cooperation and the exchange of information among Member States working within a voluntary network connecting national authorities responsible for eHealth designated by the Member States." It is expected that the ePrescription interoperability guidelines drafted by this study will be finally endorsed by this eHealth Network.

The current study co-exists alongside other policy studies such as the European Interoperability Framework study and a study on an overview of national legislation with regard to electronic health records.

It is foreseen that the results of the large scale pilot epSOS (ending in 2014) and other projects and studies will be adapted and taken forward by the Connecting Europe Facility (CEF). It sets out to facilitate the deployment of cross-border interoperable ICT services of general interest by overcoming the barriers of the high initial investment costs and risks associated with this deployment. The CEF foresees almost €9.2 billion to support investment in fast and very fast broadband networks and pan-European digital services. As regards digital services, the money would be used for grants to build infrastructure needed to roll-out e-ID, eProcurement, electronic health care records, Europeana, eJustice and customs-related services. The money would serve to ensure interoperability and meet the costs of running the infrastructure at European level, linking up Member States' infrastructures.[1]

The experience of epSOS has shown that bringing Member States together to build and deploy interoperable infra- and info-structures also contributes to complementary deployment at national, regional, and local level. The semantic and other technical assets developed in the scope of epSOS, but also other current large scale (eGovernment) pilot projects, are expected to be transferred into organisational structures facilitated and supported by the Connecting Europe Facility.

ePrescription services status in the EU

In many Member States national, regional or pilot ePrescribing service implementations exist, and most of them also participate in the epSOS project, thereby being familiar with the opportunities, but also the issues and challenges the introduction of ePrescription services implies. Union Member States were – around 2011/2012 - some kind of implementations or at least pilots exist comprise:

- ePrescription services across the country, or at least some regions:
  Denmark, Estonia, Greece, Netherlands, Spain, Sweden, UK (England, Scotland)

- Mature pilot projects for ePrescription that are set to move to routine operation
  Austria, Belgium, Finland, Italy (regional), (Norway)

- Small pilots with a declared political ambition to develop nationwide ePrescription services
  Czech Republic, Cyprus, Poland, Portugal, Croatia

- Prescription projects with eDispensation only or otherwise not fitting the ePrescription definition
  France, Ireland, Northern Ireland, Wales

All of these countries participate in epSOS. Furthermore, the following countries are also involved in epSOS project activities: Czech Republic, Germany, Hungary, Luxembourg, Malta, Norway, Poland, Portugal, Slovenia, Slovakia, Switzerland, Turkey

Already a cursory survey of core implementation elements revealed a large variety of situations with respect to ePrescription across the Union. The above grouping does, e.g., not allow for nuances such as primary care vs. hospital-care ePrescription systems, stand-alone systems and those integrated into wider national platforms, different levels of availability of the ePrescription services to certain groups of healthcare professionals, etc. This variety of national situations has not stopped European countries to join efforts in the epSOS large scale pilot with the objective to provide cross-border interoperable ePrescription and patient summary services.

[1] http://europa.eu/rapid/press-release_IP-11-1200_en.htm?locale=en

Benefits and costs from ePrescribing

Benefits

The implementation of ePrescribing systems is driven by the benefits expected for the respective healthcare system, its citizens, healthcare providers, payers, and society at large. To arrive at rational decision making, these benefits should be confronted with the likely costs to be expected by the health system/the Member States implementing them.

Changing from a paper based prescribing process to an electronic procedure may yield a number of important benefits to stakeholders, key of which is

- ✓ patient safety.

Increased medication safety is achieved through the seamless availability of all medications prescribed for a given patient in a standardised digital format, and not in sometimes difficult to read handwriting. This can lead to significant reductions in prescription errors resulting both from drugs dispensed and suggested dosage information the patient obtains. Often, these features are enhanced by IT supported alert or clinical decision support systems which support the prescribing and/or dispensing professional in identifying drug-drug interactions and other safety related problems.

Other benefit drivers may be

- ✓ More efficient, time saving prescribing process
- ✓ Improved medication stock management
- ✓ Easier archiving of prescription records
- ✓ Improved public health surveillance and analysis
- ✓ Integration with reimbursement and control systems
- ✓ Reduced risk of fraud and prescription falsification
- ✓ Avoidance of duplicate prescriptions to replace lost or misplaced ones.

In two case studies it was shown that already in a regional context such as Stockholm County or Andalucía estimated annual net socio-economic benefits may come close to € 100. They do, however, not necessarily derive from direct financial or cash savings, but rather from intangible benefits such as time saved or delivery of better care which otherwise would have been very expensive to achieve by conventional means. The Andalucían ePrescribing system Receta XXI is a module of Diraya, the region's EHR and general health information system. Specific benefits result because with Receta XXI, general practitioners (GPs) can prescribe for periods of up to one year, thus avoiding repeat visits of patients to their office, and pharmacists' can cancel prescriptions and send them back to the relevant GP for revision in case they discover a patient safety issue.

Costs

The major types of cost relate to one-time investment/re-investment expenditures (and their annual depreciation cost), implementation cost, and maintenance/operation cost. Beyond the often intangible costs of change management, considerable direct financial costs in terms of cash outlays have usually to be borne by both the government respectively the healthcare system for the ePrescribing platform and by healthcare provider organisations (HPO) including pharmacies, which depending on the healthcare system may include physicians operating as independent entrepreneurs. They usually have to carry the one-time investment as well as their respective implementation and maintenance/operation costs over the full life-time of the system.

Partially or totally these costs may be taken over by Third Party Payers or the health system/the government, e.g. through specific reimbursement rules, investment subsidies or other financial models.

From the case studies, it was estimated that over a ten-year period historical overall costs of between € 13 and € 75 per inhabitant may arise, and extra financial outlays of between €7 and €35 per inhabitant, or roughly € 0.70 to 3.50 per year. Mutatis mutandis, these estimates can be extrapolated –with increasing economies of scale - onto other regions and larger countries.

However, these figures will be considerably lower these days for countries where the diffusion of eHealth systems to healthcare providers – including medication record and ePrescription modules – has progressed to a significant degree. For Estonia, it was estimated that the implementation of a national ePrescription system afforded almost € 0.5 m (or € 0.37 per person for a population of

1.34 m; this amounts to about € 0.06 per person for the years 2007 to 2012), and for Luxembourg a prospective study estimated a range from a minimum of € 136,000 (2013 to 2015) to a maximum of € 420,000 (2011 to 2015), thereby assuming that "most of the work will be done in-house by the project manager (0.5 FTE - full-time equivalent)." This would imply less than € 0.20 per inhabitant per year. Depending on the eHealth infrastructure of the region/country, its size and the diffusion of relevant eHealth applications among healthcare provider organisations, one may expect over a ten-year period annual costs of around € 0.05 to € 0.30 per inhabitant.

Benefits and costs of cross-border ePrescribing

Benefits

In a cross-border context, this would not yet account for the extra benefits and costs of assuring cross-border ePrescription services. These are difficult to estimate, but considering the marginal relevance of cross-border healthcare service provision, these extra benefits are probably negligible.[2] Substantial benefits will, however, be reaped at the national or regional level. As the epSOS experience has shown, such European and even trans-Atlantic activities will lead to higher levels of awareness among stakeholders in those Member States where ePrescription or ePatient Summary services were not yet established. As participation in such digital cross-border exchange of patient data presupposes the availability of compliant interoperable eHealth services at home, it is to be expected that the quite substantial beneficial impact will indeed be reaped at the national level, first of all.

Costs

With respect to costs to be expected, Member State collaboration and sharing of information models, semantic assets, value sets, open source components and tools should be strongly encouraged and supported by the EC. Such collaboration would avoid redundant work, minimise costs for all and set positive examples for others to follow.

Concerning the costs to be expected depending on prior experience and national readiness status, epSOS has shown that the initial planning and ICT implementation costs for a cross-border ePrescription service are manageable:

A) For a regional or national system which already avails itself of ePrescription facilities and has *epSOS ePrescription piloting experience* it is estimated that the full-blown implementation of cross-border ePrescription services should come at marginal (investment) costs of perhaps anywhere between € 40,000 and 150,000 for staff input of up to 1 year FTE, dependent on the retention or not of staff (and their experience) involved in epSOS work, the overall complexity of the regional/national eHealth platform, and other related factors impacting on the set-up of this service. Concerning annual maintenance/operation cost it seems reasonable to assume that most of the work will be done in-house by a project manager and staff spending perhaps 0.2 to 0.3 FTE on this at a cost of € 20,000 to 40,000 p.a. at the national (coordination) level. in larger countries it is reasonable to assume that considerable economies of scale will prevail, but that nevertheless overall costs may increase up to 1 to 2 FTEs.

B) For epSOS participating Union countries with national ePrescription service experience and/or experience from epSOS pilot implementations for eSummary services, but without epSOS ePrescription pilot experience, additional costs will be incurred: it is estimated that the costs for implementing an additional ePrescription service is only half of the average epSOS experience and may turn out between € 250,000 and 500,000 depending on national salary levels and other factors.

C) For all other epSOS participating Member States 2 further cost components are to be expected:

a) The cost for setting up a (national) cross-border ePrecription infrastructure and service, for which it is suggest to allocate the full investment expenditure as estimated based on the epSOS experience, i.e. costs for about 3 to 5 FTE or € 500,000 to 1m.

[2] Cf. OECD. Health at a Glance: Europe 2012, OECD Publishing

b) The cost for setting up a basic national ePrescription infrastructure. The investment expenditure may vary between € 500,000 and several millions. Without a detailed analysis at the national level, any more precise estimate would seem inappropriate.

On the potential cost for a missing generic national platform, see D).

D) For all other Member States, in addition to the costs estimated for A) to C), further costs of setting up a basic national eHealth platform are to be expected. Overall figures may be derived from the estimates provided for Estonia (€ 12 m) and Luxembourg (€ 22.6 m to 37.2 m), but these would need to be adapted to the national context, like the ubiquity and quality of the national ICT infrastructure, eGovernment services which may be developed upon, the priorities of the respective national health policy, and the complexity of the health system set-up, together with a scale factor for the size of the country.

Requirements resulting from the need to

- ✓ implement a national contact points to „inform patients about the elements to be included in a [pan-European] prescription",
- ✓ make all citizens aware that prescriptions which they plan to be filled in another Member State must be "issued further to a request of a patient who intends to use them in another Member State",[3] etc.

are expected to account for up to € 0.02 to € 0.05 per inhabitant per annum, depending inter alia on the means applied to inform and train patients, citizens, professionals and others accordingly.

Principal requirements for data exchange and interoperability

Interoperability (IOp) is a generic concept concerning the exchange of data, information, and knowledge for collaborative purposes. In the digital field, it is often a fuzzy one - referring to data exchange among technical systems or "application entities," and less to the exchange of information among persons or organisations, taking into account business and workflow processes, procedures, and the cultural context.

In the context of providing seamless healthcare and other health services requiring the collaboration of various actors,

> *(e)Health system interoperability refers to facilitating and safeguarding the exchange, understanding and acting on patient and other health information and knowledge among linguistically and culturally disparate medical professionals, patients and other actors within and across health systems in a collaborative manner.*

The related interoperability requirement areas are not *levels* of achieving a certain goal in a consecutive fashion, but rather describe *complementary fields* which all need to be present to a certain degree in order to achieve basic interoperability. For the ePrescribing context, four *interoperability domains* are proposed, highlighting a complex *data access and exchange* domain with its specific relevance in a cross-border context:

- ➢ Policy domain
- ➢ Governance and legal domain
- ➢ Organisational domain
- ➢ Data access and exchange domain

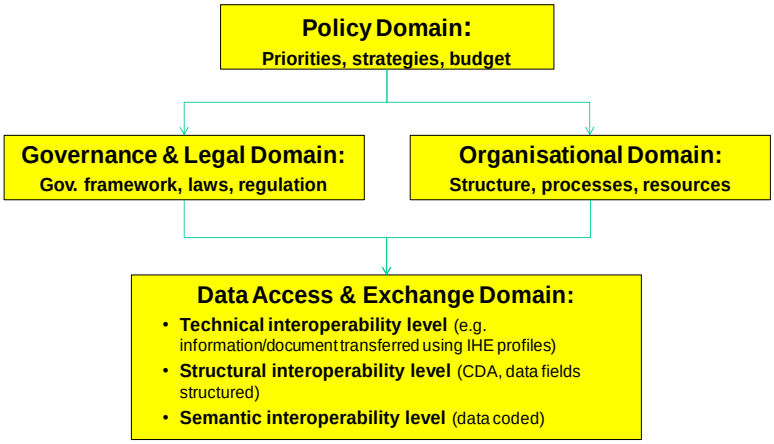
In order to allow for a univocal transfer of data, the receiver fully understanding the structure in which the data, information or knowledge are presented, and lastly the data being understood correctly with respect to their 'meaning', it is suggested to differentiate in the data exchange domain three *levels* of interoperability, which indeed build on each other, but which may be present to different degrees in a given set of data or information:

- ✓ technical interoperability

[3] Commission Implementing Directive 2012/52/EU laying down measures to facilitate the recognition of medical prescriptions issued in another Member State

- ✓ structural interoperability
- ✓ semantic interoperability

This can be summarised in the following graph:



From this IOp concept, principal requirements for a European cross-border exchange of electronic medical information are derived. They reflect the agreement achieved so far across epSOS participating countries, and they should become a starting point for any further extensions and developments in the ePrescribing field:

1. Use case: ePatient Summary and ePrescription services are to provide healthcare providers with a dataset of key health information at the point of care to deliver (a) safe patient care in an (b) unscheduled as well as scheduled contact to (c) patients from another country.

2. Patient centricity and stakeholder involvement: (a) The focus should be on the needs and expectations of citizens, patients and their carers. (b) All stakeholders, including healthcare providers and industry, should be involved.

3. No intrusion or interference: The exchange of patient data must (a) conform to the already in place or planned solutions, (b) respect the eHealth policy and implementation strategy, laws, and organisational structures of participating countries.

4. Relationship of trust: (a) In a transparent manner security, privacy, and authentication laws and regulations for electronic data exchange in all countries must be satisfied; (b) a National eHealth Contact Point could serve this purpose. (c) The right of patients to audit who has viewed or processed their data should be assured.

5. Reproducibility: The ePrescription service should be (a) based on neutral, adaptable techniques, thereby being (b) reproducible by all participating countries, and (c) flexible and capable of being supported by the health services of all participating countries within the context of their national health regulations, strategies and eHealth implementations.

6. Standards: Particularly in heterogynous and trans-border contexts, (a) agreement should be based on open standards to optimise overall cost and effort, including re-use of data; (b) the meaning of information needs to be preserved through semantic structuring and coding of patient information.

7. National eHealth platforms: (a) Well-organised national eHealth infrastructures are a prerequisite for successful, sustainable cross-border solutions; (b) in this context, a National eHealth Contact Point per country to interchange patient information should be established.

Open versus proprietary standards

In an operational sense, standards are "technical specifications." Whereas *proprietary standards* are developed for private use, the specifications of which are usually not disclosed and protected by IPRs, *open standards* are open for use by all, and where the documentation needed is available free of charge or for a low fee. When a solution is based on open standards, it allows for multivendor implementations and promotes interoperability of software and data as far as possible.

When ePrescription services take place in the complex field of public transborder healthcare, the goal should be to use open standards for including but not limited to documents, messages, identification, security aspects wherever possible. epSOS has made wide use of open standards like those available from HL7 for structuring documents. And the epSOS Master Value Sets Catalogue assembled the agreed, official code systems for a commonly understood medical terminology. Consequently, it may be most efficient for Member States together to support the further development of a tool box focusing on a core set of scalable ePrescription modules, which would be flexible enough to connect to a variety of national and regional healthcare structures, take into account the size of the healthcare system, cultural idiosyncrasies, resources available, etc. Such a tool-box should be based on open standards and be open for integrating open source software with commercial software, and provide interfaces for bespoke additions.

The integration of eHealth infrastructures with other national and European infrastructures should also be considered in this context. Particularly eGovernment infrastructure components should be integrated into an eHealth platform whenever meaningful, thereby potentially, in the longer term, realising considerable resource savings.

Pending ePrescription challenges

Considering the above discussed principal requirements for data exchange and interoperability, national as well as international eHealth and ePrescribing experts involved in an interactive exploration process as well as two validation workshops identified as particularly relevant, remaining challenges for the desired level of patient data exchange interoperability in a cross-border situation:

- ✓ Security and Privacy
- ✓ Transparency
- ✓ Preservation of information
- ✓ Openness and Reusability
- ✓ Technological Neutrality and Adaptability

Other open issues specifically concerning ePrescription challenges concern the

- Particularly heterogeneous validity period of prescriptions across European countries:
  This issue is also not resolved in the "non-exhaustive list of elements to be included in medical prescriptions" of the Implementing Directive 2012/52/EU laying down measures to facilitate the recognition of medical prescriptions issued in another Member State.

- Diversity of security and fraud prevention measures, particularly the use of digital signatures:

  Due to different implementations of electronic signatures across Europe and above all the lack of a centralized European public key infrastructure, the (mutual) recognition of electronic signatures faces some practical problems. For the time being a solution could be to allow substituting the prescriber's signature with the electronic signature of the National eHealth Contact Point having access to a national list of authorized prescribers of medications.

- Degree to which information elements of prescriptions must be available in coded form or not:

  This refers particularly to the insufficient coding instruments available to univocally represent active ingredients in medications across borders. Already epSOS faced this problem. In the absence of a better approach, the Anatomical Therapeutic Chemical Classification System including defined daily doses (ATC/DDD) of the World Health Organization (WHO), based upon the International Nonproprietary Names (INN) is proposed as a standard. A pan-European solution for resolving this problem may involve the further expansion of the medicinal

product data from European Medicines Agency (EMA) as a basis for a European Medicines database.

- Status of ePrescription services as a "medical device":

  There is an ongoing discussion as to whether medical information services like ePrescription may qualify as a medical device having to meet European regulation. However, as they are not a diagnostic or therapeutic intervention in the narrower sense, such services may not be regarded a medical device at present.

Draft ePrescription guidelines

There does not exist a formal definition of what "guideline" means in the context of European acts or documents, and the weight and meaning of guidelines vary considerably across European Commission Directorates. Also from a legal perspective, given the limited EU competences in the field of healthcare delivery, the term "guidelines" as referred to in Art 11 para 2 lit b (Directive 2011/24/EU) should be interpreted in a legally non-binding way, as there is no legal base for harmonisation in this field. According to Art 11 para 2 lit b D 2011/24/EU these guidelines shall be "supportive", so that they can be formulated only as recommendations.

Concerning the *level of specification of these guidelines*, the discussions with various experts in the field suggest that a 'medium' level of specificity may be most appropriate, given the status such guidelines may acquire in the further policy and implementation process. On the one hand, too specific and detailed guidelines may become obsolete within a short period of time due to continuing changes in technical, semantic, legal and organisation domains; on the other hand, very generic guidelines may only be able to identify key areas needing collaborative attention and agreement, but without setting a consensual framework from which to progress further in an efficient manner.

Roadmapping ePrescription services at the European and Member State level

Finally, the study suggests next steps for ePrescription activities at EU and national levels. The roadmap is guided by the use case as sketched in Art. 11 of the cross-border healthcare directive: "If a medicinal product is authorised to be marketed on their territory,... Member States shall ensure prescriptions issued for such a product in another Member State for a named patient can be dispensed on their territory in compliance with their national legislation." Because the implementation of the cross-border healthcare directive is mostly a Member State responsibility, steps may be initiated, driven forward and financially supported by the EC, but in the end it will have to be the Member States to render the envisaged ePrescription exchange system operable.

Proceeding in an economically efficient and meaningful way, it seems prudent to build upon earlier achievements at European as well as Member State levels, in order to not lose public as well as private investment in and build upon the success factors and lessons learned from the epSOS experience.

European level actions

To allow for continuous cross-European ePrescribing services as already provided for by epSOS pilots, and in order to further facilitate, diffuse, simplify and speed them up, the following coordinating actions were identified at the European level, involving both Member States and the EC in a collaborative mode:

- Mandatory, most urgent actions:

  Implementing digital signature services at the eGovernment or eHealth service level, because this is a major barrier for more efficient service processes.

  - Achieving a common European level or bilateral legal agreements, among countries planning to maintain or to newly establish ePrescription services. It may be based on the epSOS legal framework. Signing will be necessary at the latest as of 07/2014; otherwise the legal base for ePrescription services to be continued vanishes.

- Agreeing on an EU wide minimum ePrescription and Dispensation dataset –aligned with implementing directive (2012/52/EC) by 2014.
- Agreement on the future structures, processes and funding for a (virtual) European organisation to maintain, further develop and (internationally) coordinate technical and semantic interoperability assets, issues and challenges. Without properly maintained assets and interoperability services, a trans-European eHealth services network will not be feasible.

➢ Very important:

- Defining a common process and rules regarding substitution of medication. This would allow for more prescriptions to be univocally filled in another country.
- Agreement on an international standard to represent multiple active ingredients in medications. Again this would allow for more prescriptions to be univocally filled in another country.
- An EU wide agreement on minimum storage duration for ePrescription and dispensation records. This would improve legal certainty and harmonise EU-wide procedures.

➢ Nice to have:

- Agreement on the role of national value added services, particularly drug-interaction checks. This would improve patient safety.
- Agreement on rules for reimbursement of ePrescriptions dispensed in country B. But this may have to become part of a wider agreement on cross-border reimbursement processes. It would avoid patients having to pay in cash for medications in country B.

It would appear that the eHealth Network in its coordinator role of connecting national authorities responsible for eHealth may take responsibility for these actions on ePrescription, in close coordination and support by the EC, so as to deliver sustainable economic and social benefits from European eHealth systems and services.

National level actions

Concerning national level actions, a comprehensive, generic *Action Plan and Roadmap* for a country planning to join the European cross-border ePrescription service community is outlined. Conceptually, it follows the interoperability domains as discussed earlier.

In a concrete situation, depending on the framework, constraints, maturity of the existing national eHealth infrastructure, technical and interoperability characteristics of the ePrescription application and other circumstances, each country will need its own entry point into such a generic roadmap. Those starting from scratch will have the opportunity to already at the design stage of the system take into account, perhaps fully implement, all suggestions of the guidelines and roadmap. More mature or fully functional systems will need to expand their system to be able to interface with the European ePrescription data model and message standards, either by adjusting their system or making use of appropriate interface and mapping modules.

In an exemplar manner, based on epSOS experience the steps and time line required at Member State level to integrate the current European solution into an advanced national infrastructure is shown. It demonstrates that the adaptation can be achieved within a reasonable timeframe of half a year.

Of course, in countries where neither a basic eHealth infrastructure nor an ePrescription solution are available, these processes, depending on the political will and urgency with which the national Ministry of Health and/or its competent authority as well as key stakeholders like healthcare providers pursue such efforts, may take anywhere between one and up to five years, if not more, judging on past experience in Member States.[4]

[4] See the experience of European countries as described and analysed in: KA Stroetmann et al. European countries on their journey towards national eHealth infrastructures - evidence on progress and recommendations for cooperative actions. Luxembourg: Office for Official Publications of the European Communities, 2011

1 INTRODUCTION

This report presents the final draft set of European guidelines in support of pan-European ePrescription interoperability. An earlier version of these draft guidelines was discussed and reviewed by both

- Experts in the context of the second validation workshop
- DG SANCO / the Executive Agency for Health & Consumers (EAHC).

They are herewith submitted to DG SANCO for further discussion and agreement with Member States as a fundamental step towards the realisation of interoperable ePrescription services across the Union.

The analysis of European ePrescription challenges and the resulting recommendations for guideline formulation flow from four interrelated types of sources and activities:

a) The results of the ePrescription feasibility analysis documented in Deliverable D3.2, which identified the core issues and challenges the guidelines should be concerned with.
b) The translation of these issues into initial draft guidelines, and the results of applying the guideline development methodology as described in Deliverable D4.1 to thise initial draft, which included the detailed and iterative involvement of a large number of ePrescription experts across Europe.
c) Taking regard of currently available policy studies on interoperability at European level, notably the study commissioned to Deloitte on a European Interoperability Framework.
d) Analysing the piloting experience made in epSOS and the possibilities and limitations of the epSOS approach.

In order to understand the development of ePrescription services as a policy priority, in chapter 2 this report reviews current EC policy priorities including the directive on patients' rights in cross-border healthcare, which is the immediate basis for this document. This report then presents in Chapter 3 the current state of play in EU Member States with regard to national ePrescription solutions, including a review of empirical data exploring benefits and costs from ePrescribing.

Chapter 4 defines the principal requirements for a cross-border exchange of ePrescription information, structured according to four domains of interoperability and making use of the epSOS experience.

Chapter 5 sums up the experience of the epSOS pilot and lists epSOS achievements against the requirements outlined in Chapter 4. It illustrates open issues identified in epSOS against a process view of the epSOS end2end services.

This analysis is followed by a more focused view on open issues that are specific to ePrescriptions (Chapter 6).

As a result of the preceding analysis, Chapter 7 then proposes a number of guideline recommendations to address still open issues and how to seek consensus on them.

The deliverable concludes with a roadmap chapter which is based on the experience accumulated in epSOS. It provides concrete steps to be undertaken by Member States who want to join the ePrescription community, provided that the legacy of epSOS in this domain can be secured.

2 EPRESCRIPTION INTEROPERABILITY AS A EUROPEAN HEALTH POLICY PRIORITY AND STEPS FORWARD

This chapter reviews policy programmes for supporting Member States in the deployment of interoperable ePrescription services. First, it summarizes the important provisions laid down in the directive on patients' rights in cross-border healthcare with regard to ePrescription. It then moves on to describe the governance bodies (eHealth Governance Initiative and eHealth Network) and how their work relates to the objectives of this study.

It is strongly recommended to both DG SANCO and the eHealth Network to observe, connect to and take advantage of the opportunities for further support which may be forthcoming from these European Union activities in due time.

Finally, some new or pending study and coordination work will be identified, which should also be taken into account and may be of relevance for longer term cross-Member-State cooperation.

epSOS experience and implications will be reflected upon and analysed separately in Chapter 5 below.

2.1 Directive on patients rights in cross-border healthcare

As already noted earlier, the immediate motivation for the setting up of guidelines stems from the Directive on patients rights in cross-border healthcare:

Art. 11 of the Directive deals with the recognition of prescriptions issued in a Member State other than the patient's state of affiliation. In order to render this feasible and support this recognition also technically, Art. 11 (2) b of the directive requests the Commission to adopt

> ***"guidelines supporting the Member States in developing the interoperability of ePrescriptions."***

This Directive also contains several provisions that are of immediate relevance to any future efforts in Europe on ePrescription services. While article 11 (2) d requests the European commission to propose guidelines on interoperable ePrescriptions, article 11 as a whole contains a number of additional clauses that will affect prescribing in Europe.

The European Commission Implementing Directive 2012/52/EU of 20 December 2012 laid down measures to facilitate the recognition of medical prescriptions issued in another Member State. This complementary directive defined a minimum obligatory set of elements any European prescription must contain. This set applies regardless of the medium used (paper or electronic prescription).

The ePrescription interoperability guidelines developed by this project and to be finally endorsed by the eHealth Network, reflect and build on the minimum data set agreed in the Implementing Directive.

The Committee on cross-border healthcare created by the patients' rights Directive[5] assembles Member State representatives in a forum where decisions on implementing acts of the directive are taken. It is advisable that this forum also considers the patient summary dataset and ePrescription dataset developed by epSOS in the decision making process on a minimum ePrescription dataset.

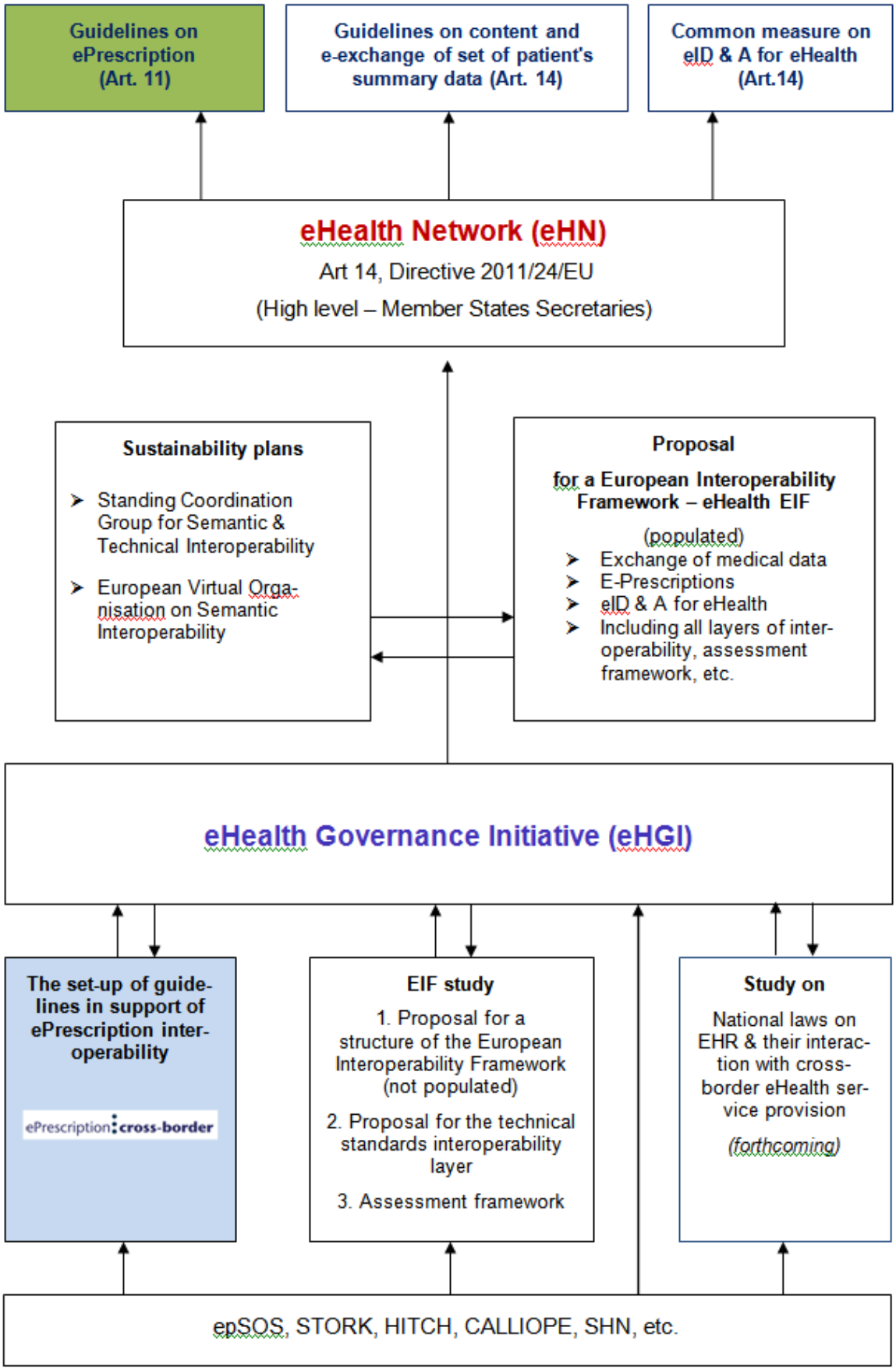
Current discussions in the *eHealth Network* (see also the section below) point also to the potential of using the databases of the European Medicines Agency (EMA) established as part of the pharmacovigilance effort to identify product interactions. Further details on this topic can be found in section 6.2

[5] DIRECTIVE 2011/24/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2011 on the application of patients' rights in cross-border healthcare. Official Journal of the European Union. EN - 4.4.2011, L 88/45-64.

It was agreed that the network members should raise awareness at the national level regarding the need to pursue building databases interoperable between the Member States and with the EMA. Whether such databases of medicinal products could be used to further develop ePrescription services is a matter of further study.

The overall policy context of the guidelines on interoperable ePrescriptions is illustrated in Figure 1 below. It visualizes the various project results that have been digested in this present work, notably the experience of epSOS. It also shows that the current study co-exists alongside other policy studies such as the European Interoperability Framework study and an upcoming study on an overview of national legislation with regard to electronic health records. The eHealth governance initiative, composed of experts at Member State level and of other stakeholders is the first important consumer of the results described in this document.

Figure 1: Guidelines on ePrescription in the EC policy framework



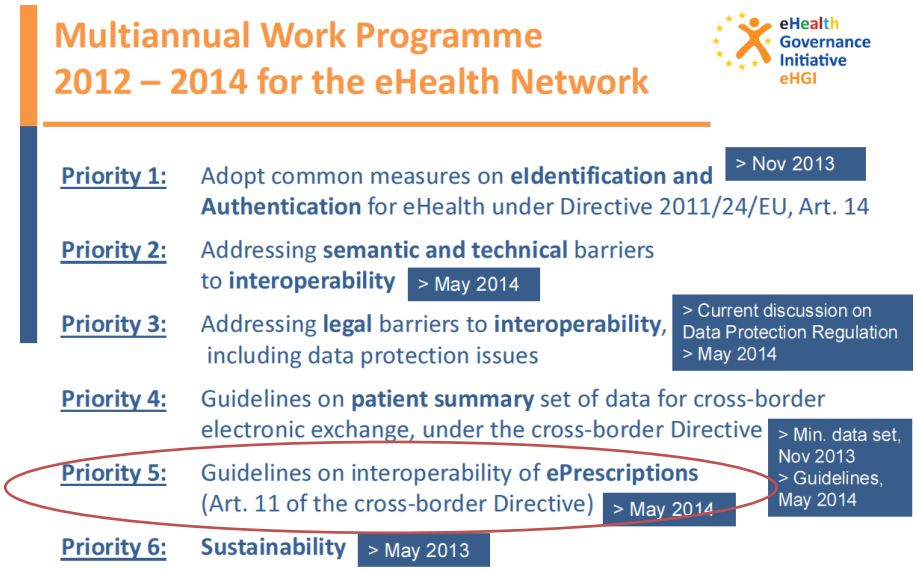
2.2 Ongoing work of the eHealth Network, eHealth Governance Initiative, epSOS, EIF

2.2.1 The eHealth Network

The eHealth Network was set up by a Commission Implementing Decision on 22 December 2011: *which sets the necessary rules for the establishment, the management and the functioning of the Network of national responsible authorities on eHealth, as provided for by Article 14(1) of Directive 2011/24/EU*[6].

The overall objective of the eHealth Network (eHN) is to work towards delivering sustainable health, social and economic benefits of European eHealth systems and services, including interoperable applications[7]. The goal is to achieve a high level of trust and security, to enhance continuity of care and ensure access to safe and high quality healthcare in accordance with the Directive on patients' rights in cross border healthcare (2011/24/EU), "the Cross border Directive". The Multiannual Work Programme 2012 - 2014 (cf. Figure 2 below) builds on the strategic priorities on eHealth specified in the Cross border Directive. It reflects Network Members' priorities expressed in their first Network's meeting and takes into account European projects and initiatives and national developments and needs. The measures proposed are not legally binding and shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care.

Figure 2: Multiannual Work Programme eHealth Network



Source: Dr. Clemens-Martin Auer, Ministry of Health Austria, eHGI Workshop on eID for eHealth, 11-12 Feb 2013, Brussels

The Multiannual Work Programme addresses six priorities.

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[6] Commission Implementing Decision of 22 December 2011 providing the rules for the establishment, the management and the functioning of the national responsible authorities on eHealth, OJEU, L344/48, 28/12/2011 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:344:FULL:EN:PDF

[7] Strategic priorities of the eHealth Network, Minutes of the eHealth Network Meeting, 7 Nov 2012

Priority 5 is dealing with the Guidelines on interoperability of ePrescriptions. Further activities that will also be relevant are *Addressing Legal Barriers to Interoperability, including Data Protection issues* foresees a final outcome in the form of

- Guidelines on legal interoperability

with the intermediate outcome being a

- Legal Interoperability Roadmap for cross border exchange of electronic Health Records and ePrescriptions

to be delivered by the end of 2014.

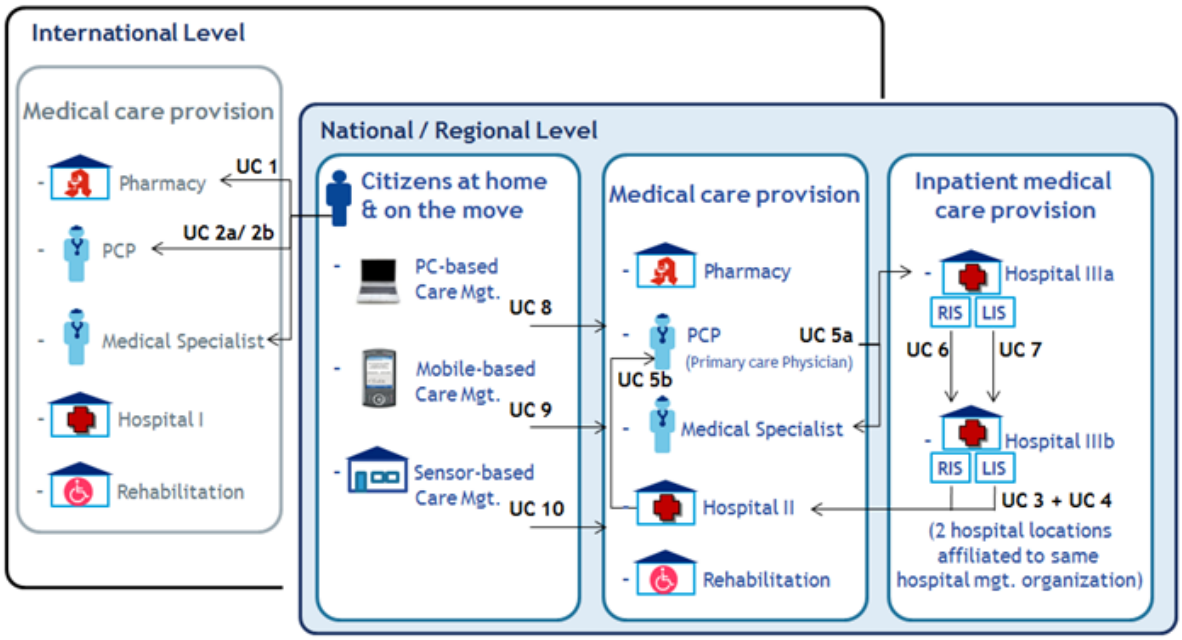
For the context of this study, another relevant priority is *Priority 1: Adopt common measures on eIdentification and Authentication.* As will be shown further below, the uneven use of digital signatures and a missing European public key infrastructure are among the remaining open issues on the way towards interoperable eHealth services in Europe.

2.2.2 ePrescription in the European Interoperability Framework

The study on a European Interoperability Framework, carried out by Deloitte Consulting is establishing a framework for the European exchange of data and (eHealth) services. In the technical report of this study, the authors identified possible use cases and assess these against existing technical profiles. Figure 3 below summarizes the total of ten use cases.

UC1 is the use case dealing with cross-border ePrescription and eDispensation.

Figure 3: The 10 use cases of the European Interoperability Framework



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2.3 eHealth infrastructure to be supported by the Connecting Europe Facility

Among other objectives, the Connecting Europe Facility (CEF) sets out to facilitate the deployment of cross-border interoperable ICT services of general interest such as eHealth by overcoming the barriers of the high initial investment costs and risks associated with this deployment. The results

of the large scale pilot epSOS (ending in 2013) and other projects and studies will be adapted and taken forward in the CEF.

The "Connecting Europe Facility" foresees almost €9.2 billion to support investment in fast and very fast broadband networks and pan-European digital services. As regards digital services, the money would be used for grants to build infrastructure needed to roll-out e-ID, eProcurement, electronic health care records, Europeana, eJustice and customs-related services. The money would serve to ensure interoperability and meet the costs of running the infrastructure at European level, linking up Member States' infrastructures.[8]

The experience of epSOS has shown that bringing Member States together to build and deploy interoperable infra- and info-structures also contributes to complementary deployment at national, regional and local level. The (semantic) and other technical assets developed in the scope of epSOS, but potentially also other current large scale pilot projects, are expected to be transferred into organisational structures facilitated and supported by the Connecting Europe Facility.

To already prepare for this, the European Commission through its CIP (Competitiveness and Innovation Programme) has therefore been sponsoring a Thematic Network which is expected to:

- Maintain and further develop interoperability assets which have a European scope, were developed by interoperability projects such as epSOS, SemanticHealthNet, Transform, eHR4CR, or which are eligible to populate the eHealth Interoperability Framework. They must be free of any intellectual property rights.

- Integrate any relevant recommendations and decisions taken by the eHealth Network.

- Foresee a proper handover strategy from the successful proposal to the CEF

- Bring together a wide range of relevant stakeholders with expertise in the development, implementation, assessment, maintenance, dissemination and use of the elements of an EU wide infostructure. It should include, inter alia, organisations representatives of the Member States (including the eHealth Governance Initiative until the project closes), regions, health care providers, industry, Standards Development Organisations and national competence centres for semantic interoperability in eHealth.

The expected long term impact of the thematic network is:

- The long term sustainability of assets, resources and components, allowing for large scale deployment and operations under the CEF.

- Contribution to a sustainable and long term collaborative governance model for the EU wide eHealth Infostructure.[9], [10]

2.4 Next steps

The ultimate result of this study, i.e. the draft interoperability guidelines on ePrescriptions, are submitted to the EC for further discussion within the eHGI. It is expected that they will be critically reviewed and agreed upon with the eHealth Network.

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[8] http://europa.eu/rapid/press-release_IP-11-1200_en.htm?locale=en

[9] See https://ec.europa.eu/digital.../cip_ict_psp_wp2013_publication.pdf for the CIP work progamme in 2013

[10] The term „infostructure“ is defined by the Calliope report on semantic interoperability as: „Terminologies and ontologies, representations of medical logic and standardized structures of ICT applications such as electronic patient records, registries, repositories, together with the rules and agreements that ensure that [patient] information is consistently and securely captured, transferred, stored, organised, transformed and managed can be referred to collectively as an “infostructure”.

As already reflected in the draft guidelines below, also the results and conclusions of the so-called implementing act on obligatory elements to be included in paper prescriptions for cross-border purpose (adopted by the Cross-border committee, cf. Directive 2011/24/EU) are an important document to build upon.[11]

As mentioned earlier, the challenges encountered by epSOS and the solutions agreed upon among Member States and other European countries when piloting trans-European ePrescription services need not only to be considered, but should provide a sound basis from which to develop further – an issue to be taken up below in chapter five. Rather than starting from scratch, these experiences and the know-how gained should be efficiently used in the further process to save time and resources.

Furthermore, the EC has launched in the fall of 2013 a new legal study to explore national laws and regulatory frameworks on electronic health records, including medication records and ePrescriptions (results expected in 2014). It should be considered whether and how this study could help to identify in some detail remaining legal challenges.

Also the endeavours of EMA on a pharmacovigilance IT database and the new ISO/CEN IDMP standards for medicinal products may become relevant and should be taken into account as deemed necessary.

[11] See COMMISSION IMPLEMENTING DIRECTIVE 2012/52/EU of 20 December 2012 laying down measures to facilitate the recognition of medical prescriptions issued in another Member State

3 THE WIDER EUROPEAN CONTEXT - EPRESCRIPTION DEPLOYMENT AND BENEFIT/COST CONSIDERATIONS

To set the draft guidelines into a wider context, this chapter provides an overview of the status of ePrescribing activities in the EU-27 by country as well as a concise reflection of benefits and costs related to ePrescription systems..

3.1 Current ePrescription deployment

Information synthesised herein is drawn – if not otherwise indicated – from the eHealth strategies study and the current epSOS pilot project. Norway and Iceland are mentioned in brackets as they were part of the survey, but do not belong to the EU.

Figure 4: Overview of ePrescription service status in the EU-27, as of 2010, (EFTA in brackets)

ePrescription national status	epSOS participation?	Piloting ePrescription in epSOS?[12]
AT: ePrescription pilot ongoing, national roll-out scheduled for 2013[13]	Yes	
BE: ePrescription organisation Recip-e was set-up to begin primary care pilots in 2011[14]	Yes	
BG: no nation-wide activities	No	
CY: only a minority of prescriptions are issued and transmitted electronically	No	
CZ: planned extension of EHR with ePrescribing module on hold due to legal concerns	Yes	
DE: ePrescription services technically possible but not implemented[15]	Yes	

[12] Country A piloting: issuing of eP; Country B piloting: dispensing eP

[13] Based on "Die Datenschutzfrage wäre lösbar" Freisleben-Teutscher, Christian; Das österreichische Gesundheitswesen - ÖKZ, 52. Jg. (2011) 12, pp.20-21.

[14] Recipe as an organization will promote ePrescriptions in the primary care sector. A different technical system is available for hospital care.

[15] Recent decisions within the German healthcare system have laid the basis for a future drug interaction check which would be provided through the current eCard infrastructure, supervised by the German association of pharmacists (See: Grätz P. G. v. (2011). "E-Card-Beschluss lässt viele Fragen offen." http://www.aerztezeitung.de/praxis_wirtschaft/gesundheitskarte/article/682997/e-card-beschluss-laesst-viele-fragen-offen.html

DK: ePrescription coverage in primary care is almost 100% and routinely used	Yes	Yes
EE: ePrescription services have moved from pilot (2010) to full deployment	Yes	Yes as country B
EL: ePrescription services have not moved beyond the level of local pilots	Yes	
ES: ePrescription services are regional routine, with uneven spread	Yes	
FI: ePrescription services are slowly being relaunched	Yes	Planned in the summer 2013
FR: eDispensation project widespread, but no integration with national EHR project yet	Yes	
HU: no ePrescription activities	Yes	
IE: no ePrescription activities, but partial eDispensation data available[16]	No	
(IS: ePrescription is nationwide routine)	No	
IT: ePrescription regional pilots in Lombardy and Emilia-Romagna	Yes	Yes, as country-A
LT: no ePrescription activities	No	
LU: no ePrescription activities	Yes	
LV: no ePrescription activities	No	
MT: no ePrescription activities	Yes	
NL: ePrescription regional routine between GPs and pharmacies	Yes	
(NO: ePrescription scheduled to move from pilot to national roll-out in 2011/12)	Yes	
PL: ePrescription pilot, but so far no national roll-out	Yes	
PT: ePrescription pilot, elements of eDispensation but currently no transmission	Yes	
RO: no ePrescription activities	No	
SE: ePrescription used routinely nationwide	Yes	Planned in the summer 2013
SI: no ePrescription activities	Yes	
SK: no ePrescription activities	Yes	

[16] See in addition to the eHealth strategies study: Brennan, James E. (2010) Electronic Prescribing in Ireland: Foundations for a national system, Master thesis in Computer Science and Information Systems, University of Limerick, p. 90ff

UK-England: ePrescription systems exist for primary and secondary care and are being used	Yes	
UK-Northern Ireland: ePrescription system with paper-based transmission (barcoded) and electronic eligibility check; hospitals are currently procuring a country wide ePrescription system[17]	Yes	
UK-Scotland: ePrescription routinely used	Yes	
UK-Wales: ePrescription system similar to the one used in Northern Ireland	Yes	

The above condensed overview of the status of ePrescription projects in Europe shows clearly that fully functioning systems are rare in Europe. At the point of writing this report the following tentative grouping of countries can be made:

Fully functional ePrescription services across the country or substantial parts of regions:

Denmark, England, Estonia, (Iceland), Greece, Netherlands, Scotland, Spain, Sweden

Mature pilot projects for ePrescription that are set to move to routine operation

Austria, Belgium, Finland, Italy (regional), (Norway)

Small pilots with a declared political ambition to develop nationwide ePrescription services

Czech Republic, Cyprus, Poland, Portugal, Croatia

Prescription projects with eDispensation only or otherwise not fitting the ePrescription definition

France, Ireland, Northern Ireland, Wales

No ePrescription activities, policy-declarations

Bulgaria, Germany, Hungary, Latvia, Lithuania, Luxembourg, Malta, Romania, Slovenia, Slovakia

This preliminary attempt at grouping countries shows to an astonishing degree the variety of situations observable with respect to ePrescription across the Union. Large or wealthy nations such as Germany and Luxembourg fall in the same category as less wealthy countries, but for very different reasons. A country such as France is in the same group of countries with no ePrescription activities, because it has so far implemented only parts of the process.

While Germany would be technically in a position to use its new eCard for the purposes of establishing an ePrescription system, the project itself - planned since the late 90's - was too difficult to implement due to political barriers and inability to agree on technical and organisational terms. It may be re-activated in a few years. On the other hand, a country such as Luxembourg is actively building up a national eHealth infrastructure but hasn't reached a stage in which it would be technically able to provide an ePrescription service. This situation contrasts with countries such as Hungary, Malta, Romania and others which face more fundamental problems of infrastructure and missing legislation.

[17] Crispin S. (2011). "JAC wins Northern Ireland pharmacy deal." Retrieved 05.04.2013, 2013, from http://www.ehi.co.uk/news/primary-care/7236/jac-wins-northern-ireland-e-prescribing

Similarly, countries that currently have only parts of the ePrescription process ready (eDispensation for example) might have achieved this stage in spite of different ambitions as to the purpose of eDispensation. One purpose such as combating of fraud (in Wales, Northern Ireland and Ireland) might co-exist with a stakeholder driven project such as the dossier pharmaceutique in France which is considered as a tool of pharmacists to strengthen their medication surveillance function in the healthcare system. In our context, it must be noted that the guidelines can probably cover only the electronic cross-border transfer of a basic prescription document, not the return transfer of an electronic dispensation record. However, this issue will need further discussion, because it may become a mandatory requirement for selected Member States due to patient safety concerns: e.g., in the case of a "standing" or repeat prescription for chronic disease patients it is very important to know whether such a repeat prescription was filled or not to avoid oversupply or misuse of such a prescription.

The classification does not allow for nuances such as primary care vs. hospital-care ePrescription systems. It does not inform either about different levels of availability of the ePrescription services to certain groups of healthcare professionals. This variety of national situations has not stopped the majority of the above countries to join efforts in the epSOS large scale pilot with the objective to provide cross-border interoperable ePrescription and patient summary services.

3.2 Exploring benefits and costs from ePrescribing

The implementation of ePrescribing systems is driven by the benefits expected for the respective healthcare system, its citizens, healthcare providers, payers, and society at large. To arrive at rational decision making, these benefits should be confronted with the likely costs to be expected by the health system/the Member States implementing them.

3.2.1 Benefits to be expected

Changing from a paper based prescribing process to an electronic procedure can yield a number of important benefits to stakeholders, key of which is

- ✓ patient safety.

Increased medication and therefore patient safety is achieved through the seamless availability of all medications prescribed for a given patient in a standardised digital format, and not in sometimes difficult to read handwriting. This can lead to significant reductions in prescription errors resulting both from drugs dispensed and suggested dosage information the patient obtains. Often, these features are enhanced by IT supported alert or clinical decision support systems which support the prescribing and/or dispensing professional in identifying drug-drug interactions and other safety related problems.

Next to the patient safety aspect, a number of more managerial aspects emerge as benefit drivers. Examples can be briefly listed as follows:

- ✓ More efficient, time saving prescribing process
- ✓ Improved medication stock management
- ✓ Easier archiving of prescription records
- ✓ Improved public health surveillance and analysis
- ✓ Integration with reimbursement and control systems (reimbursement rule systems)[18]
- ✓ Reduced risk of fraud and prescription falsification
- ✓ Avoidance of duplicate prescriptions to replace lost or misplaced ones.

Further benefits concern

- ✓ the unbroken chain of information between the prescribing professional (in a GP surgery, a health centre, or also a hospital) and the pharmacy;

[18] This seems to have been a primary motivation of the Portuguese ePrescription activities, see "Portugal: ePrescriptions Mandatory Since 1 August 2011", available at http://www.egovmonitor.com/node/43252

- ✓ The prescription the professional writes into the medical record of patients has exactly the same information which the pharmacist uses to dispense the drugs.

To present an example, it was estimated that the ePrescribing system in the Stockholm County generated an estimated annual net economic benefit of over € 95m in 2008. In 2005, five years after the beginning of planning and development, there was already a net benefit of approximately € 27m. However, when reflecting on these benefits, it must be noted that they do not necessarily derive from direct financial or cash savings, but rather from intangible benefits such as time saved or delivery of better care which otherwise would have been very expensive to achieve by conventional means. E.g., the considerable savings of time for healthcare provider organisations (HPOs) estimated are often directly transferred and used for more effective patient diagnosis and treatment, and not for firing staff. In the Stockholm case, it turned out that healthcare provider organisations obtained an estimated 80% of the benefits, mainly from time savings and avoided costs of providing the same timeliness, convenience, and reduction in errors without eHealth. The safety aspect of correctly issued and read prescriptions was the main item in the 20% of total benefits reaped by citizens.[19]

In terms of real-life experience with fully functional ePrescribing systems, the Spanish region of Andalucía also provides an interesting example.[20] The Andalucían ePrescribing system Receta XXI is a module of Diraya, the region's EHR and general health information system. Since 2004, Diraya enables the full sharing of patients' healthcare data, including medication information between doctors in primary care, and hospital specialised outpatient and emergency care. Integrated prescribing decision support tools enable the application of regional standards and facilitate prescribing procedures. The specific module Receta XXI allows pharmacies to access centrally stored electronic prescriptions directly, and to share information on patients' current and long-term medications with doctors in primary healthcare centres. With Receta XXI, general practitioners (GPs) can prescribe for periods of up to one year, and pharmacists' can cancel prescriptions and send them back to the relevant GP for revision in case they discover a patient safety issue.[21]

Better quality and efficiency are the most prominent benefits of Andalucía's ePrescribing system, too. I was estimated that during the period 2000 to 2010 quality gains accounted for about 26% of all benefits. They include improved patient safety by reducing the risk of adverse drug events by using explicit, proven prescribing protocols and prompt monitoring by pharmacists. Efficiency gains represent 74% of the benefits. The main contributors include fewer GP visits for patients with long-term prescriptions, and sustainable generic prescribing by active ingredient rather than brand name. These efficiency gains result in significant time savings for patients and doctors, reduced travel costs for some patients, as well as cash savings from generic prescribing.

A particularly remarkable benefit is the reduction by more than 15% in GP visits for chronically ill patients once they have obtained their first prescription using Receta XXI for an episode of care. This is due to them now being able to receive an ePrescription valid for up to 12 months without the need for a revisit to the treating physician.

3.2.2 Costs incurred

When considering costs of such implementations, one has to consider, on the one hand side, the type of stakeholders affected, and on the other the type of costs they have to bear. Major stakeholder groups usually involved are

- ✓ Patients, carers, including informal carers like family members and neighbours
- ✓ Healthcare professionals (physicians, nurses, pharmacists, others) and health workers

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[19] Cf. KA Stroetmann, T Jones, A Dobrev, VN Stroetmann. eHealth is Worth it: The economic benefits of implemented eHealth solutions at ten European sites. Luxembourg: European Communities, 2006

[20] See the report „The socio-economic impact of Diraya, the regional EHR and ePrescribing system of Andalucía's public health service" available at http://www.ehr-impact.eu/cases/cases.html

[21] A Dobrev, T Jones, V Stroetmann, K Stroetmann. Interoperable eHealth is worth it - Securing benefits from electronic health records and ePrescribing. Luxembourg: Office for Official Publications of the European Communities, 2010

- ✓ Healthcare provider organisations (primary, secondary, tertiary care organisations and facilities; pharmacies, others)
- ✓ Third Party Payers or the "government" (depending on the type of healthcare financing system)
- ✓ Society at large.

The major types of cost relate to

- annual depreciation of one-time investment/re-investment expenditures,
- implementation, and
- maintenance/operation cost.

They concern hardware, software, facilities, human resources, change management, training, etc.

Some costs will usually be intangible, like unpaid overtime, decreased efficiency during the implementation stage – e.g. due to impeded workflows, resistance by staff and extra learning efforts, and possibly other negative impacts caused by planning for and implementing a new, large scale application.

Whereas direct costs for patients (and society at large) are usually close to nil – and intangible costs like learning to handle an ePrescription small -, healthcare professionals may encounter considerable, albeit often also intangible costs, like sustained (private or overtime) time commitments by selected GPs and pharmacists from the start of the development phase. Others concern time to training and adapting some of their existing procedures to the new system, re-training when new versions of the software system are implemented, or coping with initial inconvenience and irritation caused by the system.

Beyond the often intangible costs of change management, considerable direct financial costs in terms of cash outlays have usually to be borne by healthcare provider organisations (HPO) including pharmacies, which depending on the healthcare system may include physicians operating as independent entrepreneurs. They usually have to carry the one-time investment/re-investment expenditures as well as their respective implementation and maintenance/operation costs over the full life-time of the system.

Partially or totally these costs may be taken over by Third Party Payers or the health system/the government, e.g. through specific reimbursement rules, investment subsidies or via other financial models.

When considering Receta XXI's financial impact and assigning all observed or estimated costs to one of the three categories (1) extra finance, (2) redeployed financial and (3) non-financial resources, it turns out that more than half of all costs over a 12 year period needed additional finance of about € 62m or 55% of overall costs of around € 113m. 36% were estimated to come from redeployed cash flow, and 9% were allocated to intangible costs. When considering expenditures for investment rather than depreciation costs, the cash flow needs are highest during the initial diffusion phase when many providers have to undertake new or additional investments into hardware and software

In case of Stockholm County, cumulative investment expenditures and operating costs for a ten-year period were estimated at approximately € 155 million. This relates to about € 70m to 80m extra financial resources needed.

It needs to be noted that all of these estimates concern only benefits and costs related to regional systems, here with around 2m inhabitants for Stockholm county and almost 9m for Andalucía. This would imply historical *overall* costs of between € 13 and € 75 per inhabitant, and *extra financial outlays* of between €7 and €35 per inhabitant, or roughly € 0.70 to 3.50 per year.

However, these figures will be considerably lower these days, particularly also for regions and countries where the diffusion of eHealth systems to healthcare providers – including medication record and ePrescription modules – has progressed to a significant degree. But their efficient country-wide usage presupposes either a dedicated ePrescription network (like in Sweden) or a basic national eHealth (and/or eGovernment) infrastructure providing for core legal, financial, organisational, data security, semantic and other components like in Andalucía.

Recent figures from Estonia illustrate this: "In 2013 96,9% of all prescriptions were fully digital and processed through the e-prescription service. The direct cost of implementing the service was almost 0,5 mEUR [or € 0.37 per person for a population of 1.34 m; this amounts to about € 0.06 per person for the years 2007 to 2012], including the set up costs, annual running costs for servers and maintenance. However, there were additional expenses for developing auxiliary registries, project management as well as system integration costs for pharmacists and health care service providers that are more difficult to determine."[22] This relatively low figure is set against earlier

[22] Communication from Peeter Ross, E-TERVIS - Estonian eHealth Foundation.

eHealth expenditure of € 12 m from 2005 to 2012 in Estonia, which amounts to about 9,1 euros per citizen (or € 1.15 p.a.). These national eHealth services include eID and other infrastructure services (partially integrated with eGovernment services), national electronic patient records, digital images, and a nation-wide health information system.

In a prospective study for the Luxembourg Ministry of Health, PriceWaterhouseCoopers, partially based on a global review of 20 related initiatives, developed a roadmap as a high-level plan for an "eHealth Service Platform."[23] "For the whole budget period (the years 2011 to 2015), the roadmap leads to funding needs ranging from 22.6 M€ to 37.2 M€." - On ePrescription, the estimates range from a minimum of € 136,000 (2013 to 2015) to a maximum of € 420,000 (2011 to 2015), thereby assuming that "most of the work will be done in-house by the project manager (0.5 FTE)." This would imply less than € 0.20 per inhabitant per year.

In summary, depending on the eHealth infrastructure of the region/country and the diffusion of relevant eHealth applications among healthcare provider organisations, one may expect over a five to ten-year period annual financial costs of around € 0.05 to € 0.30 per inhabitant, depending on the state of development of a regional or national eHealth platform, and whether only the cost for a national infrastructure service or costs for all participating healthcare provider organisations are included.

3.2.3 ePrescription benefits and costs in a cross-border context

1.1.1.1.Some general cost considerations

The above presented estimates do not yet account for the extra cost of assuring cross-border ePrescription services. Due to missing data and a reliable empirical base, these are difficult to estimate, but epSOS has shown that the initial planning and ICT implementation costs are manageable. In all European countries that have participated in epSOS, cost estimates to move from the piloting to an operational environment concern marginal costs, in the sense that they are extra costs of supporting the additional development step from piloting to full operation and integration with the healthcare system.

On the requirements and costs resulting from the need to

- ✓ implement a national contact points to „inform patients about the elements to be included in a [pan-European] prescription",
- ✓ make all citizens aware that prescriptions which they plan to be filled in another Member State must be "issued further to a request of a patient who intends to use them in another Member State",[24]
- ✓ fully inform and train healthcare professionals and pharmacists to be aware of these requirements and to comply with them,
- ✓ to add needed modules to existing software systems to assure meeting the need to issue such specific ePrescriptions meeting all cross-border specifications (unless national regulations are adapted to European rules)
- ✓ to participate in European-wide maintenance and further development of necessary governance, regulatory, organisational and data harmonisation/exchange assets (including those needed for technical, structural, and semantic interoperability)

no experience is available. We would expect that they may perhaps accrue to up to € 0.02 to € 0.10 per inhabitant per annum, depending *inter alia* on the concrete means and communication channels applied to inform and train patients, citizens, professionals and others accordingly as well as on economies of scale/size of country. Again, as a function of already existing organisations and infrastructures in the respective countries, these costs are to be understood as marginal costs.[25]

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[23] PricewaterhouseCoopers S.à r.l. Luxembourg Ministry of Health eHealth Service Platform Study – Final report. Luxembourg, 2010.

[24] See Commission Implementing Directive 2012/52/EU laying down measures to facilitate the recognition of medical prescriptions issued in another Member State

[25] Perhaps the epSOS experience will deliver more reliable estimates once the pilot implementations have been fully assessed.

1.1.1.2.ePrescription readiness and cross-border service implementation costs

Securing and taking advantage of epSOS achievements

The epSOS project, driven initially by 12 and towards the end by 22 participating Member States has over its life-time of 6 years achieved a variety of results and outputs which will be of great relevance for any Member State planning to (also) implement a cross-border ePrescription service in future. Amongst the epSOS achievements are:

a) Major technical deliverables which developed a solid basis for the pilot services cover fields like

- ✓ governance
- ✓ use cases
- ✓ data content
- ✓ semantics
- ✓ specifications
- ✓ architecture
- ✓ testing mechanisms.

b) These resources and assets will be maintained as part of an evolving EU eHealth infrastructure. The *eHealth Network* has established a subgroup of Member States dedicated to the continuation of the epSOS services. Also, the EXPAND project has as one of its objectives to secure the sustainability of epSOS pilot services in anticipation of a handover to the Connecting Europe Facility (CEF).

c) 16 pilots of epSOS services achieved live operations during the project, constituting a substantial progress for eHealth supported cross-border healthcare provision.

d) Much of the rich experience from epSOS is captured in the project's evaluation results and its recommendations, informing future endeavours in the area of cross-border eHealth services.

e) Further access to information and repositories of epSOS and its outputs has been secured. Recognizing that epSOS results will be relevant for future initiatives, actions have been taken to facilitate access to the outputs also beyond project duration. The epSOS.eu website will remain accessible until the end of 2017. It contains a wealth of information about epSOS, including national contacts, deliverables describing project results, information about the design process, etc.

f) The epSOS project has resulted in a new European open source community, the OpenNCP community. This community has been instrumental in developing open source software to support national eHealth implementations. The OpenNCP community has prepared a roadmap for possible future development and intends to remain active, provided continued support remains available, in particular from national stakeholders.

g) Another achievement of epSOS is the development of thorough pre-pilot testing procedures to ensure that systems and components meet certain functional requirements.

h) Many outputs of epSOS, including the open source software, will also remain available from JoinUp,[26] a resource to share and reuse interoperability solutions for public administrations.

In summary, as recently noted at the 5th *eHealth Network* meeting on May 13, 2014[27]: "Some countries have piloted epSOS Patient Summary service, namely: France, Italy, Switzerland, Portugal, Luxemburg, Malta, Estonia, Austria, Slovenia and Spain. Some of them, as well as others, have piloted the epSOS ePrescription (eDispensation) service: Croatia, Denmark, Finland, Greece, Hungary, Italy, Spain and Sweden.

In the last 12 months, countries like: Croatia, Luxemburg; which joined epSOS later, made a tremendous effort and a significant internal investment (even with the support of more experienced countries and solid grounded open technical solutions) to be able to stand up to the challenge (i.e. legal, standards, best practices, data quality) of exchanging health data in cross-border services from 2014 and beyond.

Some countries are moving services from pilots to daily basis operational systems based on bilateral agreements (e.g. Sweden and Finland/Denmark for the ePrescription service, Portugal and Luxemburg for the Patient Summary) due to regional population circulation dynamics and genuine population and governments' interest in offering these services. This way forward is being pushed

[26] https://joinup.ec.europa.eu/nexus/content/repositories/releases/eu/europa/ec/joinup/ecc/

[27] 5TH EHEALTH NETWORK 13 MAY 2014. COVER NOTE BY SECRETARIAT - Topic 2: Upkeep of cross border services (post epSOS) – decision required. EC – DG Health & Consumers Ref. Ares(2014)1377695 - 30/04/2014

not to give visibility to epSOS pilots but to give an assertive answer to specific needs. Such phenomena need to be seriously addressed by countries, not individually but as an effective collaborative organism. At present some have expressed interest to keep doing this in a broader EU-wide alignment but not to be stopped by that."

Clustering Member States according to their cross-border ePrescription readiness

To arrive at some rough cost estimates for introducing a national cross-border ePrescription service – which excludes the cost of some services to be provided centrally at the European level, like a central terminology reference service and coordination tasks -, it is useful to group Union Member States according to their eHealth readiness and maturity as evidenced by their prior experience with ePrescribing services, and their participation in the epSOS project and the services piloted. The following Figure 5 provides an overview of the countries participating in epSOS – 22 EU and 3 non-EU nations – and whether they were involved in piloting ePrescription and eSummary services.

Figure 5: epSOS participating countries and activities

epSOS Participating Nation	ePrescription services (Pharmacies)	Patient eSummary services (hospitals, medical practices)
Austria		X
Belgium		
Croatia	X	
Czech Republic		
Denmark	X	
England/UK		
Estonia		X
Finland	X	
France		X
Germany		
Greece	X	
Hungary	X	X
Italy	X	X
Luxembourg		X
Malta		X
(*The) Netherlands*		
Poland		
Portugal		X
Slovenia		X
Slovakia		
Spain	X	X
Sweden	X	
Norway		
Switzerland		
Turkey		

Source: http://www.epsos.eu/point-of-care-database/poc-database.html and epSOS Deliverable D4.E.1 Report on Pilot Operations. 23/01/2014

Based on this, and the information provided in Figure 4, the following clustering of Union Member States is suggested:

A) epSOS participating Union countries with experience from epSOS pilot implementations for ePrescription services

Croatia, Denmark, Finland, Greece, Hungary, Italy, Spain, Sweden

All of these countries respectively their regions involved in epSOS pilot implementations have also prior experience with intra-region ePrescription services. As a consequence, the full-blown implementation of cross-border ePrescription services should come at marginal (investment) costs of perhaps anywhere between € 40,000 and 150,000 for staff input of up to 1 year FTE, very much dependent on the retention or not of staff (and their experience) involved in epSOS work, the overall complexity of the regional/national eHealth platform and its ePrescription component, and other related factors impacting on the set-up of this service.

Concerning annual maintenance/operation cost it seems reasonable to assume that most of the work will be done in-house by a project manager and staff spending perhaps 0.2 to 0.3 FTE on this at a cost of € 20,000 to 40,000 p.a. at the national (coordination) level. In Member States with several regional health systems, probably similar or somewhat lower amounts will have to be spent per region. Similarly, in larger countries it is reasonable to

assume that considerable economies of scale will prevail, but that nevertheless overall costs may increase up to 1 to 2 FTEs.

These cost estimates do not cover further interoperability and system integration costs for pharmacies and healthcare service providers. Whether they are close to nil or may amount to € 1,000 and perhaps even more per organisation will very much depend on the state of their ICT systems and the need for an upgrade of the software, the interoperability level of the regional or national system, the need for training, and other factors specific to the individual situation and context.

B) epSOS participating Union countries with national ePrescription service experience or experience from epSOS pilot implementations for eSummary services

Austria, Belgium, England/UK, Estonia, France, Luxembourg, Malta, (The) Netherlands, Portugal, Slovenia

These countries represent quite diverse health system set-ups. Nevertheless, based on their prior experience with national ePrescription services, and/or their epSOS involvement it seems reasonable to assume that they can be grouped together with respect to their readiness for implementing cross-border ePrescription services. This all the more as the eSummary for patients already includes a medication record which is aligned to the data needs for ePrescriptions.

In addition to the costs identified above for the countries grouped under A), further costs will arise for basic planning, set-up and implementation work to be undertaken with respect to cross-border ePrescription services. Relevant steps to be undertaken are outlined below in Chapter 8 Roadmapping at the European and Member State level - A roadmap proposal.[28] Reviewing the efforts allocated within epSOS to various tasks and activities, it turns out that as a very rough first estimate about half of personnel efforts were allocated to the preparation and implementation/running of concrete service pilots (tasks like implementation planning [T4.B.6] and implementation at Member State level [T4.C to E]). This amounts to about 3 to 5 FTE per distinct pilot implementation. Taking a mean value of 4 (or 48 person months) and assuming that, based on earlier experience and a steep learning curve, the marginal costs for implementing an additional ePrescription service is only half of this, the actual costs may turn out between € 250,000 and 500,000 depending on national salary levels and other factors like in-house allocation of work versus outsourcing, compatibility of national standards with epSOS agreements etc.

C) Other **epSOS participating Member States**

Czech Republic, Germany, Poland, Slovakia

These countries still have the advantage of having participated in epSOS activities and the related generic learning experience (assuming that the staff having the relevant experience and know-how has been retained and/or that it has been adequately documented). However, having neither being involved in concrete epSOS piloting of ePrescription or eSummary services, and also not being able to avail themselves of a national ePrescription infrastructure, and depending on the concrete national/regional situation 2 major cost components are to be expected:

a) The cost for setting up a (national) cross-border ePrecription infrastructure and service, for which we suggest to allocate the full investment expenditure as estimated based on the epSOS experience, i.e. costs for about 3 to 5 FTE or € 500,000 to 1m.

b) The cost for setting up a basic national ePrescription infrastructure, based preferably on or integrated into a national eHealth platform. Remembering the earlier discussions on Estonia and Luxembourg, and considering a scale factor, the investment expenditure may

[28] Based on details provided in epSOS D3.8.2 Final National Pilot Set Up and Deployment Guide; cf. also D4.E.1 Report on Pilot Operations

vary between € 500,000 and several millions. Without a detailed analysis at the national level, any more precise estimate would seem inappropriate.

On the potentially additional cost for a missing generic national platform, see D).

D) All other Member States

Bulgaria, Cyprus, Ireland, Latvia, Lithuania, Romania

These countries do not have the advantage of having participated in epSOS activities and the related generic learning experience. Getting acquainted with all the epSOS outputs and learning experience and adapting it to the respective national context may be a cost factor of between € 500,000 and 1m, considering the budgets of countries participating in epSOS.

Furthermore, in addition to the costs estimated for A) to C) above, further costs of setting up a basic national eHealth platform on which to base a cross-border ePrescription service are to be expected. Overall figures may be derived from the estimates provided earlier for Estonia and Luxembourg, but these would need to be adapted to the national context, like the ubiquity and quality of the national ICT infrastructure, eGovernment services which may be developed upon, the priorities of the respective national health policy, and the complexity of the health system set-up, together with a scale factor for the size of the country.

1.1.1.3.Benefits

To account for the extra benefits of providing cross-border ePrescription services is even more difficult. But considering the marginal relevance of cross-border healthcare service provision the benefits are probably very low at the health system level. According to a recent OECD/EU publication[29], in 2010 imports of health care services as a share of total health expenditure accounted for, on average, only 0.50% across Europe, and health-related exports by domestic providers supplying medical services to non-residents were 1%.[30] How much of this relates to prescriptions in unknown, but considering that expensive cross-border services concern probably to a considerable extent planed surgery, and that these figures include recreational and cultural [well-being] services, the values can be expected to be even considerably more marginal for the share of cross-border prescriptions. This is in line with a very rough DG SANCO estimate - "a breakdown of cross-border healthcare costs by type of care, which implies a crude estimate for healthcare expenses for cross-border prescribed medicinal products and medical devices of 0.08% of all public healthcare expenses."[31]

Whereas the earlier cost estimates can be expected to involve new cash outlays, the benefits will in all probability be reaped to an overwhelming extent from impacts at the national or regional, rather than at the pan-European level. As the epSOS experience has shown, such European and even trans-Atlantic activities will lead to higher levels of awareness among stakeholders in those Member States where ePrescription or Patient eSummary services were not yet established. As participation in such digital cross-border exchange of patient data presupposes the availability of compliant interoperable eHealth services at home, it is to be expected that the quite substantial beneficial impact – as demonstrated by the above mentioned case studies - will indeed be reaped at the national level, first of all. In particular, the adaptation of existing national ePrescription solutions to the semantic approach of the epSOS cross-border solution opens up new possibilities in medication safety, decision support systems and secondary use of data, in particular for the purposes of quality measurement and pay for performance projects. Realising these benefits may

[29] Cf. OECD. Health at a Glance: Europe 2012, OECD Publishing. http://dx.doi.org/10.1787/9789264183896-en. Even these values are probably considerably over-estimated, because they refer to the balance of payments concept of health-related travel and health service expenditures for personal, *recreational and cultural* services.

[30] In some small to very small countries, the figures are considerable higher, and in some large countries far below these values.

[31] DG SANCO/unit D2 Healthcare Systems, June 2011

require additional investments and regulatory changes that produce further costs. A robust estimate of the overall balance of benefits versus costs is presently not feasible.

Member State collaboration and sharing of information models, semantic assets, value sets, open source components and tools should be strongly encouraged and supported by the EC. Such collaboration would avoid redundant work, minimise costs for all and set positive examples for others to follow.

4 PRINCIPAL REQUIREMENTS FOR A CROSS-BORDER EXCHANGE OF MEDICAL DATA

This chapter reviews the principal requirements that need to be met in order to achieve the electronic exchange of (medical) data across borders between different EU Member States. In other words, the focus is on what is commonly called interoperability.

In a first subchapter, we briefly revisit the concept of eHealth interoperability, then review the four dimensions or domains of interoperability, and introduce as a new conceptual extension the idea of three levels of data exchange interoperability which are particularly relevant in our context.

Following this, the chapter will present principal requirements for a cross-border exchange of electronic medical information, which also apply to the transfer of electronic prescription data. This is followed by a brief summary of the "structural" elements of the epSOS approach that results from the formulated requirements. This approach reflects the agreement achieved so far across participating Member States, and it should therefore become a starting point for any further extensions and developments.

The chapter concludes with a summary of key factors that presently still limit the level of ePrescription interoperability in a cross-border setting.

4.1 Data exchange and interoperability

The concept of interoperability was already discussed in the inception report of this study. Here we will present some further considerations and conceptual developments to allow for more pointedly highlighting aspects of cross-border healthcare interoperability in a multilingual and multicultural context.

In its most basic form, interoperability (IOp) is a generic concept concerning the exchange of data, information, and knowledge in any context.

In the digital field, it is often a fuzzy one - mostly referring to data exchange among technical systems or "application entities," and less to the exchange of information among persons or organisations (taking into account business and workflow processes, procedures, and the cultural context of organisations). Various functional and/or area-related IOp distinctions can be found. But they also mostly focus on technical aspects. When discussing semantic challenges, this does usually not concern human information exchange and understanding, but "machine" interpretation and handling of data.

This necessitates a more comprehensive understanding and definition of IOp in the healthcare and public health field, where the collaborative provision of healthcare services by health professionals and health workers – which necessitates a common understanding of the exchanged (digital) contents - is at the core of the subject. To allow for a common (European) understanding and focused, goal-oriented discussions, the European Commission sponsored i2-Health study developed and defined a European Union eHealth Interoperability Framework[32], which was adopted by the European Commission and its Member States[33].

It was reflected upon by the study on a European Interoperability Framework[34], and developed and expanded into the eHealth architectural domain by the European Thematic Network "CALLIOPE -

[32] i2-Health - Interoperability Initiative for a European eHealth Area: European eHealth Interoperability Roadmap, Final Public Project Report, Bonn/Brussels (Dec. 2007), http://www.i2-health.eu/

[33] European Commission. Connected Health: Quality and Safety for European Citizens. Report of the Unit ICT for Health in collaboration with the i2010 sub-group on eHealth and the eHealth stakeholders' group. Brussels: European Commission (2006); Chapter 6 - Towards A European Roadmap For Achieving eHealth Interoperability, pp. 24 ff

[34] Deloitte Consulting (2013 (unpublished)). The vision of the eHealth European Interoperability Framework (EIF) (2/4). European Commission – ISA Work Programme

eHealth European Interoperability Framework (eHealth EIF). Brussels, European Commission.

Creating a European coordination network for eHealth interoperability implementation"[35], and influenced ISO TC 215's "Capacity-based eHealth architecture roadmap".[36]

Defining interoperability in its most basic form,

> *interoperability refers to the ability to communicate and exchange data and information such that a common understanding of their meaning is possible.*

Such sharing of information and knowledge has been a basic precondition for the social development of humankind. In the age of ICT systems, interoperability tends to be associated with

> *the ability of telecommunications and digital systems - and the processes they support - to exchange data and to enable the sharing of information and knowledge.*

This is a relatively open definition - predominantly referring to exchanges among technical systems, and less to exchanges among persons and their organisations.

When also taking functional needs into account, specific domain perspectives like the perceived need for and benefits expected from the exchange of meaningful data, and organisational, legal, political requirements come into play.

Moving towards a health system specific definition, one may stipulate that in the

> *(e)Health area interoperability refers to facilitating and safeguarding the exchange, understanding and acting on patient and other health information and knowledge among linguistically and culturally disparate medical professionals, patients and other actors within and across health systems in a collaborative manner.*

At the core of such a conceptual view lies the model of a generic health service delivery system, which consists of interrelated value chains of individual health service providers. Together they 'produce' and sustain health by promoting good health and well-being, supporting disease prevention, undertaking diagnostic and therapeutic interventions, providing acute healthcare, rehabilitation and long-term care services. To enable, facilitate and support such health service delivery in a comprehensive, integrated fashion, supporting processes as well as facilitating tools and services are necessary, connected to and interconnecting these core service processes – be it via ICT-based, electronic means or otherwise. Only as a complex, dynamic ecosystem of interrelated healthcare processes all of these effectively lead to optimal health.

4.2 Four domains of interoperability in a cross-border setting

In line with the above considerations, it is suggested to refine the conceptual interoperability framework as presented in earlier deliverables, notably to further develop it concerning specificities of interoperable ePrescription services. Whereas often co-called "levels" of interoperability have been identified, we suggest that these interoperability requirement areas are not *levels* of achieving a certain goal in a consecutive fashion, but rather describe *complementary fields* which all need to be present to a certain degree in order to achieve even basic interoperability. As a consequence, we prefer to talk about domains of interoperability. Revisiting these discussions, we identify the following four interoperability domains, and highlight a complex *data access and exchange* domain with its specific relevance in a cross-border context:

- Policy domain
- Governance and legal domain

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[35] CALLIOPE (CALL for InterOPErability): EU eHealth Interoperability Roadmap. European Commission, Brussels (December 2010), http://www.calliope-network.eu

[36] ISO. Health informatics — Capacity-based eHealth architecture roadmap — Part 2: Architectural components and maturity model. ISO/TC 215/SC N 721, draft (2013)

- Organisational domain
- Data access and exchange domain

European public services such as a cross-border exchange of medical data require a comprehensive approach to interoperability across all its domains, since otherwise there is the risk that Member States might opt for mutually incompatible solutions which could eventually result in new barriers to the delivery of European Public Services.

In order to enable public administrations to provide jointly European public services, interoperability should be addressed at these four domains.

Policy domain

Member State as well as global experience strongly underline the core relevance of clearly defined health policy goals to guide eHealth policy, strategy, and implementation, as well as the need for strong political leadership, and support by all relevant stakeholders to indeed realise a national platform, including ePrescription applications and services.

In democratic countries, societal needs are reflected in policy goals as well as political measures to implement such policies, and eHealth platform financing is usually a predominantly government or public health system budget issue, i.e. such issues should also be allocated in the policy domain.

Governance and legal domain

This concerns the provision of basic governance frameworks and compatible regulations in participating nations, including a common and consistent legislative foundation (privacy, access control) allowing interoperation among organizations and enterprises. In terms of cooperating EU Member States it embraces the appropriate synchronisation of national legislations including a proper legal weight and recognition to electronic data originating in a given Member State irrespective of wherever at the EU level it needs to be available and used.

Organisational domain

It is the ability of at least two entities interacting with each other within an appropriate governance structure in order to achieve the mutually agreed service- related goals. Consequently organizational structures and procedures of different collaborating organisations such as public administrations have to be made somehow compatible.

Data access and exchange domain

In technical and engineering contexts, it is predominantly this domain which is focused on and analysed when discussing interoperability issues. This does not only concern the technically correct, univocal transfer of data so that the person (or machine) accessing or receiving the data can indeed see and use them 'as is', but also the application of conventions or standards such that the receiver fully understands the structure in which the data, information or knowledge are presented, e.g. header information/metadata, and lastly the conceptual level, i.e. to assure that the data transferred are understood correctly with respect to their 'meaning'. Accordingly, it is suggested to differentiate in this domain three *levels* of interoperability, which indeed build on each other, but which may be present to different degrees in a given set of data or information:

- ✓ technical interoperability
- ✓ structural interoperability
- ✓ semantic interoperability

This data access and exchange domain and its three levels are of particular importance in a cross-border environment, i.e. also for our ePrescription considerations:

Technical (data) interoperability level

> Implementing cross-border interoperability requires a consistent set of standardized communication and interaction protocols in order to correctly access and exchange among different eService interfaces. Providing this architecture, technical interoperability denotes the ability of systems to exchange data, perform processing, and synchronize transactions.

As an initial, and in many health system contexts already highly relevant step, basic data IOp is achieved via an exchange of, e.g., electronic 'paper' documents in PDF format or similar, i.e. the document is accessed or transferred as is and cannot be integrated with similar data from another document, except for meta data accompanying the document and allowing for filing it, e.g., by patient name, healthcare provider issuing the document, date of the document, and/or purpose of sending the document.

At the next level of complexity – and also widely applied across national and district platforms -, the exchange of patient data is realised in the form of structural intreroperability.

Structural (data) interoperability level

Here documents are meant which are structured according to standardised headings, like provided for by the HealthLevel 7 (HL7) Common Document Architecture (CDA) standards, e.g. for prescriptions, continuity of care documents, etc. This allows for regrouping and assembling patient data according to such headings on the contents of the sub-fields, like medications prescribed, symptoms, allergies, and the like.

Such documents may be translated into an XML coded format before exchange, requiring agreement, e.g., on a standard for the contents of the respective field names.

Semantic (data) interoperability level

A further integration level is achieved when the contents of some or all fields is fully coded (like diagnoses coded in WHO ICD 10) This is necessary in case (patient) data are to be integrated, aggregated and analysed either in a single electronic health record, or as part of a larger health data warehouse, e.g. in our context for an ePrescription to be dispensed in another country, or for research and surveillance purposes.

Semantic interoperability focuses on the ability to share information meaningfully while the precise meaning of the information exchanged is preserved and well understood by all parties concerned. As a result it allows engaging in cooperative activities in order to perform collaborative processes even across linguistic barriers.

To achieve some degree of semantic IOp and to communicate in unambiguous language with collaborating healthcare providers, there exists a large number of "lists" to describe biomedical terminologies.[37]

Achieving full semantic IOp is a long way to go, and may never be achieved fully in the health field. To assure success, one probably should not even attempt to solve all (semantic) IOp challenges, but rather follow a step-wise approach, like making use of term binding for selected documents, like a prescription or so-called archetypes and selected record structure items.

This is the approach also pursued by epSOS services. They represent a nice example and attempt to create and agree upon a small set of documents or rather data exchange models where the full contents of most or even all fields is fully coded such that they can be safely translated into other languages.

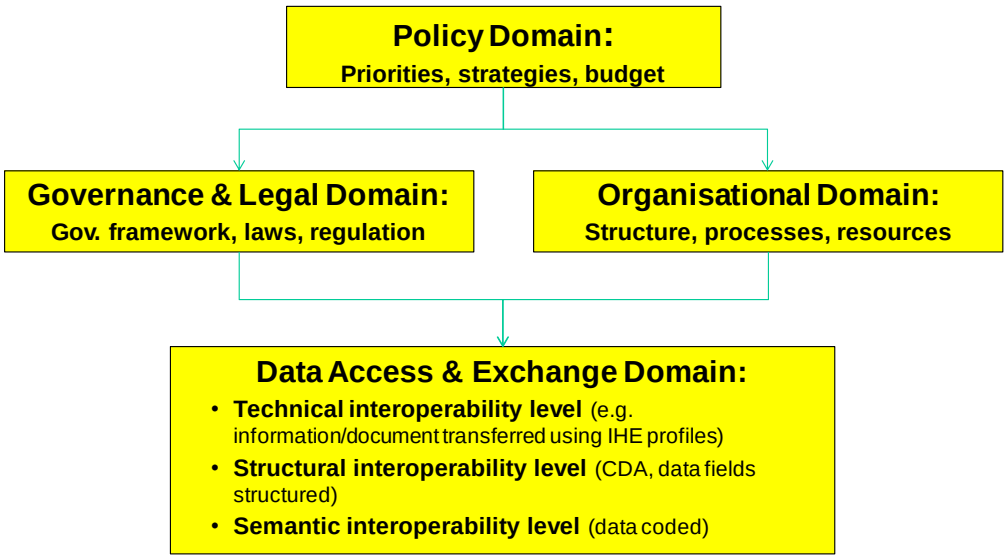
In addition, if access to patient data and other health information is not directly to the storage medium and data files, but rather via an exchange of messages, then the application of exchange or messaging standards/specifications like those provided for by IHE (Integrating the Healthcare Enterprise [23]) profiles like XDS/XDS.b, a profile or model for cross-enterprise document sharing (others are

[37] For more details, see e.g. Stroetmann, Veli N., et al.: Semantic Interoperability for Better Health and Safer Healthcare. SemanticHEALTH, European Commission, Luxembourg (2009)

XCPD, XDA, XDF, XDR, ...) becomes necessary. Some IHE profiles provide not only for integration, but also for contents/some structure specifications.

The following Figure 6 summarises these concepts in a succinct manner:

Figure 6: Interoperability domains for action



4.3 Principal requirements

With respect to the guidelines to be developed, it needs to be noted that there are a number of principal requirements that need to be met in order to establish a functioning infrastructure for cross-border exchange of medical data, including ePrescriptions. These can be summarized as follows:[38]

[38] This is based upon the experience gained through the epSOS pilot.

Figure 7: Principal requirements for the cross-border exchange of medical data

Principal requirement	Comment	IOP focus
1. The primary application of electronic Patient Summary and ePrescription is to provide the healthcare provider (HCP) with a dataset of key health information at the point of care to deliver safe patient care in an unscheduled and scheduled contact.	The end-user of the epSOS service is a healthcare professional operating in a specific organisation The epSOS service is based on a use case approach	Organisational
2. The solution must be focused on the needs and wishes of citizens, patients and their carers (including wishes with respect to confidentiality and consent)	Requirements on the solution must be derived from user needs which translate into legal and technical constraints	Legal Data access and exchange
3. Any access is in the context of a resident of one Member State (MS) visiting another MS and seeking healthcare in that MS	The epSOS service is offered in participating Member States and piloting non-Member States only and only in relation to a healthcare encounter (e.g. no research use)	Policy
4. The solution must maintain, and preferably enhance, patient safety	The solution must have appropriate semantic and legal safeguards to guarantee patient safety	Data access and exchange - Semantic Legal
5. The interchange of information between different MSs must observe the planned or already in place solutions or services and respect the regulations and laws of these MSs regarding Patient Summary and ePrescription. From this prerequisite, the following statements are deducted:	The epSOS solution must be technologically neutral and compatible also on a legal level with existing infrastructures	Data access and exchange Legal
5.a The solution must be capable of being supported by all member state administrations within the context of their national health regulations, strategies and eHealth implementations	The epSOS solution must be flexible enough to be adapted to different healthcare policy contexts	Policy Organisational

5.b A policy of no intrusion or interference in the other MSs must be applied (e.g. the valid regulatory framework is the regulatory framework of the country where the service is provided to the patient).	Patients do not export specific national rights into country B but are subject to existing (legal) framework in country B	Legal
5.c A relationship of trust with the other MSs exists (e.g. validity of the identity of a professional in other MS). Security and privacy requirements and legislations for electronic data exchange must not be weakened and must be satisfied.	There must be a valid system of mutual recognition of qualifications and technical and legal safeguards	Data access and exchange Organisational
6. Agreement on common standards by all EU Member States, should be reached.	Interoperability is facilitated by the use of jointly agreed standards (e.g. for the representation of clinical content)	Policy Data access and exchange
7. The eHealth industry and other stakeholders must be involved.	Long term sustainability of epSOS depends on the uptake of specifications and technical solutions by industry	Policy
8. Any contractual arrangements must comply with relevant national and European procurement processes.		Legal
9. National well-organised eHealth infrastructures are pre-requisite for cross-border solutions.	The epSOS solution sits "on top" of existing eHealth infrastructures and depends on them	Policy
From this statement, there should be existence/deployment, even as advanced trials of ePrescription and/or Patient Summary Services in the Countries where a pilot site will be implemented.	epSOS pilots can only function in relatively mature national environments. This initial claim needs to be revised in light of the epSOS experience (see chapter 5 below)	Policy
10. The solution must be capable of being replicated by all Member States	The results of epSOS must be technologically neutral	All IOP levels

11. A National eHealth Contact Point per MS to interchange the information has to be established[39]	The exchange of information relies on a network of national eHealth contact points that communicate with each other	All IOP levels

The above list of principal requirements identified in the epSOS context is valid also for the general development of a pan European exchange of ePrescriptions. Chapter five below revisits this list and takes stock of the achievements that were made in the context of cross-border piloting.

4.4 Structural elements

To optimize on time as well as resources and expert effort needed when finalising the guidelines amongst Member States and starting to implement them, it is advisable to revisit the epSOS experience and make use of the structural and contractual elements of the epSOS approach that may be expected to survive the end of the project itself. These are:

1) The use of national eHealth contact points (NCPs)
2) The approach of "mutual trust" (circle of trust) between these NCPs
3) The agreement on a common set of standards (and interoperability profiles)
4) The emphasis on replicability in other Member States
5) The respect for existing legal provisions and service infrastructures in respective Member States

This list of requirements is also aligned with work on a European Interoperability Framework.[40] In a recently published report[41], the key principles for a European Interoperability Framework are described as follows:

a. Security and privacy

b. Transparency

c. Preservation of information

d. Reusability

e. Technological neutrality and adaptability

f. Openness

g. User or citizen centricity

h. Use case approach.

The principles of security and privacy, transparency, preservation of information, reusability, technological neutrality and adaptability and openness have their source in the generic EIF. The epSOS large-scale pilot's project deliverable D3.3.3 epSOS Interoperability Framework selected the above-mentioned six principles from the generic EIF, which were prioritised and refined taking as a criterion their relevance for the eHealth domain. The principle of patient centricity is inspired by the

[39] Based on epSOS (2009). Deliverable D5.1.2 epSOS Initial Scope.

[40] Deloitte Consulting (2013 (unpublished)). The vision of the eHealth European Interoperability Framework (EIF) (2/4). European Commission – ISA Work Programme, eHealth European Interoperability Framework (eHealth EIF). Brussels, European Commission.

[41] http://www.ehealthnews.eu/download/publications/3474-ehealth-interoperability-framework-study

principle of user centricity coming from the generic EIF and is translated by the study team into the eHealth context. The last principle of the prioritisation of the use case approach has its source in Mandate 403 eHealth Interoperability on standardisation in the field of eHealth.

Security and Privacy

The proposed principle of security and privacy in the eHealth domain focuses on the privacy aspects of the patient's medical information.

On one hand, patient medical information should be subject to constraints granting patients the right to verify (and correct) information held about the patient, e.g., diagnosis and treatment history. In addition, a patient should be granted the right to be consulted and have the right to opt out of health information exchanges, for instance, when his/her medical information is intended to be used for other purposes than that for which it was originally supplied.

On the other hand, patient medical information should be exchanged in the eHealth systems under strict rules of privacy and confidentiality and in full compliance with the relevant regulations, e.g., on privacy and data protection.

Transparency

The principle of transparency, when translated into the specificities of the eHealth domain, concerns transparency within the processes that govern the gathering and sharing of patient medical information. In particular, the principle suggests the right for a patient to "track" the state of his/her information (e.g., to have a view over who has viewed or processed his/her information) and the right to provide feedback on the process itself.

Preservation of Information

The principle of preservation of information in the context of the eHealth domain calls for preservation of medical records and medical information held in an electronic format. The rationale behind this requirement relates to medico-legal purposes and retention of information legibility, reliability and integrity in order to access the information whenever needed. To this end, in order to ensure information accessibility, formats should be defined that cover electronic certifications (e.g., electronic signatures and mandates).

Reusability

The principle of reusability in the eHealth context suggests the leveraging of existing practices with proven and tested value. This involves selecting relevant and useful solutions. A necessary condition for reusability is therefore the willingness of healthcare entities to share their solutions, concepts, frameworks, and specifications with interested parties. To this end, the data should be held or exported in a standardised form so that they can be imported into other systems. As such, the tools and software components themselves need not be interoperable or shared. The willingness of healthcare entities to share with interested parties can be expressed by leveraging the principle of openness described in section 6.6 within the collaboration between different entities to reach commonly agreed goals.

Technological Neutrality and Adaptability

The principle of technological neutrality and adaptability in the context of eHealth is seen as a requirement addressed to all providers of technologies, products, specifications and standards (e.g., vendors, SDOs, and profile development organisations). This principle calls for avoidance of imposition of technologies and products on the healthcare stakeholders. Another requirement laid down by the principle is the requirement of adaptability of technologies and solutions in order to meet the changing needs in the eHealth domain, such as new standards or new clinical requirements.

Openness

The principle of openness translated into eHealth context can be seen as sharing knowledge among healthcare entities and eHealth market players in order to contribute to the knowledge progress in terms of finding new solutions. To this end, technical specifications, software and software development methods should be developed jointly (using international standards) and the results

should allow for interconnection, reusability and sharing, thus contributing to openness in the interoperability context.

Patient Centricity

The principle of patient centricity is a further instantiation of the principle of user centricity taken from the generic EIF. The principle of patient centricity involves the notion of patient and his/her health issues being at the centre of eHealth services; as a main driver defining the scope of and how eHealth services are delivered. To this end, this principle covers the notion of service personalisation, multichannel delivery and single point of contacts to streamline the service delivery. As a part of the principle, patient safety is also considered as an important element that should be translated into the delivered services in terms of privacy, integrity and accuracy of medical information shared between patient and healthcare providers. The principle of patient centricity is in line with the vision of the 2012 eHealth Action Plan to enhance patient empowerment.

Use Case Approach

The principle of use case approach is common in IT systems development methodologies (such as the Rational Unified Process - RUP). It is at the core of the IHE-developed draft ISO TR28380 IHE Global Standards Adoption Process, and was used to develop the Mandate 403 phase I report. The principle of a use case approach is suggested to be a part of the eHealth EIF in order to address the challenge of the complexity of eHealth-related requirements. A layer of complexity within the use case approach principle is a possible overlap of use cases that address the same requirements multiple times. To accommodate this complexity, use cases are defined as business or high-level use cases that are broken down into low-level use cases supported by profiles. These profiles, in turn, describe the way that a set of base standards should be used. Such profiles will need to address many areas of interoperability in the eHealth domain, such as information transport, security, data structures and related data models, associated terminologies, and privacy and service contracts. Thus, these kinds of profiles will need to address the main eHealth requirements concerning e.g., security, privacy, patient identification, record sharing and access, care coordination record content, specialty record content, home monitoring, referral and consultation workflows.

4.5 Challenges potentially limiting data access and exchange

Considering the earlier discussed interoperability concept several challenges might act as potential constraints to the desired level of data and information exchange interoperability in a cross-border situation. These can be identified as follows[42]:

- **Security and Privacy**
  - It must be assured that patients and health care professionals interact in an environment which fully respects regulations on privacy and data protection. Hence, the service has to guarantee the privacy of the patients as well as the confidentiality of any information provided and exchanged.
- **Transparency**
  - Patients and HCPs need to have the right to review and verify the collected information in order to be able to decide if the collected information may be used for other purposes than it was originally supplied for. Additionally any party involved the data exchange should be able to understand administrative and business processes as well as the right to track the procedures they are involved in.
- **Preservation of information**
  - By preserving medical records and other forms of information in electronic form it should be tried to ensure their legibility, reliability and integrity over

[42] See also the epSOS work on architecture (epSOS deliverable D3.3.3)

time. For the purpose of documenting procedures and decisions these information have to be preserved

- **Openness and Reusability**
  - The interoperability framework itself implies a certain degree of openness which means that specifications, software and software deployment methods promoting collaboration can be freely accessed, reused and shared. Reusability is key to an efficient development of European cross-border services
- **Technological Neutrality and Adaptability**
  - Organisations should focus on functional needs and defer decisions on technology in order to avoid imposing specific technologies and products. Access to the services should be independent of any specific technology or product.

4.6 Proprietary versus open source standards

In an operational sense, standards are "technical specifications." A standard implies the existence or opportunity of an agreement between different parties which are interested in implementing and using these specifications. The operational purpose of a standard is to achieve the highest level of order within the execution of particular activities, or the creation of particular results. For example, two hospitals may decide to share patients' x-ray images over a computer network. In order to support and seamlessly integrate the information, both hospitals have to agree on, first, a data format for the content and, second, a communication format for the transmission. Data formats specify the information within data files, whereas the communication standard defines the format to electronically transmit the medical images over a network.

A distinction of types of standards by institutions/organisations developing them is important to understand the interests behind standardisation processes and who drives or could drive them. From an institutional perspective one may distinguishfour types of standards: official, voluntary, proprietary, and open standards.[43]

Official standards are made obligatory through regulation by governments, for example by law. Prior to being made mandatory they were approved by Standards Development Organisations (SDOs) such as the International Standards Organisation (ISO).

Voluntary standards are developed by SDOs, normally on request from interested parties such as industry, but are not made mandatory by governments. For example, the European Committee for Standardisation (CEN) has the objective to develop voluntary technical standards.

Industry standards are defined by one single company or groups of companies. Initially they are always proprietary, i.e. their specifications are not disclosed. The companies may seek to reach acceptance of such standards in the market process, i.e. by successfully selling goods that operate with these industry standards. This procedure has been successfully demonstrated multiple times in the world of ICT, including the introduction and distribution of the Microsoft operating systems MS-DOS and MS-Windows. For industry standards that are widely used, the notion "de facto standard" has become common. Companies may also develop industry standards for internal communication within a single establishment or between several establishments, without seeking to make the standard adopted by other companies.

Open standards are characterised by the circumstance that everybody can participate in their development without being a member of a specific group or institution. Further aspects that constitute such a model and the idea of openness are that standards are available to anybody for free or at a low cost, and standards are free to use by anybody; in particular they do not require proprietary software to run.

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[43] European Commission. ICT standards in the health sector – Current situation and prospects. A Sectoral e-Business Watch study by empirica. Brussels, June 2008

In practice, many standards do not fall neatly into one of these categories. For example, governments may be involved in unofficial SDOs and influence the development of industry standards, and industry may be involved in unofficial SDOs or influence governmental decision about standards.

For purposes of this study, it is sufficient to distinguish between

proprietary standards which are developed for private use, the specifications of which are usually not disclosed and protected by IPRs, and

open standards which are open for use by all, and where the documentation needed is available free of charge or for a low fee. When a solution is based on open standards, it allows for multivendor implementations and promotes interoperability of software and data as far as possible.

If a standard is open, it is possible to add specific functionalities to the solution that the user needs, or to adapt a product or service to specific needs. In case there is an alternative for the solution that is based on the same standards, it is also possible to replace the original solution by the alternative. Thereby, the solution is interoperable and does not cause a lock-in for the applying organisaiton. In cases where there is no solution based on open standards, it should at least make use of publicly available API's in order to keep the solution as open and interoperable as possible.

It is therefore for good economic reasons, that the usage of open standards in eHealth is becoming more and more "standard" procedure globally, particularly in heterogynous (and trans-border) contexts.[44]

Usable, widely available, accepted, and implemented standards can contribute to economic growth and increased competition among ICT application producers and service providers – and thereby to efficiency gains for the society, as well as to the competitiveness of national and European ventures. However, the situation in eHealth standardisation is still somewhat characterised by conflicting standards and thus a lack of network effects as well as an absence of well-developed standards for specific use cases. Various SDO developed standards have become fairly prominent, but further development and harmonisation will be necessary. Consequently, the wide use of open (ICT) standards in the ePrescription field, quite independent of the different ePrescription planning and implementation policies or the present application status of Member State could impact positively on economic growth as well as on the efficiency of our healthcare systems. According to the report "Connected Health" published by the European Commission.[45] the potential value of the interoperable exchange of health information between healthcare institutions is substantial.

As electronic medication services take place in the highly complex, heterogynous field of public transborder healthcare, the goal must be to use open standards for including but not limited to documents, messages, identification, security aspects wherever possible.

For all of these technical, operational, and semantic reasons, it seems advisable for pan-European ePrescription services to also adopt open standards and use other open source components to the greatest extent possible. For example, epSOS in its agreements for cooperation has made wide use of open standards like those available from HL7 for structuring documents. And the epSOS Master Value Sets Catalogue assembled the agreed, official code systems for a commonly understood medical terminology. eDispensations, ePrescriptions and Patient Summaries, which are all based on value sets extracted from the epSOS Master Value Sets. Standardized code systems used for epSOS documents are: ICD-10, SNOMED CT, ATC, EDQM, and Unified Code for Units of Measure (UCUM).

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[44] For a good example illustrating this case for the secondary use of electronic healthcare record (EHR) data, see e.g. Fernández-Breis JT et al. Leveraging electronic healthcare record standards and semantic web technologies for the identification of patient cohorts. J Am Med Inform Assoc. 2013 Dec;20(e2):e288-96. doi: 10.1136/amiajnl-2013-001923.

[45] See European Commission. Connected Health - Quality and Safety for European Citizens. Report of the Unit ICT for Health in collaboration with the i2010 sub-group on eHealth (formerly known as the eHealth working group) and the eHealth stakeholders' group. Luxembourg, 2006

In the absence of a better international approach, the Anatomical Therapeutic Chemical Classification System including defined daily doses (ATC/DDD) of the World Health Organization (WHO), based upon the International Non-proprietary Names list (INN) is used as a standard. Furthermore, standards concerning medicines for human and veterinary use for the safe and appropriate medication as introduced by European Directorate for the Quality of Medicines & HealthCare (EDQM), a Directorate of the Council of Europe are applied.

Other open source components include, e.g., the open source NCP solution that can be used to connect national infrastructures to the epSOS environment.

In summary, it may be most efficient for Member States together to support the further development of a tool box focusing on a core set of scalable ePrescription modules, which would be flexible enough to connect to a variety of national and regional healthcare structures, take into account the size of the healthcare system, cultural idiosyncrasies, resources available, etc. Such a tool-box should be based on open standards and be open for integrating open source software with commercial software, and provide interfaces for bespoke additions.

The integration of eHealth infrastructures with other national and European infrastructures should also be considered in this context. Particularly eGovernment infrastructure components should be integrated into an eHealth platform whenever meaningful, thereby potentially, in the longer term, realising considerable resource savings.

5 LEARNING FROM MEMBER STATE EXPERIENCE FOR GUIDELINE DEVELOPMENT

The previous chapter has outlined key principal requirements for cross-border exchange of patient data, and also reflected on key features of the epSOS approach to cross-border exchange of health data – a core base for future exchange of any patient data across the Union. In order to further facilitate this process and provide for the basis of a pan-European ePrescription becoming reality in line with the mandate of the cross-border directive on healthcare, we briefly review some relevant Member State experience and lessons learned, because this will provide for further input on the focus of guideline development to support and facilitate the development of a single European health services market. The chapter begins with a summary of principal requirements and achievements to be observed for each requirement, based on already existing Member State cooperation. It concludes with a process view of a pan-European ePrescription service, illustrated by an end2end service process. This will also facilitate the roadmap development to follow in the final chapter.

5.1 Member State achievements against principal requirements

In order to better understand key open issues that need to be dealt with by the guidelines, it is advisable to first take stock of Member State achievements as already realised within the epSOS context. These can be measured against the principal requirements that were identified in section 4.3 above.

Req 1. The primary application of ePrescription services is to provide the healthcare provider (HCP) with a dataset of key health information at the point of care to deliver safe patient care in unscheduled as well as scheduled contacts

epSOS achievement(s):

- The ePrescription as well as eDispensation datasets were successfully defined.
- epSOS use cases were specified to accommodate scenarios for both scheduled and unscheduled care.

Req 2. The solution must be focused on the needs and wishes of citizens, patients and their carers (including wishes with respect to confidentiality and consent)

epSOS achievement(s):

- Through the Calliope thematic network, the epSOS use cases, and the patient summary and ePrescription datasets as well as other technical results of the project were made known to and discussed with a large audience, including patient organisations, and feedback gathered.
- The epSOS evaluation workpackage has conducted service content evaluations that confirmed the acceptability of the epSOS solution for patients and healthcare professionals.[46]

Req 3. Any access is in the context of a resident of one Member Sate (MS) visiting or temporarily living in another MS and seeking healthcare in that MS

epSOS achievement(s):

- Throughout the epSOS piloting phase, new pilot sites also outside of the consortium have begun planning for epSOS services (e.g. Switzerland, Croatia)

Req 4. The solution must maintain, and preferably enhance, patient safety.

epSOS achievement(s)

[46] Albeit a regulatory impact analysis comparing the costs incurred with the overall benefits to be expected from such services is missing.

- The ePrescription is transferred both in the agreed-upon exchange format and in the original country A format to guarantee that no information is lost.
- The epSOS service process is designed such that it cannot work without reliable patient identification and prior consent of the patient.

Req 5. The exchange of patient information between different MSs should be adaptable to the planned or already implemented ePrecription technical solutions and services, and respect the regulations and laws of these MSs regarding ePrescription

From this prerequisite, the following statements are deducted:

5.a) The cross-border ePrescription solutions Member States implement must be technologically neutral and compatible also on a legal level with their existing infrastructures.

epSOS achievement(s):

The epSOS FET team has developed an open source NCP solution that can be used to connect national infrastructures to the epSOS environment.

5.b) The solution must be capable of being supported by all Member State administrations and competent authorities within the context of their national health regulations, strategies and eHealth implementation. The ePrewcription solution must be flexible enough to be adaptable to different healthcare policy contexts.

epSOS achievement(s):

- The FET solution is sufficiently flexible to accommodate different healthcare environments.
- The epSOS framework agreement was able to be implemented in almost all epSOS piloting regions/Member States.

5.c) A policy of no intrusion or interference in other MSs must be applied, e.g. the valid regulatory framework is the regulatory framework of the country where the service is provided to the patient. Patients do not export specific national rights into country B; rather, they are subject to existing legal and organisational framework in country B.

epSOS achievement(s):

- epSOS has not conferred new rights to users of its services.
- The epSOS framework agreement was able to be implemented in almost all epSOS piloting regions/Member States.

5.d) A relationship of trust with all other MSs exists (e.g. validity of the identity of a professional in other MS). Security and privacy requirements and legislation for electronic data exchange must not be weakened and must be satisfied. Also, there must be a valid system of mutual recognition of qualifications and technical and legal safeguards.

epSOS achievement(s):

- The epSOS framework agreement was able to be implemented in almost all epSOS piloting regions/Member States
- The framework agreement includes as an annex the epSOS security policy
- A contract between the national eHealth contact point and the piloting points of care which translates the epSOS framework agreement to local conditions ensures that security requirements are met.

Req 6. Agreement on common standards by all EU Member States, should be reached

epSOS achievement(s):

- The semantic interoperability of ePrescription content is achieved through agreement on a common terminology dataset bound to ePrescriptions.
- Technical interoperability is achieved through joint use of IHE exchange profiles.
- The epSOS open NCP solution is developed as an open source solution.

Req 7. The eHealth industry and other stakeholders must be involved.

epSOS achievement(s):

- The epSOS industry team is part of the management bodies of epSOS
- The industry team has contributed testing facilities and tools through IHE Europe.

Req 8. Contractual and procurement arrangements must comply with relevant national and European regulations and procedures.

epSOS achievement(s)

- For common components development (providing participating countries with software solutions), epSOS has found a solution that is in line with EC rules on procurement.
- For further support services, epSOS has provided Member States with procedural tools to contract with specific industry experts.
- Beyond the epSOS pilot duration, planning for the sustainability of services has begun by the eHealth Network which will avail itself of the resources to be made available via the Connecting Europe Facility (CEF)

Req 9. National eHealth infrastructures, including an ePrescription service, are pre-requisite for cross-border solutions

To consider participating in the exchange of cross-border ePrescription services, there need to be in existence or at least at the implementation stage advanced trials of ePrescription services in the respective countries

epSOS achievement(s):

- Participating in epSOS pilots has encouraged a number of Member States to enter the active piloting phase of ePrescription services.
- This has also contributed to further eHealth platform developments at the national level.

Req 10. ePrescription solutions developed together must be replicable by other Member States

epSOS achievement(s)

- epSOS provided replicable components (MTC; MVC, open NCP) for the piloting environment.
- The legal aspects were dealt with in a framework agreement that allowed for adaptations to national contexts.

Req 11. A National eHealth Contact Point per MS to interchange the information has to be established

epSOS achievement(s):

- Member States developed together two compatible technical solutions for so-called Open National eHealth Contact Points (Open NCP) to facilitate the exchange of ePrescription data.
- Further (organisational) aspects of NCPs and their obligations in the scope of implementing the cross-border patients' rights directive need to be tackledin future.

5.2 Process view of cross-border end2end services

We conclude this chapter with a process view of a pan-European ePrescription service, illustrated by an end2end service process. This will also facilitate the roadmap development to follow in the final chapter of this report. Based on the preceding discussions and analyses, the following Figure 6 describes in tabular form these business processes and identifies appropriate process steps as well as the relevant interoperability domains where actions are to be allocated:

Figure 8: Open issues identified with respect to the core business Process and Process Steps

Processes and Process Steps			
Business process	**Process steps**	**Interoperability domain**	**Open issues**
Preparation	Establishment and commissioning of an eHealth NCP • Conclude Legal Agreements • Establish process to create and maintain Master Translation Catalogues (MTCs • Make PS and prescription available in epSOS standards • Obtaining patient's prior agreement to epSOS pilots • Establish workflow at PoC • Establish an Information Security Management System (ISMS), including regular Audit • Identify/involve professionals and carry out training • Establish appropriate communication and publicity measures to inform users Inform/notify DPA; get authorization from DPA	Governance & Legal Organisational Data access and exchange	• Maintenance of Master Translation Catalogue may become a heavy burden • Not all Member States can represent the full dispensation dataset in the epSOS standard • The NCP "brokered trust" makes end2end security impossible • The legal sustainability of epSOS beyond the pilot duration depends on a new set of multilateral agreements that do no longer rely on the Grant and Consortium Agreement of epSOS
	Communicate results and obtain permission to enter the epSOS pilot		

Access to cross border care	Patient accesses cross-border care/epSOS related info	Legal Organisational Data access and exchange	
	PoC identified (clinical centre, pharmacy, emergency service)		
	Patient accesses (epSOS) HC services		• Very low level of real patient encounters in epSOS pilot
Healthcare encounter (I)	Identification of Patient (including Authentication and Authorisation)	Policy Legal Organisational Data access and exchange	
	Identification of Health Professional (including Authentication and Authorisation)		
	Patient consent (including prior Agreement to participate in the pilot)		
	Health professional requests access and receives Patient Summary/e-prescription/medication record from abroad according to professional role		
	Health professional receives semantically mapped epSOS document		
	Health professional creates new/updates clinical or e-prescription or dispensation record stored in the country of treatment		
Healthcare encounter (II)	Patient access own health data and requests semantically mapped presentation	Legal Organisational Data access and exchange	
	Patient shares health data with health professional		
New health record/order created and stored	Health professional creates new/updates clinical or dispensation record in country of treatment	Legal Organisational Data access and exchange	
	New data is rendered available for return to country of usual residence (A) upon request		
	Notification of existence of new data is sent to country A of usual residence (A)		

Patient summary is updated in country A	NCP A requests transmission of new data	Legal Data access and exchange	
	NCP B transmits epSOS new record in the form of an epSOS document		
	Patient summary is updated		

6 OPEN EPRESCRIPTION CHALLENGES

This chapter now focuses on core open issues that are specific to ePrescription services. It begins with a brief introduction to methodological issues, the information gathering approach, and a summary of key results from the *feasibility analysis* of this study.

It then summarizes key open issues that have been identified through iterative processes of involving and exploring together with the various national experts and scientists involved in this phase of the study, also reflecting on earlier expert group work in epSOS (notably the technical liaison work of WP3.D).

6.1 Methodological issues and information gathering approach[47]

The study deliverable *D2.1 Draft feasibility survey methodology and instrument* provided an overview of the ePrescription and eGovernment processes and projects in Europe that guided and shaped the feasibility analysis of ePrescription cross-border services. It proposed a semi-structuring of issues and questions to be pursued further during this phase of the project, reflecting on Member State experience that core challenges on the road to European wide deployment of cross-border exchange of patient data for improved healthcare services reside in the organisational and legal interoperability domain.

In order to give in-depth meaning to the survey results, the report also reviewed the current state of play of eGovernment interoperability thinking and projects through the presentation of the European Interoperability Architecture. This work provided already important pointers to the components that are required to interconnect national administrations in Europe: the use of structured documents, the need to reliably identify, authenticate and authorize individuals and healthcare professionals as well as the need for intra-European routing services to connect national eHealth contact points.

A review of the available evidence on ePrescription projects across the EU complemented this analysis and revealed that the process of recording, transferring and dispensing an ePrescription is not yet fully implemented in many EU Member States. A large variety of national situations were described, ranging from fully functioning ePrescription services (in countries such as Denmark, Sweden, Scotland and Andalucía for example) to more complex situations such as in Germany, where a sophisticated infrastructure is in principle available, but the implementation of actual services hampered by a number of political, legal and organisational challenges.

Questions on challenges like identification of patients and healthcare professionals and providers, authentication, transfer of information, as well as legal and organisational issues were developed. An attempt was made to design questions comprehensively, without going into excessive detail. One survey design principle in particular was to avoid an unnecessary level of detail that is not significant in the higher-level context of this study. Details, such as security, consent design, mappings, and transport formats may be fully accounted for by choosing adequate technology in subsequent steps.

A key element of the approach chosen for information gathering was the consultation of experts. These interviews served the dual purpose of constituting a valuable source of information as well as of validating the information gathered elsewhere. They helped to:

- ✓ confirm findings
- ✓ challenge results
- ✓ explain, expand and contribute to important details and background
- ✓ highlight particularly innovative practices that deserved to be further analysed

Altogether, more than 30 experts from around 15 Member States, covering IT specialists, public health specialists, but also policy, interoperability and semantic experts were involved.

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[47] This is a brief summary of the extensive exploration reported upon in D2.1 Draft feasibility survey methodology and instrument.

6.2 Key results from the feasibility analysis survey

Deliverable D3.2 of this study reported on the results of an extensive survey of national experts with regard to their national ePrescription solution. Questions focused on topics such as technical and semantic interoperability standards and issues, legal provisions, and security aspects.

After completion of the survey, a subset of questions was selected, which promised to deliver information on the features of an ePrescription solution most critical for cross-border information exchange, and at the same time most likely to illustrate commonalities and heterogeneity of approaches.

The responses to these questions were given a numerical value –and where applicable from the type of answers provided – these were summed up to arrive at a score for each country for each of the items previously identified. A typical approach would consist in assigning a "zero" to answers such as "no", or "not available", while graded values (from 1-3) were assigned to response items which together describe parts of a solution in a country. In the case of authenticity and integrity of an ePrescription for example, administrative means of integrity control were ranked lower than the use of digital signatures.

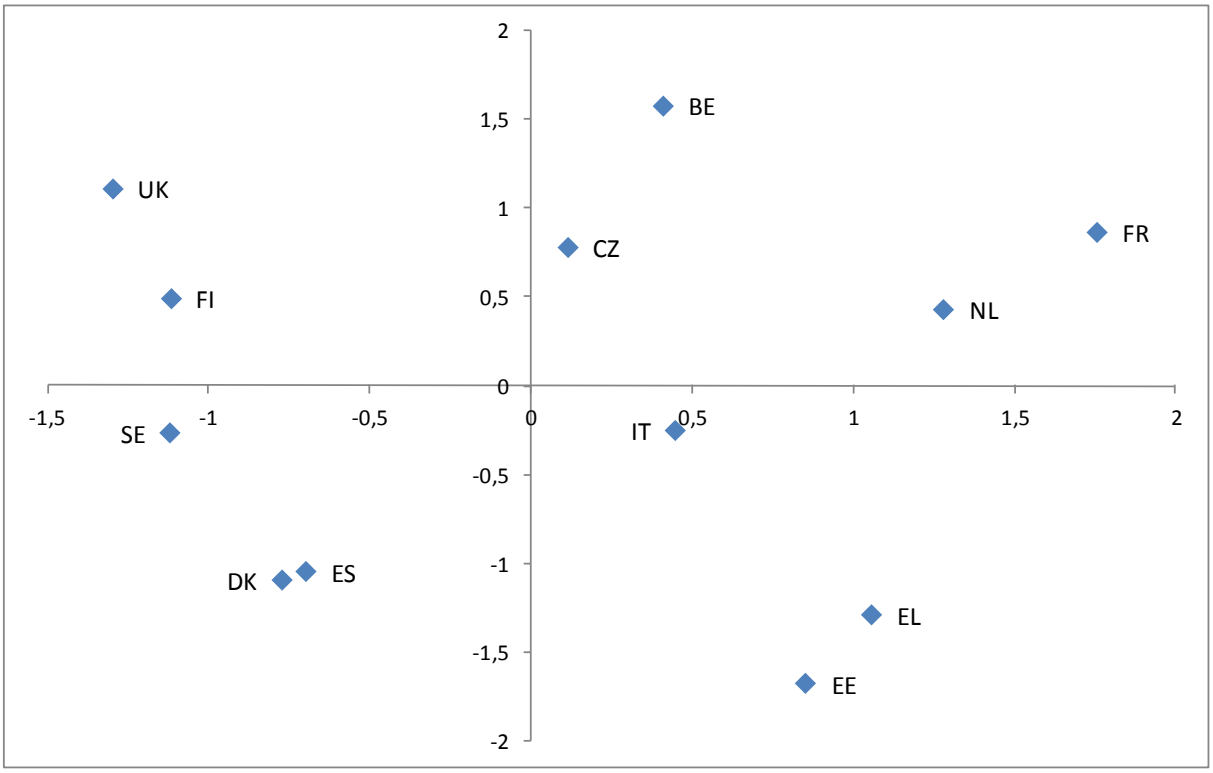
Results

Selected indicators from the country survey underwent multivariate analysis to determine whether there are clear patterns allowing to group countries, e.g. according to ePrescription maturity. As described in the Inception Report, 'Correspondence Analysis' was used for this purpose. Input data can be found in the Annex of that report, along with numerical results.

The analysis yielded an 11-dimensional solution, out of which the first four variables can be interpreted according to eigenvalue criteria. All in all, the analysis showed no clear pattern that would allow to group countries according to overarching similarities. Rather countries can be distinguished along the lines of certain characteristics of their ePrescription system.

The plot of countries along the first two dimensions is shown below in Figure 9:

Figure 9: Member State cluster analysis



The most heterogeneous aspect, depicted along the first (horizontal) dimension is validity period of prescriptions... Countries with long validity periods are depicted towards the left, those with shorter periods to the right.

The second most heterogeneous aspect, depicted along the second (vertical) dimension relates to security measures, particularly the use of digital signatures, and the coded structure of prescriptions. Those countries not using digital signatures and using lesser degrees of coding are grouped towards the bottom. Countries using more coding and digital signatures are grouped towards the top.

Further, two interpretable dimensions (not depicted here) distinguish countries in terms of security measures and again coded structure (dimension 3), and the encoding of active ingredients, brand names or both and the existence of a list of health professionals entitled to prescribe medication (dimension 4). These dimensions are also responsible for heterogeneity of national ePrescription solutions.

This analysis may point to the necessity to work further towards a common European approach in the mentioned domains, in order to reduce the heterogeneity that is currently observed between Member State solutions.

6.3 Insufficient coding instruments to represent active ingredients in medication

The problem is the lack of a binding classification/coding instruments to represent active ingredients in medication. Already epSOS faced this problem. In the absence of a better approach, the Anatomical Therapeutic Chemical Classification System including defined daily doses (ATC/DDD) of the World Health Organization (WHO) based upon the International Nonproprietary Names (INN) shall be used as a standard.

In the epSOS WP1.4.10 the Clinical and Semantic Expert Group looking at the requirements and possible solutions to "How to describe medicines in epSOS" have concluded that there is a common understanding on the fact that the only actual solution for resolving the problem of the EU cross-boundary medicine identification seems to involve the use of the pan-European medicinal product data from EMA as a basis for a European Medicines database.

Though the only[48] actual solution for resolving the problem of the EU cross-border medicine identification seems to be a centralized / federated European Medicines database, we can attempt to mitigate the impact of the issues described above by revising the way medicines are represented in epSOS.

As building a centralized European Medicines database goes well beyond the scope of the epSOS project, the epSOS Clinical and Semantic Expert Group evaluated the ideas and possible solutions presented and two main approaches came out from the discussions:

· The usage of SNOMED CT concepts for representing the Pharmaceutical Product independently from its commercial form, identified as Non Proprietary Medicinal Preparation (NPMP based solution)

· The maintenance of the current approach using a different system for describing the individual active ingredients. A possible candidate for this is the INN - the International Nonproprietary Name, but alternatives can be taken however in account (e.g. SNOMED CT including its active ingredient model, or a separate Active Ingredient based solution)

For both solutions the team agreed however not to leave out the ATC code mainly because this is often the only data available for describing medicines in some MS.[49]

6.4 Missing interoperability of digital signatures across Europe

Due to different implementations of electronic signatures across Europe and above all the lack of a centralized European public key infrastructure (mutual) recognition of electronic signatures faces some practical problems. For this reason the guidelines draft includes a provision that allows to substitute the prescriber's signature by the electronic signature of the national contact point according to Article 6 Directive 2011/24/EU. Reflecting the preliminary work of epSOS these national contact points shall form a web of trust, i.e. may rely upon the information released by them, may these information refer to the national list of authorized prescribers or medication.

6.5 Status of epSOS services as a "medical device"

According to Article 1 (2) (a) Directive 93/42/EEC a medical device is defined as "*any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:*

- *diagnosis, prevention, monitoring, treatment or alleviation of disease,*
- *diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,*
- *investigation, replacement or modification of the anatomy or of a physiological process,*
- *control of conception,*

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means".

The legal Work Package 2.1 of epSOS has not yet made a decision, whether epSOS is deemed a medical device according to Directive 93/42/EEC or not (Deliverable 2.1.1 – Legal and Regulatory

[48] In principle the existence of a federated or centralized EU (commercial / non-commercial) medicines DB is not a "sine qua non" requirement, however based on the epSOS experience this seems to be the only viable solution for achieving a sustainable and safe cross borders eP/eD process.

[49] This paragraph is an extract from the work documented in the epSOS WP3.D report on "Semantic Sustainability – ePrescription cross border", February 2013

Requirement at EU level, final, February 24th 2012, p 44). Although medical information services like epSOS support the diagnostic and/or therapeutic processes, their primary intention is not aimed at diagnostic and/or therapeutic work in the narrower sense. Medical information services like epSOS or the intended electronic medication services subject to these guidelines have in common, their supportive but not decisive role. Against this backdrop such information services shall not be regarded medical devices. Services that factually propose medical decisions as for example interaction checks do this opinion needs to be adapted, i.e. such services are likely to be regarded medical devices.

6.6 Harmonization of national policies and implementation strategies

Conformance with existing policy structures, processes and measures has been the major goal of the ongoing harmonization process. Lessons learned from policy frameworks most notably epSOS, the eHealth Governance Initiative and EESSI determined the red line of the work done. Especially the reference to the eHealth Governance Initiative ensures the link to pan-European policy making and implementation of structures and processes against the backdrop of sustainability.

The EESSI policy regulations have been reflected especially to learn from the cross border exchange of information required by the social security bodies in the Member States. Wherever possible the existing infrastructure of EESSI shall be used for the cross border cooperation in the field of eHealth.

Based upon the survey undertaken in 2012 covering the most relevant questions of for example the minimum requirements for prescriptions, the following guidelines draft has been elaborated.

National rules that interdict communication of personal medication data to another country are insurmountable obstacles to the participation in cross border medication services. Requirements laid down in the following draft guidelines concerning validity of ePrescriptions, identification and authentication, security issues or data protection are not deemed such obstacles, but necessary pre-requisites for a secure and benefiting cross border communication of medication data.

The diversity of national and regional structures, cultures and roles of healthcare providers are encapsulated by the national contact points as defined in Article 6 of the Directive 2011/24/EU. These national contact points make up the backbone of the cross border cooperation structures and processes and integrate national procedures and logistics into the European level of cooperation.

With regard to technical interoperability important questions of syntax, system architectures and terminologies need to be answered. As electronic medication services take place in the field of public health, the goal must be to use open standards for including but not limited to documents, messages, identification, security aspects wherever possible.

To ensure a high level of human health protection reliable identification mechanisms need to be provided. This does not necessarily require ID tokens like Electronic Health Insurance Cards, as long as the accurate identification of the patients is guaranteed. To this end Member States should provide at least registers of authorized health professionals, minimum identification data included in the electronic medication data and specific lists of authorized medication, revealing *inter alia* medication that is subject to qualified prescription requirements.

7 FINAL EPRESCRIPTION GUIDELINES

Initially, the methodological approach used to validate the draft guidelines will be briefly summarised, to be followed by reflections on the concept of guidelines and their field of application. It reviews the two dimensions guidelines may have in the context of this study: as mere recommendations to Member States or/and as a "roadmap" document that structure political action.

Then the presentation of the final set of draft guidelines follows, together with a detailed explanation of their scope, ambition and concepts.

7.1 Approach and methodology for drafting and validating guidelines

In order to establishing a definite framework and methodology for drafting initial interoperability guidelines, a methodology inspired by and borrowed from software development was developed in Deliverable *D 4.1 Brief guideline formulation methodology paper*. It is based on the so-called "V-model", which represents a software development process, which is an extension of the well-known "waterfall model". Study work went through an initial development cycle of "concept of guideline purpose & operations", "guideline requirements specification", rough "high-level guideline design", more fine-grained "guideline modules design", and virtual "guideline usability testing", followed by collection of appropriate feedback from experts internal to the project team. All of this became input for a second cycle. External rerview and validation by experts followed.

The initial integration and consistency check of the guidelines included a first round of internal expert consultations, and also involved about 12 experts from 8 Member States, among them IT specialists, public health specialists, semantic, legal and security experts.

After this initial cycle and review, for each of the four interoperability levels, a second round of revisiting and improving the initial draft guidelines, based on and following the methodology developed earlier, followed. The result of this iterative guideline formulation process was an interim report on draft guidelines - *D4.2 DRAFT Guidelines* - which provided the base for final validation.

These draft guidelines were submitted to external experts and discussed at a second validation workshop in Brussels, edited, discussed with DG SANCO representatives, and finalised.

7.2 On the overall approach for the validation of guidelines by experts please refer above to Section *6.1 Methodological issues and information gathering approach*.Guidelines as non-binding recommendations

It is generally very difficult to clearly describe what the term guideline means or what guidelines are in the context of European policy making. There does not exist a formal or legal definition of what "guideline" means in the context of European acts or documents, and the weight and meaning of guidelines vary considerably across European Commission Directorates. Also from a legal perspective, given the limited EU competences in the field of healthcare delivery, the term "guidelines" as referred to in Art 11 para 2 lit b (see Directive 2011/24/EU) should be interpreted in a legally non-binding way, as there is no legal base for harmonisation in this field. According to Art 11 para 2 lit b D 2011/24/EU these guidelines shall be "supportive", so that they obviously can be formulated only as recommendations.

Recalling the objective set out in the directive in Art 11, Section 2 that

"the Commission shall adopt guidelines supporting the Member States in developing the interoperability of ePrescriptions without prejudice to national rules

- governing prescribing and dispensing,
- on reimbursement of medicinal products,
- regulating a pharmacist's right to practice according to the professional and ethical rules that s/he is subject to in the Member State of treatment",

it is indeed quite challenging to formulate guidelines in an appropriate manner meeting the needs for the interoperable cross-border exchange of electronic prescriptions and, at the same time, observing and respecting the rights of Member States in the field of healthcare.

Concerning the *level of specification of these guidelines*, the development process for the draft guidelines presented below as well as the discussions with various experts in the field and the input received at the two workshops undertaken indicate that a 'medium' level of specificity may be most appropriate, given the above discussed status such guidelines may acquire in the further policy and implementation process. On the one hand, too specific and detailed guidelines may become obsolete within a short period of time due to continuing changes in technical, semantic, legal and organisation domains; on the other hand, very generic guidelines may only be able to identify key areas needing collaborative attention and agreement, but without setting a consensual framework from which to progress further in an efficient manner.

7.3 Guidelines as policy structuring documents

At the end of this report a tentative roadmap containing preliminary timelines and milestones for MS implementation is presented. The application of the guidelines is illustrated through the ePrescription use case as defined in the epSOS project and accepted by participating Member States and other European countries as a basis for implementation. Here we understand the concept of "roadmap" as a script which delineates a space of possible actions, which are ordered based on assumptions of the likelihood of events that will impact on these actions. Examples would be the availability of international terminologies for a certain domain or the likely amount of time needed to develop such terminology from scratch.

For the organisation of deriving final specifications for draft guidelines and a roadmap towards eventual implementation into Member State eHealth strategies, the following analytical process was followed:

(1) Based on the ePrescription scope laid down in the inception report and (2) considering the results of the country non-clusters identified in the feasibility analysis, the roadmap (3) deals with the four domains of interoperability and defines recommended actions at each of the levels, (4) adapted to the identified needs of Member States. Proposed actions are grouped into short-term, medium-term and long-term actions.

Regarding point (2), the cluster analysis documented in D3.2 had shown no meaningful group of countries sharing certain characteristics of ePrescription. Instead, the cluster analysis revealed two important factors that determine the key difference between Member State approaches: these concern the use/non-use of digital signatures and the validity period of an ePrescription.

7.4 Synthesis of feedback phase and clarifications on initial draft

Following the guideline validation workshop organized with a number of experts in July 2013, feedback was sought from DG SANCO. This feedback included clarifications on important concepts used in the guideline proposal and clarity with regard to existing EU legislation in fields such as data protection and electronic identification.

1.1.1.4.Implied use case of implementing directive 2012/52/EU

At present, implementing directive 2012/52/EU "laying down measures to facilitate the recognition of medical prescriptions issued in another Member State" is based on the following implied use case according to Art. 2 "Scope":

A patient requests a prescription from a prescribing healthcare professional with the ex-ante intention to use this prescription abroad.

1.1.1.5.Electronic prescription and dispensation use case

The technical difference between an electronic prescribing system and the above use case resides in the necessity to communicate the dispensation of a prescription electronically back to the country in which the prescription was made.

1.1.1.6.Relation of implementing directive 2012/52/EU and proposed guidelines

The following table summarizes the relationship between the data elements required for a paper prescription which is issued for use in another Member State (Art. 2 of the directive) and the ePrescription dataset that was defined in the epSOS large scale pilot.

Figure 10: Relation of implementing directive 2012/52/EU and proposed guidelines

Item	Implementing directive	epSOS ePrescription dataset equivalents	Comment/Explanation
Identification of the patient	Surname First Name Date of Birth	Surname First Name Date of Birth	Items are minimum data required in epSOS
Authentication of the prescription	Issue date	Date of issue	Item is a minimum data required in epSOS
Identification of the prescribing health professional	Surname(s) First name(s) (written out in full, i.e. no initials) Professional qualification Details for direct contact (email and telephone or fax, the latter both with international prefix) Work address (including the name of the relevant Member State) Signature (written or digital, depending on the medium chosen for issuing the prescription)	Given name Family name Professional ID Profession	Listed epSOS items are minimum items; further maximum items include the full range of contact details and organization address and identifier While epSOS recognized the usefulness of sharing contact details of the prescribing professional, implementation showed that not all participating Member States were able to share this information yet. The signature equivalent to the paper prescription is the digital signature.
Identification of the prescription	Common name Brand name (in specific circumstances) Pharmaceutical formulation Quantity Strength Dosage regimen	Common name in epSOS (INN) is allowed as a substitute for the ATC code	Common name in the implementing directive refers to the INN nomenclature of the WHO

1.1.1.7.The National Contact Point: comparison of concepts between directive 2011/24/EU and the epSOS LSP

Article 6 of the patients' rights directive requires Member States to set-up (one or several) national contact points and to communicate their contact details to the Commission. It follows from this that the National Contact Point by virtue of directive 2011/24/EU is a physical/organisational entity that provides information to patients on:

"their rights and entitlements in that Member State relating to receiving cross-border healthcare, in particular as regards the terms and conditions for reimbursement of costs in accordance with Article 7(6) and procedures for accessing and determining those entitlements and for appeal and redress if patients consider that their rights have not been respected, in accordance with Article 9." (Art. 5b of Directive 2011/24/EU).

Further to this provision, the directive requests a number of additional information items to be made available through the NCP. These are:

"contact details of national contact points in other Member States" (Art. 6.2)

"healthcare providers, including, on request, information on a specific provider's right to provide services or any restrictions on its practice, information referred to in Article 4(2)(a), as well as information on patients' rights, complaints procedures and mechanisms for seeking remedies, according to the legislation of that Member State, as well as the legal and administrative options available to settle disputes, including in the event of harm arising from cross-border healthcare" (Art. 6.3)

The National eHealth Contact Point (NCP) conceived and developed in epSOS has a a number of roles that may overlap partly with the NCP role defined in directive 2011/24/EU.

The epSOS National Contact Point (epSOS NCP)[50] is an organisation delegated by each participating country to act as a bi-directional technical, organisational and legal interface between different national functions and infrastructures. The NCP is legally competent to contract with other organisations on its territory in order to provide the necessary services which are needed to fulfil the epSOS business use cases and support services and processes. The epSOS NCP is identifiable in both the European epSOS domain and in its national domain, acts as a communication gateway, and establishes a Circle of Trust amongst national Trusted Domains. The epSOS NCP also acts as a mediator as far as the legal and regulatory aspects are concerned. As such, an NCP is an active part of the epSOS environment and business use case, if and only if it is compliant to normative epSOS interfaces in terms of structure, behaviour and security policies.

Three major roles of the epSOS type NCP are highlighted in the above:

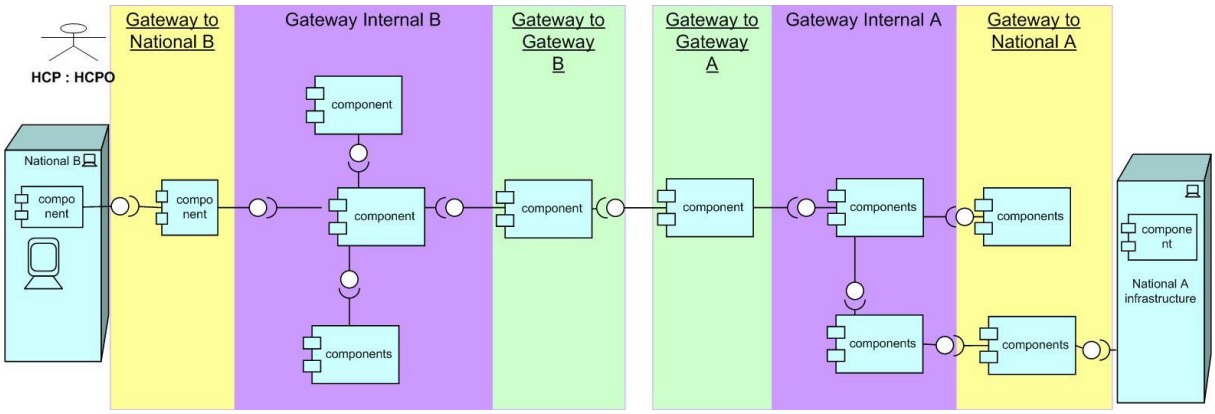
1) A legal role
2) A communication role
3) A trust role

In its first role, the epSOS NCP ensures that only authorized healthcare professionals access and use cross-border electronic healthcare services of patient summary and ePrescription. This partly overlaps with the provisions of Art. 6.3 above. The NCP also acts as a mediator in situations described in article 6.3. However, it does not provide written information on specific patients' rights regarding complaints procedures etc. Member States may decide to host the electronic NCP instance at the same organizational entity as the NCP of Directive 2011/24/EU.

In its communication role, the epSOS NCP has a bi-directional perspective. On the one hand, it sits on top of the national eHealth infrastructure, from which it can retrieve relevant information. On the other hand, it is facing NCPs located outside of his country and can receive requests from other NCPs. A high level summary of the communication tasks of an epSOS type NCP would be to ensure that country A and B can communicate information from gateway to gateway in a standardized environment and then process the received information for use in the national infrastructure. This is illustrated by the respective "Gateway Internal A/B" domains below.

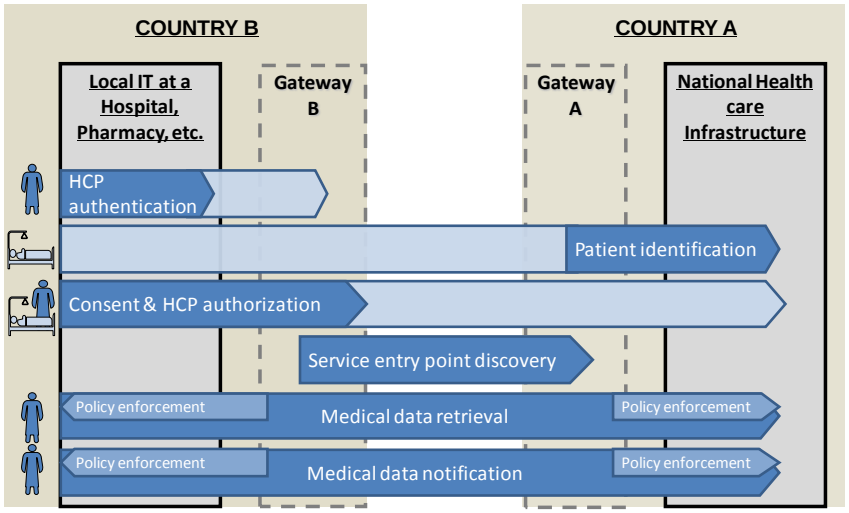
Figure 11: The two faces (gateways) of a national contact point

[50] As defined in Deliverable D2.1.2 "Legal and Regulatory Constraints on epSOS Design- Participating Member States" available at www.epsos.eu



In terms of key processes, the epSOS NCP ensures that healthcare provider (HCP) authentication, authorization and other key processes such as patient consent can be carried out through the national gateways:

Figure 12: Cross-border processes mediated through a national contact point



1.1.1.8.Electronic identification and authentication through an NCP

National Contact Points (NCPs) are implemented federally in order to allow for a virtual integration of autonomous sources of medical data and identity information.[51] The independence of the information sources is preserved as all access to an information source is mediated through the epSOS services which are implemented at NCP level. This complies to a Business-to-Business paradigm where end users and data sources are decoupled by enterprise level entry services that map external requests onto internal operations and vice versa. Part of this mediation is the brokerage of trust that is achieved by matching security objects of the NCP-to-NCP trust domain into a local trust domain and vice versa.

The administration of the identities of patients and health care professionals (HCPs) is decentralized. Authentication of a HCP can only be done within the country of care that recognizes this HCP. The existence of a treatment relationship between a patient and a HCP can only be attested within the legal framework of the point of care (PoC). With epSOS HCP authentication and treatment relationship attestment are therefore performed within the country of care (e. g. by using an existing Identity Provider service of the national infrastructure). A brokerage of the HCP authentication and treatment relationship confirmation into the epSOS domain is performed in a

[51] This paragraph is based on epSOS Deliverable D3.4.2 „epSOS Common Components Specification"

way that the NCP at country B confirms the respective claims and maps them onto a unified syntax and semantics that can be processed by the NCP of country A.

The epSOS "Circle of Trust" consists of pairs of mutually trusted consuming and providing gateways. A consuming gateway provides the computing environment for the operation of an epSOS service consumer and acts as the exit point from the national domain into the epSOS domain. A providing gateway operates the Web Service Endpoint (WSE) of the service provider and acts as the entry point from the epSOS domain into the national domain. Each gateway is operated under the legal responsibility of an NCP.

A basic assumption of epSOS is that mutual trust exists between NCPs. The authenticity and integrity of the services in the gateway-mediated NCP-2-NCP communication is secured with digital certificates. Examinations of the certificates and their exchange (with a limited number of NCPs) are to be synchronized among the epSOS service providers.

1.1.1.9.Electronic identification and authentication: role of digital signatures

The feasibility analysis identified the missing interoperability of digital signatures as an issue that explains heterogeneity in the national ePrescription solutions (see section 6.4 above). "During the epSOS process security critical deviations have been realized between the different (national) approaches. Despite the enormous standardization effort, that has been made, and resulted for example in the exclusion of Elliptic Curve algorithms without community agreement or the exclusion of the potential unsecure SHA-1 algorithm, some issues have been left open. One of the most important refers to the status quo of the Certificate Authorities. According to Appendix 7 of D3.10.1 ("epSOS-Security-Deviations-Factsheet") page 6 the Certificate Authorities of the participating nations "are not proven to be fully interoperable or even in the position to provide operational verification chains". Other issues that need to be addressed have regard to differences in the implementation and application of Trust Service Lists.

For the sake of "harmonized conditions for the processing of personal data concerning health", explicitly referred to by recital 122 of the Proposal for a General Data Protection Regulation, these issues should be top prioritized in the near future, to have the foundations laid for a secure transfer of personal electronic health data. Harmonization of security standards - especially with regard to digital signatures - is deemed a necessary requirement for the interoperability of electronic prescriptions and therefore the ability to provide continuity of care.

1.1.1.10. Importance of the (proposed) data protection directive

According to the current proposal for a General Data Protection Regulation, health data shall be understood in a very broad manner and include for example any information on diseases, medical histories or clinical treatments (Recital 26 of the Proposal for a General Data Protection Regulation).

An important amendment, that will require additional supervision in the near future, is the transfer of power to the European Commission to enact implementing acts on the harmonization of data security measures within the European Union. This will be an example for legal means to overcome the problem of security deviations. According to Art 30 of the Proposal for a General Data Protection Regulation, the European Commission may adopt the necessary implementing acts to prevent any unauthorized access to personal data. The requirements for using health data will be stricter than the requirements for using "usual" personal data, so that implementing acts with regard to personal health data, as for example electronic prescriptions, are very likely to be enacted soon after the entry into force of the General Data Protection Regulation. To have this accomplished in the best possible way, all the experiences, that have been made, and the standards, that have been proposed till now, should be collected and structured.

7.5 Validated final guideline proposal

This section presents the guidelines on ePrescription as

- ✓ discussed by experts in the validation workshop, held on July 2nd 2013 in Brussels,

- ✓ afterwards adapted in line with the suggestions obtained,
- ✓ reviewed by Commission staff,
- ✓ submitted for a final check and extensions to selected (national) experts,
- ✓ and finalised by the contractor.

DIRECTIVE 2011/24/EU of 9 March 2011 on the application of patients' rights in cross-border healthcare, Article 11, 2., states that "the Commission shall adopt" (b) "guidelines supporting the Member States in developing the interoperability of ePrescriptions." This

ePrescription draft GUIDELINE Proposal
of 24 November 2013

is submitted for discussion and final adoption by the eHealth Network.

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 114 (Internal market) and 168 (Public health) thereof,

Having regard to Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, and in particular Article 11 (Recognition of prescriptions issued in another Member State) (2) b thereof stipulating that the Commission shall adopt guidelines supporting the Member States in developing the interoperability of ePrescriptions,

WHEREAS:

(1) According to Article 168 (1) of the Treaty on the Functioning of the European Union (TFEU), a high level of human health protection is to be ensured in the definition and implementation of all Union policies and activities.

(2) Based on Article 100a of the Treaty establishing the European Community the Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data has been adopted.

(3) Based on Articles 47 (2), 55 and 95 of the Treaty establishing the European Community the Directive 1999/93/EC of the European Parliament and of the Council of 13 December 1999 on a Community framework for electronic signatures has been adopted.

(4) Based on Article 95 of the Treaty establishing the European Community the Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use has been adopted.

(5) Based on the Articles 114 and 168 TFEU the Union adopted the Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare.

(6) Art 11 (2) (b) of the Directive 2011/24/EU instructs the European Commission to adopt guidelines supporting the Member States in developing the interoperability of ePrescriptions.

(7) These guidelines should take into account the non-exhaustive list of elements to be included in (paper) prescriptions according to the Implementing Directive 2012/52/EU laying down measures to facilitate the recognition of medical prescriptions issued in

another Member State. This implementing directive has been based upon Article 11 (2) (a) of the Directive 2011/24/EU.

(8) These guidelines are addressed to the Member States of the European Union and apply to the implementation of voluntary interoperable electronic prescription services across Member States, but have also relevance for the European Economic Area.

(9) Art 14 (2) b of Directive 2011/24/EU assigns objectives to the eHealth Network to draw up guidelines on patient data that can be shared between health professionals to enable continuity of care and patient safety across borders.

(10) Member States have been playing an active role in the development of these guidelines, in particular by providing their knowledge and experience. In 2012 a survey was conducted, based upon a questionnaire of the 90 most relevant technical, legal and organisational questions regarding cross-border medication services within the European Union. The results of this survey revealed good practices and common approaches among the Member States, which determined the framework for these guidelines.

(11) Preliminary work in the field of eHealth, in particular by the European large scale pilot "European Patients' Smart Open Services" (epSOS), the eHealth Governance Initiative (eHGI) and the STORK (Secure idenTity acrOss boRders linKed) project, provide a solid and reliable foundation for these guidelines.

(12) In June 2012 the European Commission published a proposal for a legal framework designed to enhance trust in electronic transactions in the internal market. , making explicit reference to "cross-border healthcare" in recital (10)[52]. In order to maximize the benefits from electronic identification and trust services, Member States may agree to apply the developments in this field at the earliest possible stage.

(13) The diversity of national and regional healthcare systems, their structures, cultures and roles of health professionals are taken into account by the "circle of trust" concept, which provides the basis for interoperability via National Contact Points. These entities are designated by the Member States and serve on the one hand as interfaces between the national and European requirements for exchanging ePrescriptions and on the other hand as guarantors regarding origin and content of ePrescriptions. National Contact Points do already exist in the field of eHealth, as for example the epSOS National Contact Points or the National Contact Points according to Art. 6 of the Directive 2011/24/EU. Member States are free to assign these tasks to entities capable of confirming the professional qualification of health professional as well as the authenticity of ePrescriptions. Either existing National Contact Points (according to Art. 6 of the Directive 2011/24/EU, or established by epSOS) or National Contact Points that shall be implemented in future can be entrusted with these tasks.

(14) Member States have developed open source components for national contact point installations and, through their eHealth Network on Nov. 19, 2013, adopted guidelines for a minimum data set for patient summary . Similarly, a minimum data set for ePrescription services was defined in the scope of the epSOS large-scale pilot. Its deliverable 3.7.2 on the Final Security Services Specification Definition – Congruity-Suitability-Analysis has been drawn up, taking reference to the importance of a European public key infrastructure, while stressing that its implementation needs to be done in an extremely careful way.

[52] COM(2012) 238 final.

(15) The National Contact Points as developed in the context of the epSOS large scale pilot will provide transformation services by semantically transforming duplicates of the original ePrescriptions created according to national rules and by electronically signed confirmation by the National Contact Points that both documents are of identical content.

(16) At present the Anatomical Therapeutic Chemical (ATC) classification system of active substances in drugs, developed by the World Health Organization, appears to be the best available answer to semantic questions of identification of medicines with regard to ePrescriptions. The epSOS Deliverable on the epSOS Master Value Set Catalogue describes the possibility to transfer the full information on a medication from country to country, regardless of the brand name of the medication, which is one of the most important prerequisites to interoperability of ePrescriptions. For these reasons application of the Anatomical Therapeutic Chemical classification system shall be deemed as minimum requirement for a Member State to participate in cross border exchange of ePrescriptions. Nonetheless the usage of ATC must not pose obstacles to future improvements of identification of medicinal products.

(17) Wherever possible, in addition the International Non-proprietary Names (INN) nomenclature of official non-proprietary or generic names given to a pharmaceutical substance, as designated by the World Health Organization (WHO), shall be used.

(18) Member States are encouraged to study further technical options to identify medicinal products, in particular the role that data on pharmacovigilance can play. A first step can be the usage of the ISO Identification of Medicinal Products (IDMP) Standards as referred to in the Commission Implementing Regulation (EU) No 520/2012 of 19 June 2012 on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 and Directive 2001/83/EC.

(19) The European Medicines Agency aims at building a European database of medicines, which, once fully operational, should be used for semantic purposes of these guidelines.

(20) The provisions of Directive 95/46/EC on the protection of personal data and free movement of such data are the legal basis for using personal health data. According to Article 8 of the Directive the most important legal foundations for using personal electronic medication data will be the explicit consent or demand of patients (Article 8 (2) (a)), vital interests, i.e. medical emergencies (Article 8 (2) (c)) or the necessity for healthcare purposes (Article 8 (3)).

(21) Most of the Member States allow ePrescriptions to accommodate multiple dispensations for multiple drugs. As this approach appears to be practical as well as common among most of the Member States it shall be incorporated into these guidelines.

(22) As electronic medication services take place in the field of public health and in accordance with Article 11 of the Directive 2011/24/EU, the goal must be to use open standards wherever possible.

(23) With the end of the epSOS large-scale pilot, the present contractual basis for cross-border exchange of electronic prescriptions ends. A transfer of the epSOS model of data exchange requires – among other things – efforts on the level of Member States to conclude multilateral agreements.

(24) These guidelines also take into account the non-exhaustive list of elements to be included in the prescriptions according to the Implementing Directive 2012/52/EU

laying down measures to facilitate the recognition of medical prescriptions issued in another Member State. This implementing directive has been based upon Article 11 (2) (a) of the Directive 2011/24/EU. Although the necessary data may differ with regard to digital and non-digital requirements, the non-exhaustive list of elements of the Implementing Directive 2012/52/EU allows for a common understanding of prescriptions regardless of the media user for their communication.

(25) The respective national law governs liability. The choice of law is determined by the existing international private law rules, e.g. the Regulation (EC) No 593/2008 on the law applicable to contractual obligations (Rome I), OJ L 177, 4.7.2008, p. 6 or Regulation (EC) No 864/2007 on the law applicable to non-contractual obligations (Rome II). Further guidance can be found at the Commission Staff Working Document on the applicability of the existing EU legal framework to telemedicine services, SWD (2012) 414 final.

HAS ADOPTED THESE GUIDELINES:

CHAPTER I

GENERAL PROVISIONS

Article 1

Object and scope

1. These guidelines are addressed to the Member States of the European Union and apply to the implementation of interoperable electronic prescription services across Member States, in order to facilitate the recognition and delivery of prescriptions issued in another Member State.

2. Member States shall use all their best endeavours to enable interoperability of electronic prescription services.

3. According to the primary responsibility of the Member States in the field of healthcare provision, as laid down in Art 168 (7) of the Treaty on the Functioning of the European Union, the following guidelines are non-binding rules. Nonetheless compliance to them is an important step towards interoperability of electronic prescription services within the European Union, which serves the purposes of the internal market according to Art 114 of the Treaty on the Functioning of the European Union.

4. These guidelines aim at supporting the Member States to achieve a minimum level of interoperability, taking considerations of patient safety and data protection into account, by defining minimum requirements for communication between National Contact Points and for interfaces between national and European levels.

5. In particular, while the non-exhaustive list of elements to be included in medical prescriptions has been fixed in Commission implementing directive 2012/52, there is a need to define the specific electronic requirements applicable to the seamless identification of the patient, of the prescribing health professional and of the health product.

Article 2

Definitions

For the purpose of these guidelines, the definitions of the directives cited within the recitals of these guidelines and the following definitions shall apply:

(a) ‘Electronic medication data’ means any electronically used personal data regarding medication of a patient, including but not limited to ePrescriptions and the electronic information about the dispensation of medication;

(b) ‘ePrescription’ means a medicinal prescription, as defined by Article 1(19) of Directive 2001/83/EC, issued and transmitted electronically, as elaborated in point 3 (f) of the Commission Recommendation 2008/594/EC on cross-border interoperability of electronic health records[53],;

(c) ‘National Contact Point’ means any entity designated by a Member State to provide an interface between the national and European aspects of exchanging ePrescriptions.

Article 3

Fundamental concepts

1. The following concepts shall be considered fundamental and provide guidance, in case questions of interpretation arise.

2. Member States are considered to

(a) have the right to freely choose their way of implementing electronic medication systems;

(b) use open standards for public health affairs;

(c) freely decide, whether they want to adapt their legislation or not;

(d) bear in mind these guidelines, when adapting their legislation; and

(e) accept prescriptions that conform to Article 9 of these guidelines.

3. The National Contact Points shall build a web of trust, thereby acting as interfaces between the national and European aspects of communicating ePrescriptions.

CHAPTER II

TECHNICAL BACKGROUND

Article 4

Minimum technical requirements for cross-border ePrescriptions

1. At European level the interfaces provided by National Contact Points shall meet the following minimum technical requirements:

(a) For encoding of text the international encoding standard Unicode UTF-8 (UCS Transformation Format—8-bit) or higher shall be used.

(b) Extensible Markup Language (XML) as an open and human as well as machine-readable standard for exchanging data shall be used, whenever possible, unless other approaches prove to be more efficient.

(c) HL7 (Health level 7) CDA (Clinical Document Architecture) Level 3 standards shall be used for structuring purposes.

(d) Medicinal products shall be described using the current Anatomical Therapeutic Chemical (ATC) classification system of active substances in drugs of the World Health Organization.

(e) Classification that cannot be provided using the ATC classification system shall be performed according to the standards defined for the identification of medicinal products in the Implementation Directive 2012/52 EU

[53] OJ L 190, 18.7.2008, p. 37.

(f) The dose form, route of administration and packaging of the medication shall be described using European Directorate for the Quality of Medicines and Healthcare (EDQM) conventions.

3. Member States are encouraged to study further technical options to identify medicinal products, in particular the role that data on pharmacovigilance can play.

Article 5

Minimum technical requirements with regard to data security

1. Member States shall assure that communication of personal health data is encrypted in line with the recommendations on precautions and appropriate algorithms as laid down in the Annex.

2. Member States shall assure that integrity of communicated personal health data is guaranteed by measures identified in Commission Decision 2009/767/EC setting out measures facilitating the use of procedures by electronic means through the 'points of single contact' under Directive 2006/123/EC of the European Parliament and of the Council on services in the internal market.

Article 6

Storage periods

1. ePrescriptions and personal data concerning dispensation of these ePrescriptions shall be kept for a minimum period of 24 months.

2. Data according to paragraph 1 shall not be kept for more than 10 years, unless

(a) demanded by patients, or

(b) required by law, e.g. as part of a patient electronic record, in particular for the establishment, exercise or defence of legal claims.

CHAPTER III

ORGANISATIONAL BACKGROUND

Article 7

Background information

1. Member States shall ensure that for reasons of authentication information is available at national, regional or any other level:

(a) on the health professionals, who are entitled to prescribe as well as

(b) on the health professionals, that are entitled to dispense.

2. The information according to para. 1 is to be timely shared via the National Contact Points, which are responsible for the proof of authenticity of origin and content of ePrescriptions. At European level National Contact Points are responsible to their counterparts for the correctness of the information provided by them. To this end National Contact Points shall provide complaint management and audit trails.

3. In agreement with the guidelines on a non-exhaustive list of patient data adopted by the eHealth Network, the registers on the health professionals who are entitled to prescribe and dispense, shall at least encompass:

(a) the name and profession,

(b) a personal identification number, including the ISO 3166 country code,

(c) the current address of the healthcare provider organisation with which the health professionals is affiliated to several HCP or the address of his private practice, and

(d) the date of issuance of the healthcare professional's licence to practice.

4. Member States are encouraged to implement these guidelines and the guidelines on minimum data for patients summaries adopted by the eHealth Network in November 2013 together.

Article 8

Organisation of dispensation

1. Prescription drugs may not be dispensed without identification of the recipient, e.g. by inspection of its European Health Insurance Card together with a photo ID or other appropriate means.

2. Member States of treatment shall be responsible for communicating back dispensation. To this end an XML message with at least the following data shall be send to the national contact point of the respective recipient:

(a) name of dispenser,

(b) ISO 3166 country code of the dispenser,

(c) address of the dispenser,

(d) a personal identification number of maximum 40 characters, including the ISO 3166 country code,

(e) medication that has been dispensed.

Article 9

Minimum requirements for ePrescriptions with regard to their content

1. Member States of affiliation are responsible, that ePrescriptions may only be issued by persons registered according to Article 7 (1) (a).

2. In addition to other usual reasons, ePrescriptions, which contain data according to paragraph 3, that are not ready for semantic interpretation by machines, may be rejected on grounds of patient safety.

3. ePrescriptions shall include at least:

(a) the elements laid down in the Annex of the Implementing Directive 2012/52/EU,

(b) a personal identifier of the patient or the hospital, that shall receive the prescribed medication,

(c) a personal identifier of the prescribing health professional.

4. The signature or electronic signature of the prescriber may be replaced by the electronic signature of the authorised national contact point of the Member State of affiliation.

CHAPTER IV

LEGAL BACKGROUND

Article 10

Data protection

1. Electronic medication data shall only be used in accordance with Directive 95/46/EC on the protection of personal data or its equivalent successor directive.

Article 11

Substitution

Substitution by dispensers is allowed, provided that the therapeutic effect intended by the prescriber can be achieved the same way as with the original prescription, unless the prescriber explicitly indicated the substitution is not allowed.

Article 12

Liability

1. Health professionals involved in electronic prescription services shall be responsible for their acts and omissions, according to the national law they are subject to. In particular they shall be responsible for not having performed drug interaction checks which are possible, e.g. when dispensing multiple drugs on a single prescription or having access to a patient medication record, unless such checks were permanently or temporally impossible for technical reasons outside their sphere of responsibility.

2. Health professionals, patients and other National Contact Points may rely upon the information released by National Contact Points.

3. In case of semantic transformation, both the transformed and the original document shall for reasons of liability be available to all persons, who are legitimated to use that data.

Chapter V

General requirements

Article 13

Evaluation and quality assurance

In order to assure safe implementation, particularly patient safety and data protection, and further development of cross-Union eHealth services, in particular ePrescription, Member States should:

(a) consider setting up a facility for cross-border eHealth and ePrescription services to quality assure, benchmark and assess progress on legal, organisational, technical and semantic interoperability for their successful implementation; this entity being separate from any national contact point

(b) undertake assessment activities, like measuring the quantitative and qualitative eventual benefits and risks (including economic benefits and cost-effectiveness) of eHealth and ePrescription services.

Article 14

Education and awareness raising

In terms of education, training and awareness raising, Member States should:

(a) undertake common activities towards increasing awareness of the benefits of and need for interoperability and related standards and specifications for eHealth and ePrescription services, and for electronic patient data exchange in general, including awareness of the need to foster the interoperability of technical systems among producers and vendors of information and communication technologies, healthcare providers, public health institutions, insurers and other stakeholders;

(b) consider recommendations for education and awareness raising measures with regard to health policymakers and health professionals;

(c) pay particular attention to education, training and dissemination of good practices in electronically recording, storing and processing prescription and medication data and other patient information as well as in collecting informed consent of the patient and lawfully sharing patient's personal data;

(d) initiate appropriate, easy to understand information and awareness raising measures for all individuals, in particular patients.

The Guidelines are addressed to Member States.

Done at Brussels,

For the Commission

Member of the Commission

Annex

Cryptographic algorithms wear out over time and are frequently reviewed, maintained, and adapted in order to provide an adequate, state-of-the-art degree of security, primarily depending on the specific resource protection requirements. In this context, the following documents may be considered:

- Advanced Encryption Standard as published by the National Institute of Standards and Technology (NIST) in the Federal Information Processing Standards Publications (FIPS PUBS) 197/2001
- European Network of Excellence in Cryptology II, ECRYPT II Yearly Report on Algorithms and Keysizes, ECRYPT-II D.SPA.20 defines typical minimal requirements on the selection of suitable cryptographic algorithms and orientates the selection on the desired degree of security
- Recommendation for Key Management, Special Publication 800-57 Part 1 Rev. 3, National Institute of Standards and Technology (NIST), 07/2012.
- Other suitable catalogues are maintained by Union Member States' national competent authorities, such as:
    - Agence nationale de la sécurité des systèmes d'information (ANSSI): Mécanismes cryptographiques Règles et recommandations concernant le choix et le dimensionnement des mécanismes cryptographiques CryptMech
    - (German) Federal Office for Information Security (BSI), Technical Guideline (TR) TR-3116: Technische Richtlinie für die eCard-Projekte der Bundesregierung, 2012 (Technical regulation for eCard undertakings of the Federal Government)

8 ROADMAPPING AT THE EUROPEAN AND MEMBER STATE LEVEL - A ROADMAP PROPOSAL

8.1 Introduction and objectives

This chapter provides a succinct outline of necessary next steps for ePrescription activities at EU and national level. This exercise is motivated by the long term vision of a single European market for medication, facilitated through interoperable electronic prescriptions that can be dispensed in all Member States. The roadmap to follow is guided by the use case as sketched in the cross-border healthcare directive: "If a medicinal product is authorised to be marketed on their territory,... Member States shall ensure prescriptions issued for such a product in another Member State for a named patient can be dispensed on their territory in compliance with their national legislation."[54] In other words, if a patient requests a prescription issued in its country of affiliation "A" to be dispensable in any other Member State "B", then a European-wide technical eHealth data access and exchange system allowing for the transfer of such prescriptions in electronic format should facilitate the realisation of this vision. In this way, every patient can receive on demand from every prescriber a prescription for dispensation by any authorized dispenser outside of its country of affiliation across the Union. This by default implies that Member States have to agree on (most of) the suggestions submitted in the guidelines, or they must be replaced by those which can achieve substantially the same results. Thos roadmapping exercise follows this line of reasoning. The starting point for any roadmap must be firmly anchored in the available experience and evidence from activities that share features of the vision to be achieved. This experience is provided by those Member States which have already implemented national (or sometimes regional) ePrescription systems, which also contributed towards and is reflected in the epSOS large scale pilot project, where one of the healthcare services implemented is ePrescription exchange across borders. All the experts consulted during this study or present at the two workshops in Brussels have been involved in such activities and contributed their knowledge, know-how, and professional experience. This also assures that the experience and know-how of relevant national competent authorities is reflected in what follows.

In the roadmap below, proposed (support) actions at the European level are grouped into mandatory, very important and "nice to have" ones (see section *European level actions* below). As the implementation of the cross-border healthcare directive is mostly a Member State responsibility as mandated for healthcare in the European Treaty (TFEU), these steps may be initiated, driven forward and financially supported by the EC, but in the end it will have to be the Member States to render the envisaged ePrescription exchange system operable. - The assessment of which path of action should be taken in the short, medium and long-term reflect the output of expert interviews conducted during the guideline validation workshop.

These suggestions are then followed by a detailed set of roadmap steps to be taken at the national level to indeed realise the vision.

8.1.1 The roadmapping approach

This section provides an overview of different types of generic roadmaps, the process of roadmapping, expected benefits and features of quality roadmaps.

Robert Galvin[55] defines Roadmaps as follows: "A 'roadmap' is an extended look at the future of a chosen field of inquiry composed from the collective knowledge and imagination of the brightest drivers of change in that field. Roadmaps communicate visions, attract resources from business and government, stimulate investigations, and monitor progress." In other words, in our context a roadmap may provide a consensus view or vision of the future implementation and health services landscape ("destination") for decision makers, and an outline or "map" on how and by which means to achieve these destinations (policy goals, ...).

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[54] Art. 11 of the Directive.

[55] R. Galvin, "Science roadmaps," Science, vol. 280, p. 803, May 8, 1998

8.1.2 Benefits of roadmapping

Garcia and Bray[56] identify the benefits of roadmapping as follows:

- roadmaps help develop consensus among decision makers about a set of needs;
- roadmapping provides a mechanism to help experts anticipating innovative developments in targeted areas;
- roadmapping presents a framework to plan and coordinate respective developments: within an organisation/company, throughout an entire discipline, or even across-industry/national or international levels.

The main benefit of roadmapping is provision of information to help make better investment decisions. Kappel[57] argues further that the roadmapping process not only produces more informed individual decisions, but brings with it ***better alignment of organisational decision making***.

Albright has also identified a set of benefits for the roadmapping process:[58]

- Roadmaps reveal gaps in product and technology plans.
- Roadmaps prioritise investments based on drivers.
- Roadmapping helps set better targets: more competitive and more realistic.
- In an industrial setting, roadmapping communicates business, technology and product plans to team members, management, customers and suppliers.

8.1.3 The roadmapping process

The roadmapping process includes the following tasks:

- Creating a vision
- Identifying objectives and challenges
- Analysing trends, challenges and opportunities
- Developing policies, strategies and implementation measures
- Pinpointing key resources necessary
- Outlining a timeline and milestones.

In order to develop a Roadmap, first a shared vision needs to be created, the goals, and the economic, legal, financial and technological challenges will be elaborated. It also needs to focus on the limitations of the policies and strategies currently used in the respective field. After assessing the gaps between the "as-is" situation and the "to-be" vision, the necessary actions and steps to achieve the vision, the required advances should be identified.

At a more generic level, the following elements have to be addressed:

- final "destination" (long term vision)
- start of the "road" (status quo in relation to the vision)
- what to be aware of during the "trip" (e.g. key challenges, bottlenecks, barriers and opportunities)
- possible/prioritised "whistle stops" (e.g. short term/medium term vision for further development/milestones)

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[56] M. L. Garcia and O. H. Bray, "Fundamentals of technology roadmapping," Sandia Nat. Labs., Albuquerque, NM, SAND97-0665, March 1998

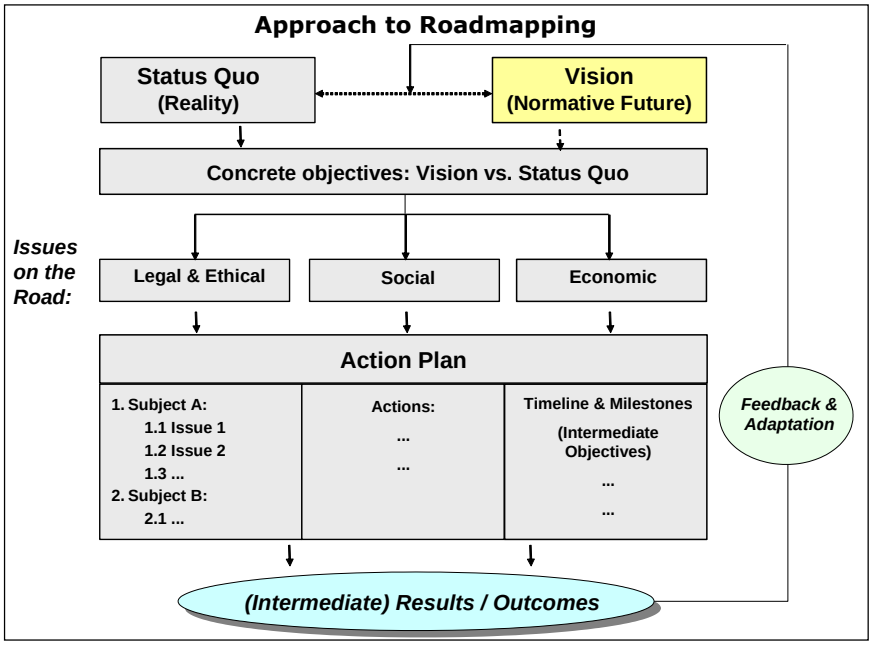
[57] T. A. Kappel, "Technology roadmapping: An evaluation," Ph.D. dissertation, Northwestern Univ., Evanston, IL, 1998

[58] Albright, Richard, et al. "Technology roadmapping in industry: a series of special reports." Research-Technology Management 46.2 (2003): 27-59.

- "fellow travellers", "transportation means" and "routes" (e.g. key elements and actors of a process that will lead to the realisation of the specified vision)
- approaches to reach the overall and the specific goals.

In this sense, a roadmap will focus on identifying requirements for further research and technology development, production and business planning, but it will also sketch a realistic picture with respect to desirable applications/ICT implementations and indicate which technologies may have the potential to make a substantial contribution in this context. To ensure that the roadmap ultimately to be generated will actually yield positive results and desired impacts it will be based upon and, wherever possible, justified by empirical evidence from the research domain and a bottom-up assessment involving relevant stakeholders.

Figure 13: A generic approach to roadmapping



8.2 A European roadmap for ePrescription implementation for cross-border healthcare provision

8.2.1 Introduction

Given the status of ePrescription exchange within and across Member States as described and analysed in earlier deliverables, and the overall situation we are faced with – like the impossibility to meaningfully cluster Member States according to their implementation status -, the following draft roadmap outlines only a generic roadmap for overall implementation in a given Member State. It identifies steps required to achieve cross-border exchange of ePrescriptions and delivery of medicinal products in any other country. It is oriented along the lines of identifying minimal requirements necessary to achieve a simple transfer of ePrescriptions, like a reliable legal base or basic semantic interoperability, not to mention technical requirements of data transfer, organisational necessities, electronic signature requirements or, in the end, also reporting of filled or only partially filled prescriptions back to the home health system and its healthcare provider(s).

8.2.2 Status quo versus normative future

1.1.1.11. Status quo – open issues and challenges

Open issues identified by epSOS

The epSOS project has provided a proof of concept and a piloting implementation for the exchange of semantically interoperable ePrescriptions and patient summary information. The project will

formally end in December 2013. An extension to allow further Member States to pilot is envisaged, but not yet formalized. It would push the end of epSOS to June 2014.

The open issues identified there are documented in Deliverable D4.2 of this study. They can be briefly summarized in the following bullet points:

- Brokered trust approach through national contact points presently substitutes for end2end security of connections between piloting Member States.
- ePrescription and eDispensation datasets cannot always be fully mapped to existing national level documents.
- There are problems of representing certain types of medicines with existing classifications such as ATC.

Further heterogeneity challenges across countries

The earlier study work undertaken (and reported upon in deliverable D3.2 Final Feasibility Analysis) showed that no meaningful grouping or "clustering" of Member States was possible to allow for an easier roadmapping process.

However, the analysis provided pointers to those aspects of the current European-wide ePrescription situation that cause the greatest heterogeneity among Member States. These are:

- The unequal validity periods of prescriptions
- The uneven use of digital signatures
- Differences in the degree to which ePrescriptions are "coded", particularly how representation of active ingredients and/or brand names is ensured.

All of these open issues and challenges became input to the expert workshop for discussion and solution to the extent possible at this stage.

1.1.1.12. Results from the feasibility analysis workshop

All of this became input to an additional comprehensive gathering of information and expert assessments, and further analysis and review. Based *inter alia* on the detailed survey of national experts, a feasibility workshop was held in June 2013 to discuss remaining open issues, where the following key challenges were identified:

A: Conceptual and processes heterogeneity of ePrescriptions across countries

Countries in Europe have a different understanding of what the process of electronic prescribing consists of. Heterogeneity of definitions in use is an overriding problem (e.g. what does "outpatient" care mean in various Member States?).

It was noted that the agreed-upon focus on primary care prescribing will, in the medium term, need to be extended to consider additional modalities of, e.g., prescribing in a hospital upon discharge of the patient.

In terms of prescriber/dispenser roles in different countries, it was noted that in certain rural/remote areas (e.g. in Switzerland or Sweden), certain doctors may be allowed to play both roles simultaneously – be a prescriber as well as a dispenser of drugs.

Substitution is understood differently across countries: first necessary level of distinction needs to be therapeutic versus economic substitution; it was observed that what might be considered substitution in one country is merely considered a correction of a prescribing error in the other country.

B: Interoperability challenges of across border messages

With regard to the transmission of dispensation information back from country B to country A (country of affiliation of the patient), it was proposed to consider that such information should remain inside the country A National Contact Point (NCP), and not become transferred into the heart of a perhaps complex national patient data infostructure.

From the perspective of the professional practice of pharmacists, it seems desirable to have as much context information on the ePrescription form as possible, whenever the country A system can provide this, instead of receiving only a narrowly defined set of data as suggested presently in the European format of an ePrescription.

C: Semantic Interoperability and the coding of information in an ePrescription

As a general result of discussions, it was concluded that an ePrescription with only fully coded elements in a standard which would be accepted across Europe is highly unlikely; elements of free text will remain (particularly also with regard to medical devices).

Furthermore, it was agreed that the EDQM code system should provide the official EC concepts for, e.g. dose form and route of administration.

It was noted that ATC codes are not always sufficient to represent drugs with multiple active ingredients. A recent prospective study (mystery shopping exercise) on the cross-border recognition of prescriptions showed that the use of the International Non Proprietary Names (INN) should be encouraged to complement ATC codes, because this would increase the probability that a pharmacy in country B would indeed successfully identify the required medicine product.

Recording only national brand names), which often differ across countries (or are not even marketed in all EU Member States) is clearly not sufficient. The study mentioned noted an odds ratio of 3.4 for increase in the likelihood of a successful dispensation when ATC and/or INN were present.

ATC, INN and EDQM are code systems adopted by the European Medicines Agency and by the National Medicinal Product Approval bodies, for mutual recognition.

It was flagged that an EU-wide correspondence list of all existing brand names for medicinal products would be desirable. However, the future perspective for such a database is unclear at present.

Currently there does not seem to exist an international nomenclature to code prescriptions of medical devices such as crutches or similar. The GMDN nomenclature is an inventory of grouper codes (some 20,000 entries), each possibly referring to several and widely diverse products.

As a consequence of the substitution discussion, it was agreed that a system needs to be developed to flag in a reliable manner any particular rules on substitution so that the pharmacist can safely dispense.

8.2.3 Vision – a normative future

The vision for interoperable ePrescriptions can be derived from the cross border patients' rights directive.[59] The long-term goal, as implied in the provisions on mutual recognition of prescriptions, is the realization of a single market for pharmaceutical products, facilitated through a seamless electronic exchange of electronic prescriptions (and the relevant patient data) across the Union.

Guiding assumptions for next steps

The guiding assumptions, as developed in the course of this study and at the expert meetings, for the further development of interoperable ePrescriptions in Europe can be listed as follows:

- The *national* prerogative for healthcare organisation and legislation will remain intact (because a change in the European Treaty – TFEU - is highly unlikely here).
- Nevertheless, voluntary coordination of eHealth systems and services across Member States and learning from each other will progress.
- The technical exchange of electronic documents across borders will also in future follow a model of National Contact Points as proposed in epSOS (Given the complexity of this process, it will be rational and efficient to develop on proven experience, and not to re-invent the wheel).The content of electronic prescriptions must mirror the non-exhaustive list of particulars to be contained in a cross-border paper prescription as defined in the Implementing Directive laying down measures to facilitate the recognition of medical prescriptions issued in another Member State[60], plus additional data fields required in an electronic transmission context.
- Any future technical solution may not interfere with and/or replace existing national eHealth infrastructures – but certain (voluntary) adaptations of national infra- and infostructures may be recommended or even become required.
- Patients using cross-border services, i.e. healthcare services outside their country of affiliation, will be subject to the entitlements and laws that apply in the country of treatment.

8.2.4 Proposed next actions

From this brief summary of status quo, vision and guiding assumptions, a number of concrete objectives and next roadmapping steps for the further development of ePrescriptions in Europe can be derived, at the level of the Union as well as at the level of individual Member States.

1.1.1.13. Maintaining the European and Member State ePrescription legacy

Proceeding in an economically efficient and meaningful way, it seems prudent to build upon earlier achievements at European as well as Member State levels, in order to not lose public as well as private investment in and build upon the success factors and lessons learned from the epSOS experience. As the Union/EC can only play a facilitating and supportive role for the cooperation and exchange of information among Member States, it would suggest itself to see the "voluntary network connecting national authorities responsible for eHealth designated by the Member States", the *eHealth Network*, as the core player to work also in the ePrescription domain towards "delivering sustainable economic and social benefits from European eHealth systems and services

[59] DIRECTIVE 2011/24/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2011 on the application of patients' rights in cross-border healthcare. Official Journal of the European Union. EN - 4.4.2011, L 88, 45-64

[60] COMMISSION IMPLEMENTING DIRECTIVE 2012/52/EU of 20 December 2012 laying down measures to facilitate the recognition of medical prescriptions issued in another Member State

and interoperable applications".[61] Above, in Chapter 2 *ePrescription interoperability as a European health policy priority and steps forward*, its priorities, ongoing work and envisaged future structure and next projects were already discussed in some detail (see also Figures 1 and 2 there).

In line with this, it is suggested that the roadmap and future implementations of ePrescription exchange services by Member States follow these objectives:

- Both the eHealth Network and the EC should, in close cooperation, encourage currently piloting Member States – and also those who may join later - to continue adapting existing ePrescription systems, implement new ones (where up to now none exist), maintain these solutions, and devise, as needed, further agreements in pursuit of expanding and diffusing present pilot applications.
- Availing themselves of the resources to become available from the Connecting Europe Facility (CEF), Member States through the eHealth Network should endeavour to maintain and further develop existing European (epSOS-based) specifications, documentation, semantic, interoperability and software (development) assets for global open access, thereby also promoting European achievements and know-how in a growing international eHealth market.
- Maintain existing or design appropriately adapted structures and processes (EC and/or Member States sponsored) to keep the community of (national) competent authorities and experts involved in the next steps towards a pan-European eHealth infrastructure at all levels of interoperability, so as to not lose presently achieved results and experience. In line with present priorities and sustainability plans, a Standing Coordination Group for ePrescription may become established (see Figures 1 and 2 above).
- Regularly review and update ePrescription standards and (IHE) profiles; seek cooperation with both EMA and global Standards Development Organisations (SDOs).
- The eHealth Network should devise measures, e.g. within the foreseen structure of the European Interoperability Framework, to continue involving industry and other key stakeholder groups in these activities.

This will require further steps to be undertaken by the Member States, supported by the EC. Figure 14 below illustrates and summaries key areas of activity and suggestions where funding for further planning, designing and implementation of key components may come from. It emerges that Member States need to initiate cooperative, European level initiatives, where an important share of costs for those activities that have relevance across the EU and cannot be easily managed by a single Member State may become core targets for EC support and facilitation.

These include new service definition and design activities that have cross-border relevance, but also central support and standards development and use. Central services in the form of system registers or master data registries are another option to be funded centrally. However, this could also be organised in a more decentralized manner, like a virtual organisational set-up with rotating responsibilities. Conformance testing of deployed solutions, an activity offered by IHE, is something that industry (the market) can offer to Member States. The costs for internal maintenance and operation need to be borne by Member States themselves.

Figure 14: Maintaining and developing ePrescription cross-border service components and their source of financing

Areas of activity	Potential Funding Source	Note

[61] See Article 14 eHealth, 1. and 2., of DIRECTIVE 2011/24/EU, op. cit.

Run national level ePrescription services and operations; adapt national ePrescription systems, implement new ones (where up to now none exist), maintain and diffuse present pilot applications	Each Member State	Clear MS responsibility; majority of spend applies to internal work in each country
Analyse and establish requirements for further design and components of established ePrescription as well as of related (dispensation) services	EC, through CEF, supplementing MSs efforts	EC can make use of its coordinating and funding capacities to instigate new eHealth supported healthcare use cases and new projects
Maintain central ePrescribing eServices, e.g. system registers, master data registries (or develop virtual, decentralised/ distributed solution)	EC, MSs applying for CEF finding	Needed to support cross-border care; may be maintained centrally or in a decentralised, virtual organisational mode. Needs long-term solution
Regularly review and update standards and (IHE) profiles; cooperation with EMA as well as global Standards Development Organisations (SDOs)	MSs	A close cooperation of national (eHealth) standards institutions or Competent Authorities is required
Involving industry and other key stakeholder groups, e.g. in conformance testing	MSs, market players	Part of market response to Member States requirements

1.1.1.14. Taking steps at European level to deal with open issues and challenges

A feasibility workshop was held in June 2013 to review the remaining open issues, particularly at the European level, where options and solutions to the following key challenges, as identified above, were discussed:

- ✓ Conceptual and processes heterogeneity of ePrescriptions across countries
- ✓ Interoperability challenges of across border messages
- ✓ Semantic Interoperability and the coding of information in an ePrescription

The draft guidelines proposed below as well as the action plan take account of and provide for steps to deal with these obstacles.

The open issues were also described in chapter 6 of this report.

1.1.1.15. Keeping up the momentum at national level

The last phase of epSOS has seen new Member States and non-Member States joining the project consortium with the clear intention to pilot and implement epSOS services. These new entrants are Luxembourg, Croatia, and Switzerland as a non-EU Member.

It is crucial to maintain the momentum for this at national level. The epSOS experience has shown that even – or perhaps particularly - Member States within a relatively early phase of national eHealth maturity have benefitted considerably from the participation in such pan-European activities as a learning experience and testing ground for national efforts.

Recognising that EU activities will not be able to provide a continuity of funding for national piloting efforts, it is recommended to establish a reporting and monitoring mechanism on national level ePrescription efforts inside the *Art. 14 eHealth Network* or the eHealth Governance Initiative as appropriate. Such evaluations should address issues like acceptance by patients and medical

professionals, usefulness as well as usability, benefits and costs for stakeholders involved, lessons learned and to be shared. This would help to further streamline and improve trans-European ePrescription services.

8.2.5 Roadmap action steps

The following action plan identifies activities regarded as necessary or at least desirable at the European level, to be followed by a more detailed action plan for the national level. In reality, of course, we are talking about sometimes highly interrelated issues which to a considerable extend impact each other and create mutual dependencies.

1.1.1.16. European level actions

To allow for continuous cross-European ePrescribing services as already provided for by epSOS pilots, and in order to further facilitate, diffuse, simplify and speed them up, the following coordinating actions were identified at the European level, involving both Member States and the EC in a collaborative mode. It should be here, where in a most obvious fashion the EC could initiate, facilitate and financially support further preparatory studies, legal and technical developments, and support for a mandatory minimal infrastructure to maintain and further expand such assets and services. For each, a short statement on its urgency and desirability is given to further explore its relevance:

- Mandatory, most urgent actions:
  - Implementing digital signatures at the eGovernment or eHealth service level. Agreement at EU level should be reached by the end of 2014 [DRAFT Guidelines Art. 5],

    because this is a major barrier for more efficient service processes.
  - Achieving a common European level or bilateral legal agreements, among countries planning to maintain or establish newly ePrescription service provision. It may be based 0n the epSOS legal framework. Signing will be necessary at the latest as of 07/2014;
    otherwise the legal base for ePrescription services to be continued vanishes.
  - Agreeing on an EU wide minimum ePrescription and Dispensation dataset –aligned with implementing directive (2012/52/EC) by 2014 [DRAFT Guidelines Art. 8, 9]
  - Agreement on the future structures, processes and funding for a (virtual) European organisation to maintain, further develop and (internationally) coordinate technical and semantic interoperability assets, issues and challenges. Without properly maintained assets and interoperability services, a trans-European eHealth services network will not be feasible.
- Very important:
  - Defining a common process and rules regarding substitution of medication: agreement at EU level by the end of 2014 [DRAFT Guidelines Art. 11];
    this would allow for more prescriptions to be univocally filled in another country.
  - Agreement on an international standard to represent multiple active ingredients in medications. This should be achieved by the middle of 2015 [DRAFT Guidelines Art. 7, 9];
    again this would allow for more prescriptions to be univocally filled in another country.
  - An EU wide agreement on minimum storage duration for ePrescription and dispensation records [DRAFT Guidelines Art. 6];
    this would improve legal certainty and harmonise EU-wide procedures.
- Nice to have:
  - Agreement on the role of national value added services, particularly drug-interaction checks. This is expected to become realistic only by 2020 [DRAFT Guidelines Art. 12];
    this would improve patient safety.
  - Agreement on rules for reimbursement of ePrescriptions dispensed in country B. But this may have to become part of a wider agreement on cross-border reimbursement processes;
    it would avoid patients having to pay in cash for medications in country B.

It would appear that the eHealth Network in its coordinator role of connecting national authorities responsible for eHealth may take responsibility for these actions on ePrescription, in close coordination and support by the EC, so as to deliver sustainable economic and social benefits from European eHealth systems and services.

1.1.1.17. National level action steps

The following Figure 15 exemplifies a comprehensive Action Plan and Roadmap for a Member State or any other European country planning to join the European cross-border ePrescription service community. It is based on these assumptions and pre-conditions:

- There exists a (basic) eHealth services infrastructure in the respective country or region.
- There exists a policy-approved national (or regional) business use case, implementation strategy and, preferably, also already a successful operation of ePrescription services.
- This implies that basic technical components, legal rules and organisational preconditions are already in place and therefore are not mentioned in the roadmap.
- Member States, e.g. in the context of the eHealth Network, will continue to develop, expand upon and adapt the European ePrescription service model as deemed appropriate so as to not write off their experience, knowledge and investments.
- All relevant (epSOS and follow-up eHealth Network) documents, legal texts, technical notes etc. are freely available to other countries, which may also access involved experts, their knowledge and know-how to learn from earlier experience.
- The estimated start and end times are only rough approximations.

The steps identified and detailed in the table are based on the thorough knowledge of the project team and the experts consulted, a deep analysis of the epSOS experience, and earlier work on national eHealth strategy development and infrastructure implementations in Member States.

In a concrete situation, depending on the framework, constraints, maturity of the existing national eHealth infrastructure, technical and interoperability characteristics of the ePrescription application and other circumstances, implementation of the roadmap may allow to compress or even leave out certain steps and proceed faster, but may also proceed considerably slower (e.g. depending on national legislation becoming necessary). Particularly critical steps which may delay overall roadmap implementation are flagged. In other words, each MS will need its own entry point into a general, generic roadmap. Those starting from scratch will have the opportunity to already at the design stage of the system take into account, perhaps fully implement, all suggestions of the guidelines and roadmap, etc. More mature or fully functional systems (like in Sweden) will need to expand their system to be able to interface with the European ePrescription data model and message standards, either by adjusting their system or making use of appropriate interface and mapping modules.

Figure 15: Action plan steps and roadmap for a Member State intending to implement ePrescription cross-border services

ID	Implementation steps	Start time (month)	End time (month)	Remarks
	Policy domain implementation steps			

ID	Implementation steps	Start time (month)	End time (month)	Remarks
01	Establish health policy support and analyse the business use case for cross-border ePrescription service implementation.	1	3	Strong policy support as well as a proven use case are key preconditions for success
02	Identify and commission project development, management and control to organisational unit or Competent National Authority	3	Finalisation of roadmap	
03	Secure temporary budget for roadmap actions, and permanent budget line(s) as necessary for maintaining an NCP etc. in the appropriate national (and regional, as required) budget(s).	4	7	This step may considerably delay implementation in case securing a longer-term budget is complex
04	Implement a political oversight, control and evaluation structure and processes, including regular assessment of safety, quality and reliability of ePrescription services, and for assuring usability and acceptance of services by both patients and healthcare providers.	6	8	Should be integrated into overall eHealth infrastructure oversight.
05	Assure involvement of all relevant healthcare providers/their organisations including pharmacists, health system actors and other relevant stakeholders; establish relevant processes	4	ongoing	
06	Undertake a public relations and information campaigns to inform the general public, particularly also chronically ill patients.	7	ongoing	Regular PR activities and updates for people travelling or temporarily living abroad will be needed

	Governance and legal domain implementation steps			
07	Familiarise with and have legal experts analyse all legal aspects of cross-border transfer of patient (ePrescription) data at the national and European level. Specifically, analyse the ➢ Frame Work Agreement (FWA) of epSOS (or follow-up document) and the legal implications of maintaining a ➢ National Contact Point (NCP for ePrescription/ patient data access and exchange).	2	3	This may already be – or should become - part of overall national eHealth infrastructure governance.
08	In case changes in national regulations or laws are needed, initiate appropriate steps.	4	Depending on individual situation	Should legal changes need to be initiated at the national level, a time line for further implementation is impossible to predict, because these processes very much depend on the given circumstances.
09	As long as no centralised cross MSs Frame Work Agreement has been agreed upon, prepare and sign appropriate FWA with all participating MSs	4	10	Reaching such agreements may be a time-consuming bureaucratic activity
10	Set up the process and procedures to extend patient/citizen consent to export patient data abroad when requesting a healthcare service there.	5	8	This may already be – or should become - part of overall national eHealth infrastructure governance.
11	Appoint data controller in line with European data protection directive and rules	8	9	This may already be – or should become - part of overall national eHealth infrastructure governance.
	Organisational domain implementation steps			
12	Establish whether the national NCP should become a division of a national Competent Authority or similar institution, or an independent public or private organisation.	3	4	Integration into existing national [(e)Health] organisational structures may be most efficient.
13	Decide on and implement the structure and processes needed to run the NCP, including communication structures to reach all relevant stakeholder groups and health system organisations within the country.	4	6	

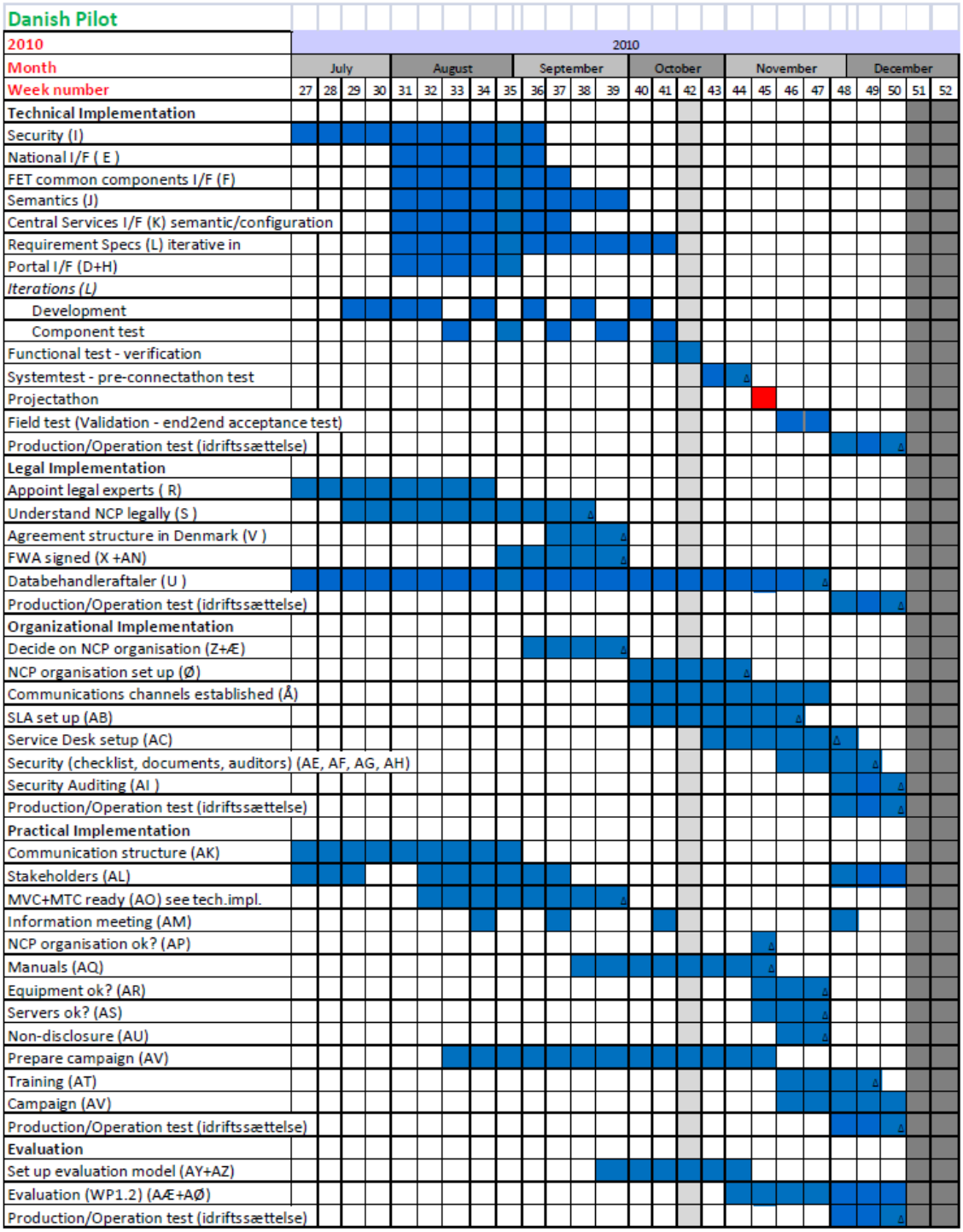
14	Select a data processor and sign an appropriate agreement with it, including a Service Level Agreement (SLA).	5	9	
15	Organise a help/service desk at the NCP, able to handle calls from national/regional healthcare professionals and organisations as well as from healthcare provider organisations and their staff in other countries.	9	10	
16	Assure that all technical, organisational and process measures comply with required national and European level security standards.	6	Ongoing	
17	Appoint a certified auditor to perform required data protection and security tests and audits.	9	10	
18	Develop and implement training programme for HCPs and pharmacists	10	ongoing	
Semantic level implementation steps				
19	Analyse, adapt to and implement European-wide agreed upon (ePrescription) semantic assets and tools at national level	6	Ongoing	Close cooperation with or transfer of this task to national (semantic) health standards organisation may be most efficient
20	Specify and allow for the transformation of national ePrescription document architecture into the European ePrescription data model.	8	11	
21	Implement European semantic services as required for cross-border exchange of ePrescriptions, such as the Master ValueSet Catalogue (MVC) and the Master Translation/Transcoding Catalogue (MTC).	10	12	
22	Test the developed semantic interface components according to common European test rules. This holds for component tests, system test, participating in Projectathon and field tests.			
Technical level implementation steps				
23	Review and scrutinise the ePrescription system's technical elements/components at national level, and the overall European (epSOS-based) architectural components for the European-level exchange of ePrescription data. NCP-In-A-Box versus MS developed bespoke NCP concept.	3	5	

24	Compare the National Contact Point (NCP)-In-A-Box concept "A" with a bespoke national NCP concept as well as the requirements for *transferring* ePrescription data of residents to another country ("B") at the national (and regional, as appropriate) level. Select the concept to be implemented.	5	6	For more details, refer to epSOS deliverables respectively latest ehealth Network documents.
25	Analyse requirements for national interface and integrability of NCP A platform with national / regional infrastructure, including ePrescription data sources, data structures and dataflow issues.	6	7	
26	Develop National ePrescription Connector for NCP A in your country.	7	10	
27	Develop portal/connector for NCP A point-of-care (PoC) interconnection.	7	10	
28	Compare the National Contact Point (NCP)-In-A-Box concept "B" with a bespoke national NCP concept as well as the requirements for *receiving* ePrescription data of residents from another country ("B") at the national level. Select the concept to be implemented.	5	6	
29	Analyse requirements for national interface and integrability of NCP B platform with national / regional infrastructure, including ePrescription data sources, data structures and dataflow issues.	6	7	
30	Develop National Connector for NCP B in your country.	7	10	
31	Develop portal/connector for NCP B point-of-care (PoC) interconnection.	7	10	
32	Data security – adapt and implement European level (epSOS based) rules and set-ups	8	10	
33	Undertake security audit	11	12	
34	Test the overall technical set-up (functional tests of components/elements and system tests), review results and adapt as and where necessary	11	12	
35	Perform validation (field test) and full operation testing	13	14	
36	Prepare manuals	6	12	

8.3 Exemplar national roadmap for the implementation of European cross-border eHealth services

In an exemplar manner, the action steps and time line required at Member State level to integrate the current European solution into an advanced national infrastructure is illustrated in the following table. It is based on the Danish epSOS pilot project timeline.[62]

Figure 16: The Danish epSOS piloting action steps and timeline



Source:epSOS D3.8.2 // Danish national epSOS pilot

[62] See epSOS D3.8.2 "National set-up and deployment guide"

This project timeline shows the different domains in which a proven national ePrescription solution needs to be expanded or adapted in order to fit the European model. It also shows that the adaptation can be achieved within a highly reasonable timeframe of half a year, if it can be build upon both a national ePrescription system, a clear policy decision and earlier preparatory activities.

Of course, in countries where neither a basic eHealth infrastructure nor an ePrescription solution are available, these processes, depending on the political will and urgency with which the national Ministry of Health and/or its competent authority as well as key stakeholders like healthcare providers pursue such efforts, may take anywhere between one and up to five years, if not more, judging on past experience in Member States.[63] On the other hand, based on the experience gained by epSOS-participating countries and learning from them, these processes may be accelerated considerably. However, on this concrete evidence is yet available.

[63] See the experience of European countries as described and analysed in: KA Stroetmann et al. European countries on their journey towards national eHealth infrastructures - evidence on progress and recommendations for cooperative actions. Luxembourg: Office for Official Publications of the European Communities, 2011

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