# DISCUSSION PAPER

# PREPARING "GUIDELINES SUPPORTING THE MEMBER STATES IN DEVELOPING THE INTEROPERABILITY OF EPRESCRIPTIONS"

Proposed by the eHealth Governance Initiative and

for consideration by the eHealth Network

Date: 13th May 2014

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## Content

## 1 Executive Summary

This discussion paper conveys the results of the workshop "*Guidelines supporting the Member States in developing the interoperability of ePrescriptions according to Directive 2011/24/EU – Article 11, 2"* organised by the eHealth Governance Initiative (eHGI) and its follow-up by the eHGI constituency.

The Member States have agreed to work – through the Art. 14 eHealth Network – jointly on the interoperability of ePrescriptions in order to facilitate the adoption of Article 11 of the Directive on the rights of patients in cross-border care (2011/24/EU). Article 11 is entitled *Recognition of prescriptions issued in another Member State.*

***As an outcome, non-binding guidelines* on electronic prescriptions to support the *Recognition of prescriptions issued in another Member State* in support of the implementation of Article 11 of the Directive on the rights of patients in cross-border care (2011/24/EU) will be submitted for approval by the eHealth Network in November 2014.**

The forthcoming guidelines respond more precisely to Article 11 (2-b) of the Directive, which defines the need for "guidelines supporting the Member States in developing the interoperability of ePrescriptions". Therefore, they are intended to be complementary to Commission Implementing Directive 2012/52/EU of 20 December 2012 *laying down measures to facilitate the validation of medical prescriptions issued in another Member State*. This implementing directive defines measures according to elements (a), (c) and (d) of Article 11(2), namely for (a) verification of the prescription (issued by legally entitled person, elements to be included etc.), (c) correct identification of medicinal products or medical devices including allowance for substitution and (d) patient information and usage instructions.

The workshop on 11 March 2014 started with the presentation of a study on options for interoperable ePrescriptions by empirica (contractor of DG SANCO) and aimed to provide further insight into the lessons learned by the Member States, particularly those already running ePrescribing systems, by European projects such as epSOS and by regulatory bodies and European stakeholder organisations.

The eHealth Governance Initiative (eHGI) has taken advantage of the "ePrescription draft guideline proposal" prepared by empirica as a useful starting point for the envisaged *non-binding guidelines on electronic prescriptions* and has submitted the proposal to the Member States for comments. The March workshop delivered the clear message that additional work will still be needed to arrive at an acceptable draft to be submitted to the eHealth Network. To support the ongoing development of the guidelines, *Section 6 Conclusions* of this paper highlights the key issues raised by the Member States for adjusting the scope and what additional elements need to be taken into account.

Provided that the conclusions of this paper are supported by the eHealth Network, the next step will be to prepare the actual "Guidelines supporting the Member States in developing the interoperability of ePrescriptions". The guideline structure will build on the lessons learned by eHGI/eHN through the preparation of the "Guidelines on Minimum/Nonexhaustive Patient Summary Dataset for Electronic Exchange in Accordance with the Cross-border Directive 2011/24/EU". It will adopt a *gradual approach* towards necessary agreements and identify *cross-cutting prerequisites for interoperability*.

It is furthermore expected that the Commission will – as a subsequent step after November 2014 – define a permanent mechanism according to Article 16(2) of Directive 2011/24/EU to practically organise the collaboration with the Member States on implementing the envisaged guidelines.

## 2 Scope of the discussion paper

This discussion paper is prepared for the consultations of the eHealth Network in May 2014. It is expected to be tabled jointly with the document "ePrescription draft Guideline Proposal" (cf. Annex 2) that has been prepared by empirica as a contractor of DG SANCO. The eHealth Governance Initiative considers the draft proposal as a useful starting point and has used it as a contribution to a workshop organised in Brussels on 11 March 2014 with these objectives:

- To consider the proposed draft guidelines and to review the lessons learned from ePrescriptions being deployed by the Member States
- To take into account the achievements of the epSOS project
- To review work in progress and the role of regulatory and standardisation bodies
- To understand the positions of stakeholders' representatives.

The conclusions of this working paper aim to support the further development of the guidelines.

## 3 Context and procedure for defining guidelines on ePrescriptions

Article 11 *Recognition of prescriptions issued in another Member State* of Directive 2011/24/EU foresees that "Member States shall ensure that 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 in force [..]", i.e. for prescriptions irrespective of whether they are on paper or in digital format.

The implementation of cross-border prescriptions is facilitated by (Dir. 2011/24/EU Article 11 (2)):

*(a) measures enabling a health professional to verify the authenticity of the prescription and whether the prescription was issued in another Member State by a member of a regulated health profession who is legally entitled to do so through developing a non-exhaustive list of elements to be included in the prescriptions and which must be clearly identifiable in all prescription formats, including elements to facilitate, if needed, contact between the prescribing party and the dispensing party in order to contribute to a complete understanding of the treatment, in due respect of data protection;*

*(b)* ***guidelines supporting the Member States in developing the interoperability of ePrescriptions****;*

*(c) measures to facilitate the correct identification of medicinal products or medical devices prescribed in one Member State and dispensed in another, including measures to address patient safety concerns in relation to their substitution in cross-border healthcare where the legislation of the dispensing Member State permits such substitution. The Commission shall consider, inter alia, using the International Non-proprietary Name and the dosage of medicinal products;*

*(d) measures to facilitate the comprehensibility of the information to patients concerning the prescription and the instructions included on the use of the product, including an indication of active substance and dosage.*

For elements (a), (c) and (d) of Article 11(2), 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 provides a framework to ensure recognition of medical prescriptions in cross-border healthcare as required by Directive 2011/24/EU.

To also enable ePrescriptions to be used in a cross-border setting, the Member States – through the eHealth Network – will complement the Commission Implementing Directive of 2012 by establishing (b) "guidelines supporting the Member States in developing the interoperability of ePrescriptions".

Given the relevant context of operation, full clarification will be needed when using key specific terms such as "National Contact Points" (NCP). In fact the term NCP has been associated with a specific meaning in the eHealth domain (see definition by the epSOS large-scale pilot), yet neither the definitions nor the existing assignments of organisations are guaranteed to be identical to those referred to in Article 4 of Commission Implementing Directive 2012/52/EU of 20 December 2012. As a first step, the role and the official mandate of these organisations need to be defined with precision; the assignments are then subject to further decisions by the Member States. Appropriate reference should be made to legal clarifications to be provided by the eHGI before project closing.

It is furthermore expected that the Commission will define a permanent mechanism according to Article 16(2) of Directive 2011/24/EU to practically organise the collaboration with the Member States on the subject.

While this document aims to support the discussion of the Member States at the upcoming meeting of the eHealth Network in May 2014 (Athens), the ultimate goal is to adopt eHealth Network Guidelines on ePrescribing in November 2014. To support this process, the eHGI considers the structure and the phased approach exemplified by the "Guidelines on Minimum/Nonexhaustive Patient Summary Dataset for Electronic Exchange in Accordance with the Cross-border Directive 2011/24/EU" (adopted by the eHealth Network in November 2013) to be a useful model.

Given the outstanding deployment of ePrescribing in some of the European Member States so far, the "Guidelines on interoperable ePrescriptions" issued by the eHealth Network are also expected to streamline the local implementation processes (the "how"), thereby supporting the fulfilment of the Digital Agenda for Europe in the domain of ePrescribing. Being non-binding, the guidelines will not interfere with decisions of Member States on *whether* to deploy ePrescription services nationally.

## 4 (empirica study) Key elements in support of ePrescription interoperability

empirica and its partners were awarded a contract by DG SANCO – through the Executive Agency for Health and Consumers (EAHC) – to produce draft guidelines on interoperable ePrescriptions. To this end, empirica conducted a feasibility analysis to explore the political eHealth and ePrescribing context across the Union. The study and draft guidelines serve as a reference for the discussions of the Member States and stakeholders in the eHGI. Key observations are included here for information:

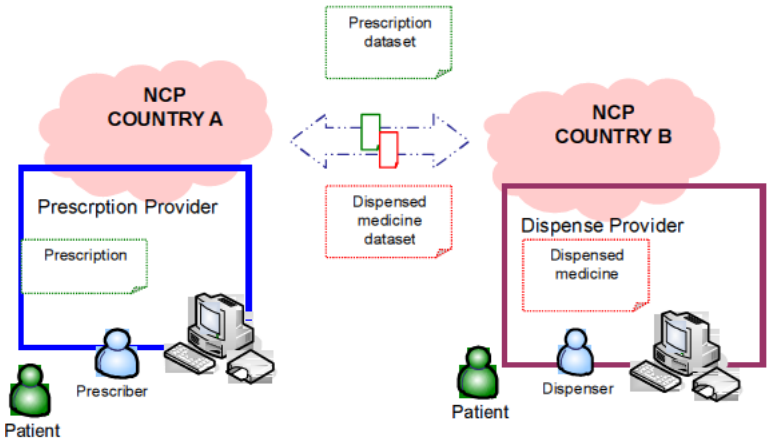


Figure 1: Key concepts: ePrescription/eDispensation

(empirica) Key concepts: ePrescription

- "'ePrescription' means a medicinal prescription, as defined by Article 1(19) of Directive 2001/83/EC of the European Parliament and of the Council, issued and transmitted electronically."
- 'prescription' means a prescription for a medicinal product or for a medical device issued by a member of a regulated health profession within the meaning of Article 3(1)(a) of Directive 2005/36/EC who is legally entitled to do so in the Member State in which the prescription is issued; (Art. 3k)
- Medicinal prescription acc. to Art. 1(19) of D2001/83/EC: Any medicinal prescription issued by a professional person qualified to do so.
- Medicinal product = "(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or
- (b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis."

(empirica) Key results from feasibility analysis workshop

- Different concepts of "***primary care prescribing***" in Europe
- Different concepts of "***substitution***" in Europe (e.g. therapeutic, economic)
- Missing code system to represent medications with multiple active ingredients
- National limitations with regard to the integration of epSOS datasets in national infrastructure

(empirica) Suggested actions

- Implementing digital signature services at the eGovernment or eHealth service level
- Achieving common European or bilateral legal agreements among countries planning to maintain or to newly establish cross-border ePrescription services
- Agreeing on an EU-wide minimum ePrescription and Dispensation dataset – aligned with implementing directive (2012/52/EC)
- 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

(empirica) Actions needed

- Definition of common process and rules regarding substitution of medication
- Agreement on an international standard to represent multiple active ingredients in medications
- EU-wide agreement on minimum storage duration for ePrescription and dispensation records

## 5 Experiences of Member States, regulatory bodies and stakeholders

ePrescription systems in Denmark, Sweden, Italy, Spain, Croatia and Finland are based on messaging (optional) and central servers supporting/providing ePrescriptions and eDispensations. As a consequence, the central servers also cover some of the functions of a medication record by making prescription and dispensation data from a recent period (e.g. two years) available to health professionals.

- While ePrescriptions make up 70-100 % of prescriptions, eDispensations are always 100% covered, i.e. digital documentation in the pharmacies at time of dispensation.
- Those countries participating in epSOS have designed a virtual "epSOS Pharmacy" that can interact with the national system. Additional consent is needed for sending ePrescriptions across borders.
- The approaches to semantic interoperability are varied, with high expectations of the upcoming European database for medicinal products (EudraMed). ATC[1] and INN[2] (cf. Commission Implementing Directive) are most often used, while SNOMED CT is used by one of the reporting countries (Spain) using a model of "virtual medication codes" and similar work is reported from Belgium. Use and dosage instructions often rely on free, non-coded text. Citing the medical reason for prescriptions seems optional in some countries and mandatory in others.
- One country (Spain) reports on interoperability measures within the country since different approaches to ePrescriptions have been implemented at a regional level.
- An IHE XDS profile is reported to be in use in one country (Denmark).
- Italy (Lombardy region) builds the workflow on paper-based bar codes. This is still also foreseen at least in a first phase in Belgium, although this is not regarded as an ideal solution given (inter alia) hardware constraints.
- One country (Sweden) reports on a detailed set of validation rules for ePrescriptions, e.g. to allow validation of the prescribing rights of the person issuing them.
- The discussion on prescribing rights reveals different regulations in Member States. However, this has no direct impact on the cross-border use case given the proposed compliance with the principle "when in Rome, do as the Romans do".

The Member States invited for presentations were obviously those with advanced ePrescription and eDispensation service deployments. To provide an assessment of the current status of national/regional roll-outs and hence the priority that may be allocated to the cross-border ePrescription use case, the eHGI has organised a quick survey on EU Member States and some affiliated states, cf. Annex 1. ePrescribing is a moving target – depending on the assessment, one third to one half of the states have services in routine use. All others – with the exception of Germany – have concrete targets for deployment. Within this framework, guidelines would also help to foster alignment between ePrescription schemes inside Member States.

[1] Anatomical Therapeutic Classification.

[2] International Nonproprietary Names, cf. http://www.who.int/medicines/services/inn/en/

The lessons learned from the Member States indicate that some convergence already exists in terms of the infrastructure and ePrescription workflow (i.e. also making the eDispensation data available for audit and to support medication records). Yet in the semantic domain no uniform trend can be identified beyond the use of ATC and INN with varying degrees of implementation. This provides further advocacy for a *gradual approach* to guidelines for interoperable ePrescriptions.

ISO, CEN and IHE are ready to support this gradual approach and have already joined forces in the pharmacy domain to provide standards and profiles to be taken into account.

## 6 Conclusions for moving forward to ePrescription Guidelines[3]

The following preliminary high-level conclusions are proposed to the eHealth Network:

- The scope of guidelines for interoperable ePrescriptions should be limited to medicinal products.
- The guidelines should foresee a gradual approach to solving the interoperability issues inherent to ePrescriptions, particularly in the semantic domain (identification of drugs, information for patients, drug use instructions) and for issues of substitution as a number of important decisions are expected to be taken in the near future.
- From the perspective of stakeholders, patient safety and ease of practice are essential. There is a need for greater clarification of the legal framework, especially in relation to data protection and liability issues.
- Different scenarios need to be described, taking into consideration the current situation and expected future answers. Paper prescriptions transmitted electronically, e.g. in PDF format, should be included in the scope.
- The role of regulatory bodies is clearly of great importance with respect to semantic interoperability (generic and brand-name consistency, similarities of dosage) as well as providing a common database on which EU-wide practice can be based.
- The European Medicines Agency (EMA) should provide a European-wide reference for drug nomenclature and hence foster the process of finalising the foreseen database. Its future deployment in the context of cross-border prescribing will still require further development and validation, linked both to the requirements and current practice in Member States, and application in cross-border prescribing.
- The involvement of a National Contact Point (NCP) in confirming the validity of a prescription may provide reassurance, but it would also interfere with the concept of end-

[3] Some written comments by the Member States (UK, Finland, Italy and Sweden) refer to the article level of the "ePrescription draft Guideline Proposal" and cannot be accounted for in this paper. However, this information will be retained and revisited in the guidelines drafting process.

to-end encryption. Such a process would also require access by the NCP to professional registration databases.

- eID issues, i.e. identification, authentication and authorisation of healthcare professionals and patients involved in cross-border care relationships, are a crucial element and should be addressed in a cross-cutting approach, building on the core service platform of CEF.

- In relation to the ePrescribing scenario, the identification of the health professional will need to be linked to the authority to prescribe and also confirmation of an existing doctor/patient relationship. Datasets to enable this are available from some Member State competent authorities, but wider linkages are required for professional bodies to support cross-border ePrescribing.

- In addition to security, interoperability and safety issues, the guidelines should also focus on usability by health professionals and patients/consumers. It should in particular provide guidance to avoid duplicated workflows caused by incompatible national and cross-border ePrescription schemes.

- Furthermore, the guidelines should provide (easy) access to the health providers to obtain access to information including the (trusted source) supporting schemes for checking the identity, professional role and local prescribing rights of the health professional who has issued the ePrescription.

- The guidelines will not repeat legislation already defined by the patient mobility directive (e.g. NOT re-iterate that national rules shall be applied by pharmacists on substitution).

- The guidelines must provide – or make reference to – a binding glossary in order to define or clarify key concepts (circle of trust, personal health data, NCP, generic versus therapeutic substitution, professional qualification, bio-equivalence etc.).

- The guidelines must not deal in detail with transversal generic issues and supporting services which are addressed elsewhere (such as identification, authentication and authorisation issues) but must streamline essential dependencies. In this respect, alignment – when possible – with Chapter IV of the patient summary guidelines should be considered. Aspects such as signature (NCP versus healthcare professionals) should be discussed further.

- The guidelines must discuss the future possibility of taking into account practical issues of reimbursement, along with the possibility of comparing reimbursement rates according to the rules of the cross-border directive.

- The guidelines must avoid any architectural design which would be in contradiction with the principles established in certain Member States (e.g. decentralised or central storage of documents). Likewise it should avoid referring to any specific cryptographic algorithms or national guidelines.

- The guidelines should make sure that all data deemed compulsory can be made available by Member States given existing or planned registers (e.g. address of health professionals).

## Annex 1: ePrescription Implementation Status April 2014 (eHGI/eHN mini-survey[4])

| Implemented e-prescribing | % | Notes |
|---|---|---|
| Belgium | | Roll out started in January 2014. Service was part of homologation criteria of GP software in 2013. 15% coverage expected by end of 2014. Incentive scheme planned before making the system compulsory from 2016 (?) on. |
| Croatia | almost 100 | Since January 2011 full operation for GPs, since May 2011 full operation except narcotics and medicines not available on the Croatian market |
| Czech Republic | | Voluntary and very few prescribers choose to issue electronically. |
| Denmark | 70 | Central Prescription DB; moving from EDI-messages to XML webservices |
| Estonia | 98 | Functionality provided via the National X-Road architecture. |
| Finland | 87 | All public providers have joined. Based on Act on el. Prescriptions in 2007, ePrescriptions will be obligatory after a short transition phase, after which paper will be allowed only in special cases such as electricity shutdowns. |
| Greece | 100 | In operation since 2010, 6.5 million ePrescriptions processed per month; Use is mandatory now. The system also covers referrals. |
| Italy | | *(Regional approach)* Implementation in progress in almost all regions following the enactment of the interministerial decree of 2 November 2011 concerning de-materialisation of paper prescriptions. Use very low. |
| (Macedonia) | 100 | 100% for reimbursed medicines; for others implementation from the beginning of 2014. |
| Romania | 100 | Since 2013 |
| Spain | 70 | *(Regional approach)* 11 out of 17 regions run ePrescriptions, the (national) Health Ministry has launched an interoperability Initiative, using SNOMED. |
| Sweden | over 90 | A multitude of national registers supports medication safety and quality. |
| The Netherlands | | Mandatory since 2014. 95% of GPs and 50% of hospitals could ePrescribe |
| (Turkey) | 100 | |
| UK | | Implemented but use is still very low |
| **Pilot Projects** | | |
| Bulgaria | | Plans for replacement of paper based with ePrescriptions by end of 2014 |
| Latvia | | Voluntary participation from 1 April 2014 to 31 December 2015 |
| Portugal | | |
| Slovenia | 1 | Implementation in pharmacy dispensing has just started; wider implementation for prescriptions to follow in summer 2014 |
| **Plans to implement e-prescribing** | | |
| Cyprus | | |
| France | | Pilot starts autumn 2014 |
| Hungary | | Under preparation but unlikely to be before end of 2014 at the earliest |
| Luxembourg | | A one-year pilot in 2016. Full deployment will follow after 2016 (tbc). |
| Poland | | Plans to implement in 2014 and introduce for use in second half of 2015 (paper and electronic prescription will then be used in parallel). Mandatory electronic prescriptions from 1 August 2016. |
| Slovakia | | Plans to complete by 2016 |
| (Switzerland) | | |
| **No implementation currently planned** | | |
| Germany | | Initial testing done, implementation postponed with no date specified. |

[4] Responses may need additions/corrections. eHGI data collection has been coordinated by PGEU.

**Annex 2: ePrescription draft Guideline Proposal (prepared by empirica, 2013)**

# 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 xx November 2013**

is submitted for discussion and adoption to the eHealth Network.

(Text with EEA relevance)

THE MEMBER STATES,

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)[5]. 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.

[5] COM(2012) 238 final.

(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.

(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) .

(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[6],;

(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.

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

(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

(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, that 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 entitiy 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.

# **Annex*** (*to Annex 2)

**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)