GUIDELINES ON ePRESCRIPTIONS DATASET FOR ELECTRONIC EXCHANGE UNDER CROSS-BORDER DIRECTIVE 2011/24/EU

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1. INTRODUCTION

1.1. Purpose

The fifth meeting of the eHealth Network in May 2014 agreed that work should proceed on the production of non-binding guidelines on electronic prescriptions, with a view to adoption of the guidelines at the meeting in November 2014. The aim is to facilitate implementation of the recognition and delivery of prescriptions issued in another Member State in support of the implementation of Article 11 of 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 (hereinafter Directive 2011/24/EU). [1]

1.2. Scope

These guidelines respond to Article 11 (2-b) of the Directive, which defines the need for "*guidelines supporting the Member States in developing the interoperability of ePrescriptions*". 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 (hereinafter Implementing Directive 2012/52/EU).[2]

Implementing Directive 2012/52/EU 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.

Member States have agreed to work jointly, through the eHealth Network established under Article 14 of Directive 2011/24/EU, on the interoperability of ePrescriptions in order to facilitate the implementation of Article 11 of Directive 2011/24/EU. Article 11 is entitled *Recognition of prescriptions issued in another Member State.*

The primary focus of these guidelines is to support the objective of cross-border electronic exchange of prescriptions. A secondary focus of the guidelines is to provide material for each Member State to use, if they wish, for reference at national level.

1.3. Legal basis of the guidelines

According to the primary responsibility of the Member States in the field of healthcare provision, as laid down in Article 168 (7) of the Treaty on the Functioning of the European Union (TFEU), these guidelines are non-binding. The term 'guidelines' should therefore be interpreted as a set of recommendations. It is up to each Member State to implement the guidelines and hence ensure that its ePrescriptions are suitable for both cross-border and national use.

[1] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011L0024&from=EN

[2] http://ec.europa.eu/health/cross_border_care/docs/impl_directive_presciptions_2012_en.pdf

1.4. Process of developing the guidelines

These guidelines have been developed in line with the process agreed by the eHGI Executive Committee as follows:

- The eHealth Governance Initiative (eHGI) has made use of the "ePrescription draft guideline proposal" prepared by Empirica (contractor of DG SANCO) as a useful starting point and submitted the proposal to the Member States for comment in early 2014.
- A workshop was held on 11 March 2014. This started with the presentation of the study on options for interoperable ePrescriptions by Empirica 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 workshop concluded that additional work will still be needed to arrive at an acceptable draft to be submitted to the eHealth Network.
- Following the workshop, a discussion paper documenting these conclusions (together with a draft text for the guidelines) was discussed at the eHealth Network meeting in May 2014.
- A first full draft of the guidelines (v2) was issued for comment in July 2014 prior to a workshop discussion in September 2014, resulting in v4. Following a further commenting round and ISO/CEN meeting in early October, v5 was issued for discussion at the eHGI Project Steering Committee; final comments led to v6. This version was subject to a "good English" review, leading to v61.

The structure of these guidelines builds 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 is proposed that an incremental approach be adopted towards necessary agreements and cross-cutting prerequisites for interoperability.

The coordination process to support this follow-up should be driven in close cooperation by the eHealth Network and the supporting mechanism.

The rest of this document comprises three parts:

- section 2 – introductory text
- section 3 – the guidelines ("what to do") and
- section 4 – explanatory text (advice on "how to" implement).

The content structure of the guidelines is shown in Table 1 overleaf.

1.5. Evolving document

This first release of the guidelines presents the basic elements for the electronic exchange of prescriptions. The document indicates areas where further work is required, notably in the review and agreement of terminological and coding schemes to be used for the identification of medicinal products. This review will need to ensure that clinical need and patient safety requirements are taken into account, and hence it is important that representatives of the health professions are involved. This on-going work will lead to further releases of the guidelines.

147 The guidelines will be further revised and updated, based on functional and/or technical
148 developments and feedback from users (Member States and other stakeholders) and in
149 response to other use cases. The European Commission may, at the request of the
150 eHealth Network, coordinate the work on revising and updating the guidelines.

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152 **Table 1: Structure of the guidelines**

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2. CONTEXT

2.1. Directive on patients' rights in cross-border healthcare

Directive 2011/24/EU provides rules for facilitating access to safe and high-quality cross-border healthcare and promotes cooperation on healthcare between Member States, in full respect of national competencies in organising and delivering healthcare.

Article 11 *Recognition of prescriptions issued in another Member State* of Directive 2011/24/EU foresees in paragraph 1 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 Article 11 (2) of Directive 2011/24/EU:

"(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), Implementing Directive 2012/52/EU 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 supplement Implementing Directive 2012/52/EU by establishing (b) "*guidelines supporting the Member States in developing the interoperability of ePrescriptions*".

2.2. eHealth Network

Article 14 of Directive 2011/24/EU states:

"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.

2. The objectives of the eHealth network shall be to:

(a) work towards delivering sustainable economic and social benefits of European eHealth systems and services and interoperable applications, with a view to achieving a high level of trust and security, enhancing continuity of care and ensuring access to safe and high-quality healthcare;

(b) […]

(c) support Member States in developing common identification and authentication measures to facilitate transferability of data in cross-border healthcare. […]"

The resulting eHealth Network agreed a Multiannual Work Programme 2012–2014 that builds on these strategic aims, reflects Member States' priorities and takes into account European and national projects and initiatives. The Work Programme includes the specific objective to adopt guidelines on ePrescriptions. This objective is consistent with the new Multiannual Work Programme 2015–2018 adopted by the eHealth Network at the meeting on 13 May 2014 in which it is expressly provided that the ePrescription guidelines shall be periodically updated.

2.3. Rationale of the guidelines

The aims of implementing the ePrescription guidelines are, in line with the principles of cross-border care:

- to ensure access to safe and high-quality healthcare;
- to achieve a high level of trust and security;
- to enhance the continuity of care for individual patients.

The guidelines and the measures herein 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.

2.4. NCPeH issues

Given the relevant context of operation, full clarification is needed when using specific key terms such as "National Contact Points". A more specific term, the NCPeH for eHealth (NCPeH), has been used in the eHealth domain (ref. epSOS large-scale pilot), yet neither the definitions nor the existing assignments are guaranteed to be identical to those referred to in Article 4 of Implementing Directive 2012/52/EU. The National Contact Point for cross-border eHealth (NCPeH) may be different from the NCP foreseen under Directive 2011/24/EU. The NCPeH acts as a communication gateway and maintains compliance to normative interfaces in terms of structure, behaviour and security policy. Appropriate reference should be made to legal clarifications to be provided by the eHGI before complete project closure.

Given the outstanding deployment of ePrescribing in some of the Member States so far, the "Guidelines on interoperable ePrescriptions" adopted 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 and how to deploy ePrescription services nationally.

2.5. Scenario

The scenario within the scope of this document is that a patient from Country A has a prescription issued in Country A and dispensed in Country B, where:

Country A: This is the country where the patient can be univocally identified and his or her data may be accessed.

Country B: This is the country that the patient is visiting and in which information about the patient is needed in case he or she needs healthcare.

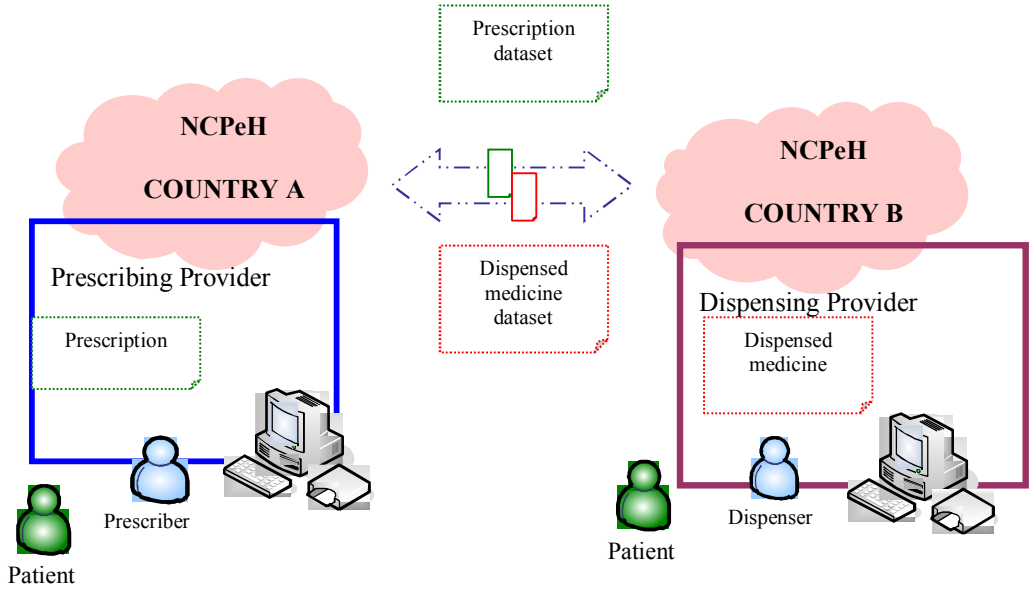

Figure 1: Scenario 1 of ePrescription Service

Further details of the scenario (taken from the epSOS documentation) are provided in Annex B.

3. GUIDELINES FOR EPRESCRIPTIONS

THE MEMBER STATES in the eHealth Network,

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 Articles 114 and 168 of the TFEU, the Union adopted 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.

(3) Based on Article 100a of the Treaty establishing the European Community, 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.

(4) Based on Articles 47 (2), 55 and 95 of the Treaty establishing the European Community, 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.

(5) Based on Article 95 of the Treaty establishing the European Community, 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.

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

(7) These guidelines are laid down without prejudice to Article 11 (1) and (6) of Directive 2011/24/EU as well as of Implementing Directive 2012/52/EU. This implementing directive has been based upon elements (a), (c) and (d) of Article 11 (2) of Directive 2011/24/EU.

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

(9) The respective national law governs liability. The choice of law is determined by the existing international private law rules, e.g. Regulation (EC) No 593/2008 of the European Parliament and of the Council of 17 June 2008 on the law applicable to contractual obligations (Rome I),[3] or Regulation (EC) No 864/2007 of the European

[3] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:177:0006:0016:En:PDF

Parliament and of the Council of 11 July 2007 on the law applicable to non-contractual obligations (Rome II).[4] Further guidance can be found in the Commission Staff Working Document on the applicability of the existing EU legal framework to telemedicine services.

(10) The implementation of these guidelines is in line with Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of personal data and free movement of such data. [5]

HAVE ADOPTED THESE GUIDELINES:

Chapter I – Scope and Definitions

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. According to the primary responsibility of the Member States in the field of healthcare provision, as laid down in Article 168 (7) of the Treaty on the Functioning of the European Union, these guidelines are non-binding. Nonetheless, compliance with 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 Article 114 of the Treaty on the Functioning of the European Union.

3. 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 for eHealth (as defined in Article 2) and for interfaces between national and European levels.

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

5. These guidelines do not cover medical devices.

Article 2: Definitions

1. 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) eDispensing is defined as the act of electronically retrieving a prescription and giving the medicine to the patient. Once the medicine has been dispensed, a report on the items dispensed is sent to the prescribing Member State in a structured format.[6]

[4] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32007R0864&rid=1

[5] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:en:HTML

b) 'Electronic medication data' means any electronically used data regarding medication of a patient, including but not limited to ePrescriptions and the electronic information about the dispensation of medication.

c) 'ePrescription' means a medicinal prescription, as defined by Article 1 (19) of Directive 2001/83/EC[7], issued and transmitted electronically, as elaborated in point 3 (f) of Commission Recommendation 2008/594/EC on cross-border interoperability of electronic health records.

d) 'Health professional' means a doctor of medicine, a nurse responsible for general care, a dental practitioner, a midwife or a pharmacist within the meaning of Directive 2005/36/EC[8], or another professional exercising activities in the healthcare sector, which are restricted to a regulated profession as defined in Article 3 (1) (a) of Directive 2005/36/EC, or a person considered to be a *health professional* according to the legislation of the Member State of treatment.

e) 'National Contact Point for eHealth' refers to the unique entity on a national level authorised by a Member State to provide an interface between the national and European aspects of exchanging ePrescriptions[9].

f) 'Prescription' means a prescription for a medicinal product or 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.

g) 'Medicinal prescription' means any medicinal prescription issued by a professional person qualified to do so.

h) 'Medicinal product' means

- any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or
- 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.

Article 3: Fundamental concepts

1. These guidelines are non-binding and Member States are considered to:

(a) have the right to choose freely (if and) how to implement ePrescription systems within their Member State;

(b) use open standards for public health activities;

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[6] See supporting detail in Article 6; the aim is that the ePrescription can be updated before another dispensation can take place.

[7] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:311:0067:0128:en:PDF

[8] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:255:0022:0142:en:PDF

[9] Each Member State may establish one or more of these entities (at regional/local level) depending on the respective National Health Service model.

(c) decide freely whether they want to adopt such requirements in local legislation;

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

(e) accept, when ready, prescriptions that conform to Article 4 of these guidelines.

2. The National Contact Points for eHealth shall build a common trust model with other Member States, thus establishing secure cross-border information exchange.

Chapter II – Functional and Semantic Provisions

Article 4: Dataset for ePrescriptions

1. Table 2 shows fields for the dataset. The data elements are taken from Implementing Directive 2012/52/EU and Draft International Standard DIS 17523[10]. Reference is also made to other relevant standards, including the ISO Identification of Medicinal Products (IDMP) standards as referred to in the Implementing Directive. The data elements ticked in the second column are mandatory; other elements are optional. Annex C provides supporting information on each data field; further details will be added in future releases of the guidelines.

2. ePrescriptions that contain data according to paragraph 1 of this Article 4, but that are not ready for semantic interpretation by machines, may be rejected on grounds of patient safety/national legislation.

Table 2: ePrescription Dataset

Data Field	ID
A.1 Core data elements	
A.1.1 Identification of the patient	
A.1.1.1 Surname [ISO TS 22220]	✓
A.1.1.2 Given name [ISO TS 22220]	✓
A.1.1.3 Date of birth [ISO TS 22220]	✓
A.1.1.4 Personal identifier	✓
A.1.1.5 Gender	
A.1.2 Authentication of the prescription	
A.1.2.1 Prescription ID	✓
A.1.2.2 Issue date	✓
A.1.3 Identification of the prescribing health professional	
A.1.3.1 Surname	✓
A.1.3.2 Given name	✓
A.1.3.3 Professional qualifications	✓
A.1.3.4 Details of direct contact	✓
A.1.3.5 Work address	✓
A.1.3.6 (Digital or electronic) signature	✓
A.1.3.7 Health care provider identifier (HCPI)	✓
A.1.4 Identification of the prescribed product[11]	

[10] http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=59952

[11] The term product includes pharmaceutical products (branded medicinal products, generic/scientific name medicinal products or pharmaceutical preparations [ISO 21549-7:2007]) or non-pharmaceutical products.

A.1.4.1 Name of the item [+ identifier as described in ISO IS 11615]	✓
A.1.4.2 Identifier of the item [with name and identifier as described in ISO IS 11616]	✓
A.1.4.3 Strength of the item [Article 1 of Directive 2001/83/EC]	✓
A.1.5 Prescription information	
A.1.5.1 Pharmaceutical dose form	✓
A.1.5.2 Quantity	✓
A.1.5.3 Dose regimen	✓
A.1.5.4 Duration of treatment (start and/or stop time)	
A.1.5.5 Directions for use	
A.1.5.6 Pharmaceutical preparation description[12]	
A.2 Optional elements of prescription	
A.2.1 Identification of the patient	
A.2.1.1 Address details	
A.2.1.2 Native language [could be taken from the ISO language table (ISO 639.2 or ISO 639-3)]	
A.2.2 Patient characteristics	
A.2.2.1 Body weight	
A.2.2.2 Body height	
A.2.2.3 Drug allergies and drug sensitivities	
A.2.2.4 Patient conditions	
A.2.3 Prescription information	
A.2.3.1 Prescription expiry date	
A.2.3.2 Repeats/refills	
A.2.3.3 Minimum dispensing interval	
A.2.3.4 Reason for prescription	
A.2.3.5 Substitution handling	

3. There is a particular issue regarding the identification of medicinal products. The European Medicines Agency (EMA) has suggested the use of the inventory of medicines established under the legal obligations laid down in Article 57 (2) of Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency ("pharmacovigilance legislation of 2010")[13]: the so-called 'Article 57 database'. Member States will work with the EMA and the European Commission to explore this issue.

Article 5: Preconditions and responsibilities

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

[12] This also includes extemporaneous preparation, compounded medication and magistral preparation.

[13] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:348:0001:0016:EN:PDF

(b) on the health professionals/heath care providers who are entitled (according to national law) to dispense.

2. Member States of affiliation are responsible for ensuring that ePrescriptions are issued only by registered persons (or, where relevant, organisations).

3. The healthcare professional must be registered with at least one healthcare professional organisation or health authority belonging to the country in order to identify him or her unequivocally. Each Member State will need a system to check the attributes (e.g. rights to access the information via eID) of the end user who requests data.

4. The information according to paragraph 1 of this Article 5 is to be shared via the National Contact Points for eHealth, which are responsible for the proof of authenticity of origin and content of ePrescriptions. At European level National Contact Points for eHealth are responsible to their counterparts for the faithful representation of the information provided by them. To this end National Contact Points for eHealth shall implement audit trails.

Article 6: Organisation of dispensation

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

2. Member States of treatment shall be responsible for communicating details of items dispensed back to the originating country according to national laws. In the case of eDispensations, the following data should be sent to the prescriber via the relevant National Contact Point for eHealth for the respective recipient:

(a) identification number of the dispenser,

(b) name of dispenser,

(c) ISO 3166 country code of the dispenser,

(d) address of the dispenser,

(e) personal identification number of the patient, together with the ISO 3166 country code,

(f) identification number of the prescription,

(g) items dispensed.

Note: The Articles in the following chapters are by definition not part of the specification of the ePrescription dataset in this guideline. Their purpose is to describe the most important legal, organisational and technical prerequisites necessary to enable cross-border exchange of ePrescriptions or health data in general. The content of each of these Articles is therefore a brief description of the scope and not the final wording nor the specification for implementation. Member States will need to agree the details of implementation of these prerequisites in different settings and outside this guideline.

Chapter III – Technical Provisions

Article 7: Minimum technical requirements for cross-border ePrescriptions

1. Member States are free to choose the implementation of their ePrescription dataset. For cross-border exchange, the format of the document for exchange should be based on agreed international standards and profiles. An example set is described in Annex C. Further work will be needed to review these.

Article 8: Minimum technical requirements with regard to data security

1. Member States shall ensure that communication of identifiable personal health data is subject to secure communication and end-to-end security measures.

Member States shall assure logging of cross-border transactions and make logs available for legal purposes, e.g. a health professional request for a patient summary is important.

Chapter IV – Legal Provisions

Article 9: Data protection

1. The application of these guidelines should at all times take place according to the provisions of relevant European and national legislation. Where such provisions do not exist or are not in force, Member States are expected to implement, monitor and audit common policies, safeguards and measures representing agreements of the eHealth Network, as foreseen in its Multiannual Work Programme (MWP).
2. Such agreements will apply to the exchange of health related data across borders in a generic way and they will include but are not limited to agreements on duties and responsibilities of the eHealth NCPeHs and on common identification authentication and authorisation measures.

Article 10: Patient safety issues specific to these guidelines

1. Health professionals, patients and National Contact Points for eHealth may rely upon the information released by the National Contact Points for eHealth of other Member States.

2. In the event of semantic transformation, both the transformed and the original documents shall for safety and audit reasons be available to all persons who are authorised to use this data.

Article 11: Substitution

1. The rules of the dispensing Member State shall apply; hence Member States are responsible for application of their rules regarding substitution.
2. It is acknowledged that the rules for substitution are outwith the remit of the eHealth Network. However, Member States will wish to ensure that agreements regarding substitution are reflected in the information flows to support cross-border ePrescriptions.

Article 12: Storage periods

1. National legislation applies to the rules regarding storage of ePrescriptions.

Chapter V – Implementation Aspects

Article 13: Evaluation and quality assurance

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

(a) consider setting up a facility for cross-border ePrescription services to quality assure, benchmark and assess progress on legal, organisational, technical and semantic interoperability for their successful implementation;

(b) undertake assessment activities, such as measuring the quantitative and qualitative possible benefits and risks (including economic benefits, risks and cost-effectiveness) of ePrescription services.

Article 14: Education and awareness raising

1. 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 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, health care providers, public health institutions, insurers and other stakeholders;

(b) consider recommendations for education and awareness raising measures targeting 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 the patient's personal data;

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

Article 15: Amendments to the guidelines

1. The eHealth Network will include in its Multiannual Work Programme the necessary activities for:

- collecting information on the approaches of Member States to implementing the guidelines;
- updating the guidelines on a regular basis to reflect the evolution of the EU legal framework, functional and technological advances and lessons learned from their use by the Member States.

These guidelines are addressed to Member States.

4. SUPPORTING INFORMATION

This chapter provides supporting information and explanatory text to aid understanding of the guidelines and the rationale behind the proposals. It therefore follows the same structure as the guidelines themselves.

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, have provided input for these guidelines.

In June 2012 the European Commission published a proposal for a legal framework designed to enhance trust in electronic transactions in the internal market,[14] making explicit reference to "cross-border healthcare" in recital (10).[15] In order to maximise the benefits from electronic identification and trust services, Member States may agree to apply the developments in this field at the earliest possible stage.

Chapter I – Scope and Definitions

Article 1: Object and scope

The guidelines will take a gradual approach to solving the interoperability issues inherent to ePrescriptions, particularly at the semantic level (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.

The following items within the scope of this first release of the guidelines:

- The scope of guidelines for interoperable ePrescriptions shall be limited to medicinal products.
- 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.
- The guidelines should make sure that all data deemed compulsory can be made available by Member States given existing or planned registers.

The following items are outside the scope of this first release of the guidelines and will be discussed as part of the review process:

- A number of Member States have highlighted an interest in reimbursement. Although not within the scope of this release, the topic will be revisited by the eHN.
- The guidelines do not deal in detail with transversal generic issues and supporting services which are addressed elsewhere (such as identification, authentication and authorisation issues) but streamline essential dependencies. In this respect, alignment with Chapter IV of the patient summary guidelines has been performed.
- Aspects such as signature (NCPeH versus healthcare professionals) will be discussed further.

[14] Proposal for a Regulation on electronic identification and trust services for electronic transactions in the internal market and its impact assessment.

15 http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52012PC0238&from=EN

- The guidelines have sought to avoid architectural design which would be in contradiction with the principles established in certain Member States (e.g. decentralised or central storage of documents). Likewise, they seek to avoid referring to any specific cryptographic algorithms or national guidelines other than as examples.

Article 2: Definitions

Formal definitions are provided in Article 2 in section 3 of these guidelines. However, it is recognised that across Europe there are other terms for which different concepts apply; examples include “primary care prescribing” and “substitution” (e.g. therapeutic, economic).

Article 3: Fundamental concepts

The contents of these guidelines are seen as advice that will help each Member State to make progress in terms of its own agenda.

Chapter II – Functional and Semantic Provisions

Article 4: Dataset for ePrescriptions

Semantic interoperability requires representing the meaning of clinical information in standardised ways that allow both humans and computers to understand clinical information. An underlying principle is that exchange mechanisms convey both meaning and context.

The guidelines represent initial agreement on an EU-wide prescription and dispensation dataset, aligned with Implementing Directive (2012/52/EC). The aim of the dataset is to support cross-border care. However, the ability to populate this dataset requires national activity. More advanced and elaborate ePrescriptions exist in some Member States, but the eHealth Network has agreed that the guidelines could serve as a common baseline for ePrescriptions at national level.

The dataset in these guidelines is based on Implementing Directive 2012/52/EU and ISO DIS 17523. Annex C gives supporting descriptions of the data items together with a summary of lessons learned from epSOS pilot sites. DIS 17523 is currently under ballot and may be subject to change, but this could be reflected in the next release of these guidelines.

It will be necessary to reach agreement on an international standard to represent multiple active ingredients in medications. The epSOS project used the Anatomical Therapeutic Chemical (ATC) classification system of active substances in drugs developed by the World Health Organization (WHO), but this was not appropriate for the requirements of cross-border exchange as it does not deliver non-ambiguous and sufficient information. The European Medicines Agency (EMA) holds an inventory of all medicines authorised for human use in the EU and EEA established under the legal obligations laid down in Article 57 (2) of Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (“pharmacovigilance legislation of 2010”): the so-called ‘Article 57 database’.

The Article 57 database provides a European-wide reference and terminology for medicinal product(s) (including information about therapeutic indications, strength, pharmaceutical form and route of administration) that may support the identification and exchange of such information for cross-border ePrescriptions[16].

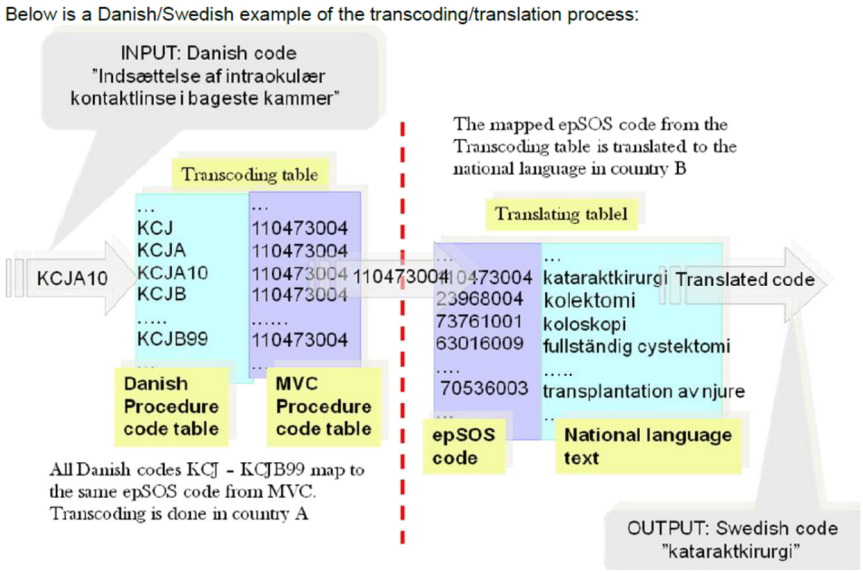
Member States will work with the EMA to explore the use of the Article 57 database to define implementation and integration strategy and to resolve possible legal and regulatory issues in close cooperation with the EU Commission. The Horizon 2020 project to explore this area may be able to assist with this study.

In the future, the implementation of the ISO Identification of Medicinal Products (IDMP) standards as referred to in Implementing Directive 2012/52 will introduce additional benefits to cross-border ePrescription business cases [references may be found in Annex D].

Use of a Master Catalogue

Across Europe, there are different languages, different standards and different coding schemes. In epSOS, this was addressed by the use of two master files: the Master Value Sets Catalogue (MVC), which applies across all Member States, and the Master Translation/Transcoding Catalogue (MTC).

Figure 3: Translation and Transcoding



Only one code system was chosen per coded element. No official mapping between code systems exists; therefore only one code system is chosen per coded field. Since transcoding at a Member State level or translation is expected, the number of terms in the value sets must be limited while providing the widest medical coverage possible. Thus, each coded element has only one code system associated with it, with its display name in English only. These terms were compiled in a Terminology Management

[16] In view of the timelines for the Article 57 data maintenance submission and the data validation performed by the EMA, the Article 57 database is expected to be functional to support the business cases in Q1 2015 provided that pharmaceutical industry complies with the Article 57 legal obligation. The Agency will work closely with the eHealth Network to monitor compliance and introduce corrective actions.

System named the Master Value Sets Catalogue (MVC) that provides the basis for data exchange.

The content of the MVC is in English; the terms are based on criteria defined by the scenario. Each nation is then required to translate the terms and transcode them into their national coding system, thus creating the Master Translation/Transcoding Catalogue (MTC).

The MVC and MTC are supported by an EU-wide Central Reference Terminology Server; each Member State needs its own Local Terminology Repository as a copy of its MTC. If an update is made to the Central Reference Terminology Server, the Local Terminology Repositories are notified and updated.

Article 5: Preconditions and responsibilities

Each Member State would be expected to have one "National Contact Point for eHealth" (NCPeH), which is the technical and organisational entity that ensures interoperability across national borders with other Member States and decouples the national infrastructure from other Member States.

The first consequence is that the external interface is standardised, with specifications of protocols, procedures and exchanged documents.

The interface with the national infrastructure is specified at a conceptual level, but each Member State remains free to adopt the most suitable solution to interface the NCPeH with their national infrastructure.

The NCPeHs 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.

The NCPeH performs the basic functional activities related to security management, health professional authentication, patient identification, consent management, document exchange, audit logging and, most relevantly, document semantic transformation between national structure, adopted coding systems and language and the document interchange format of the "Pivot Document".

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

Member States may wish to consider the content of a register of health professionals who are entitled to prescribe and dispense, for instance:

(a) the name and profession,

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

(c) the current address of the health care provider organisation with which the health professional is affiliated or the address of his or her private practice,

(d) the date of issue of the healthcare professional's licence to practice,

(e) the speciality might be recorded as the prescribing of some medicinal products may be restricted.

Member States will need to consider their approach to implementing digital signature services at the eGovernment or eHealth service level in the light of the electronic identification and trust services (eIDAS[17]) regulation adopted in July 2014.

In relation to the ePrescribing scenario, the identification of the health professional will need to be linked to access the data (i.e. confirmation of patient consent) and the authorisations to prescribe. 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.

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 digital ID of health professional and/or health care provider organisation is also used for authentication purposes by a majority of Member States. Similarly, a majority make use of digital signing for health professional/health care provider organisations in their country. In some countries a prescription is not valid without the (electronic) signature of the health professional.

For most Member States, the digital identity of the health professional is coupled to the health professional role, and authorisation for accessing patient information is based on the role, e.g. GP or pharmacist, of the health professional. In most of these Member States, this is based on the *digital* identity of the health professional. In the majority of Member States, the health professional prescribing role or health professional medication dispensing role can be inferred from the digital identity of the health professional.

To be able to link patients with their patient records, the existence of a patient identifier is necessary. For cross-border purposes, a unique patient identifier is also a necessary requirement for each individual patient to be linked to the patient record in the country of origin. Analysis of data shows that most Member States already have a national patient identification number available. In some cases Member States have a regional patient identification number.

Article 6: Organisation of dispensation

Most of the Member States allow ePrescriptions to accommodate multiple dispensations for multiple drugs. There is, however, a gap in code systems able to represent medications with multiple active ingredients.

Member States of treatment shall be responsible for communicating back dispensation in line with the fields identified in Article 5. These may be sent in the form of an XML message.

[17] http://ec.europa.eu/digital-agenda/en/trust-services-and-eid

Chapter III – Technical Provisions

Article 7: Minimum technical requirements for cross-border ePrescriptions

These guidelines focus on the content issues and the description of possible ways to produce this content for cross-border exchange, taking into consideration existing national implementations.

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

The fundamental requirement for exchange of information is to use a structured approach to the recording of information.

Following the clinical rationale that drove the definition of the datasets, the semantic group chose the standards to provide the transport mechanism for the data.

The work in epSOS was based on the following technical components:

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

(b) Extensible Markup Language (XML) as an open and human as well as machine readable standard for exchanging data

(c) HL7 (Health level 7) CDA (Clinical Document Architecture) standards

(d) Medicinal products described using the current Anatomical Therapeutic Chemical (ATC) classification system of active substances in drugs (but note comments elsewhere on the limitations of this approach)

(e) 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.

Interoperability testing

Member States will need to implement software to support cross-border exchange. One option would be to re-use the Open Source components developed in epSOS and released for all in the "JoinUp" EC-supported Open Source Community. These components can be adopted by participating nations and system integrators, to build their own NCPeH solution.

In epSOS, regardless of the adopted solution, all participating nations were required to follow the testing strategies in which:

- The demonstration of compliance with the adopted normative standards (e.g. IHE, HL7) by independent third party(ies) (in epSOS, IHE International via the Gazelle Test Tools and Connectathon interoperability testing events).
- The establishment (at least in the epSOS LSP) of two environments:
    - The Pre-Production Test (PPT) environment for technical interoperability testing and clinical end-2-end validation and quality improvement
    - The Operation environment, where real patients' data is exchanged.

To assure high-quality, safe and secure cross-border implementation, it will be necessary for Member States to agree on testing strategies, possibly with a Europe-wide testing

facility.

Article 8: Minimum technical requirements with regard to data security

The diversity of national and regional healthcare systems, their structures, cultures and roles of health professionals are taken into account by a "common trust model", 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 as guarantors regarding the origin and content of ePrescriptions. National Contact Points already exist in the field of eHealth, such as the epSOS National Contact Points or the National Contact Points according to Article 6 of Directive 2011/24/EU. Member States are free to assign these tasks to entities capable of confirming the professional qualifications of health professionals as well as the authenticity of ePrescriptions. Either existing NCPeHs (according to Article 6 of Directive 2011/24/EU, or established by epSOS) or NCPeH that shall be implemented in future can be entrusted with these tasks.

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.

A high level of IT security is necessary in order to take full account of security principles which follow from Directive 95/46/EC and the specific risks related to the processing of personal data in cross-border healthcare:

- All staff implementing the project should be provided with clear written instructions on how to use the cross-border system appropriately in order to prevent security risks and breaches;
- Suitable arrangements should be made for using prescription storage and archiving systems to protect the data against unauthorised access, theft and/or partial/total loss of storage media;
- For data exchange, secure communication protocols and end-to-end security must be adopted;
- Special attention must be paid to adopting a reliable and effective electronic identification system that provides the appropriate level of assurance (of both participating staff and patients) in compliance with eHN decisions;
- The system must be able to correctly record and track in an auditable way the individual operations that make up the overall data processing;
- Unauthorised data access and/or changes should be prevented when the back-up data is transferred and/or stored;
- In emergency situations, any access should be logged and subject to audit.

For security purposes, the logging of transactions, e.g. a health professional request for a patient summary, is an important feature. Unauthorised access to private medical data can be detected or prevented when a transactions log is available. Logged information in most cases consist of:

- Who has accessed information;
- When information has been accessed; and
- What information was requested.

In most Member States, a tool is used to identify suspicious behaviour or other anomalies based on available logging data. Misuse of private medical data could be detected or even prevented by using this functionality.

Chapter IV – Legal Aspects

Article 9: Data protection

The main challenge faced by epSOS was the great diversity in the implementation of the Data Protection Directive across Member States. It was necessary to establish a "common trust model" governed by a number of privacy, security and safety policies adopted by national health authorities.

The processing of healthcare data must have a clear legal basis. In the absence of other legitimate grounds, this can be the patient's two-step explicit consent (first for participation in general and then at the time of the subsequent encounter with a health professional).

Where requested by the country of affiliation (A) and the country of treatment (B) can make it feasible, it is possible to allow patients to also give their first consent in country B, for instance in a secure way over the Internet.

The processing of personal data must be strictly limited to the minimum required for the fulfilment of cross-border purposes, which must be specified, explicit and legitimate.

In exceptional circumstances, the processing of personal and sensitive data can be justified without second consent in country B (e.g. if in an emergency situation, the data subject is physically or legally incapable of giving his or her consent). In such a case, however, a full audit trail should be maintained. Furthermore, the patient or person acting on behalf of the patient should be informed about the override of consent upon leaving the Point of Care, including details of access, or the patient should be provided with access to audit trails.

Each query about the personal data available through cross-border services should be for a real need of access to specific information related to the care or treatment to be provided or the medicine to be prescribed or dispensed in a particular case.

All data controllers handling cross-border data must notify the competent supervisory authority in accordance with the national legislation, regardless of whether the data subjects are nationals or residents of another Member State and irrespective of whether the data handled originates from data controllers in other Member States.

A data subject should be able to address questions about access and demands for rectification/erasure/blocking to any of the controllers as well as to any other body involved in the exchange of information within cross-border healthcare. A demand for access to or the rectification/erasure/blocking of data which is given to a cross-border partner who does not handle data about the data subject should be forwarded to the data controller in charge within the cross-border system, even if the relevant controller is established in another Member State.

A common cross-border website should provide information on the specific rights of data subjects according to the different legislations of all the participating Member States. The information on the website should clearly specify the rights, conditions and practicalities according to the national legislation of each Member State.

The EXPAND thematic network has developed a "Temporary Legal Agreement (TLA) to upkeep epSOS developed cross-border eHealth services*".*

Agreement on the Data Protection Regulation will provide both clarity and consistency, but is likely to require local actions and agreed cross-border arrangements to ensure compliance.

The proposed general Data Protection Regulation and its subsequent delegated and implementing acts aim to improve consistency and reduce diversity in data protection and rights, including access to personal data and deletion or suppression of sensitive information. As such, it could in the future abolish the need for specific agreements concerning data protection and, in conjunction with the transposition of Directive 2011/24/EU, significantly reduce the scope of such (interoperability) agreements.

Article 10: Patient safety issues specific to these guidelines

The semantic transformation is performed according to the translation, mapping and transcoding performed by designated competent legal entities in the cross-border countries, in which:

- the responsibility for the accuracy and integrity of the process lies with each national designated competent legal entity for such semantic processing;
- liability for errors in the semantic mapping could be a shared cross-border responsibility between the respective Member States and is managed at the level of cross-border healthcare and as part of its trust building framework.

Article 11: Substitution

There is no common definition, process or set of rules across Europe regarding the substitution of medication. In order to aid discussion, the following definitions might be used:

- Generic substitution: occurs when a different formulation of the same drug is substituted. Usually, generic versions of a drug are considered by the licensing authority to be equivalent to each other and to the originator drug. [18]
- Therapeutic substitution: is the replacement of the originally prescribed drug with an alternative molecule with assumed equivalent therapeutic effect. The alternative drug may be within the same class or from another class with assumed therapeutic equivalence.[19]

For the purposes of these guidelines, it is recognised that the substitution is not within the scope of the eHN other than in enabling appropriate information exchange to support the agreed policy.

Within a Member State, national dispensing rules shall apply. Most Member States, but not all, allow generic substitution. For cross-border purposes, it is assumed that the rules of the country where the dispensation is made should be accepted by the prescribing country. This issue will be need to be worked out for clarification of the

[18] Some exceptions might apply such as for biologics, biosimilars, drugs with a narrow therapeutic index and non-interchangeable modified release preparations.

[19] British Journal of Pharmacology, November 2011, 72(5), 727-730

consequences for both sides and proposed in the next version of the guidelines. In formulating these guidelines, some guiding principles have been proposed. Member States may wish to consider these:

- *Therapeutic substitution is not allowed without formal prior consultation with the prescriber. As a consequence, it is not possible to substitute active ingredients, dose, pharmaceutical form and route of administration.*
- *For the countries which do not allow generic substitution or for countries which have put specific limitations on generic prescriptions, it is thus advisable to allow for substitution of package size and/or brand name in these situations:*
    - *in the event of shortages in the pharmacy, where the prescribed product is not available in the country,*
    - *urgency: if the product is available in the country but the pharmacist does not have it at that moment and the patient needs it urgently,*
    - *if the brand name or size is not authorised or commercially available in country B, or*
    - *if the rules of substitution in country B force the change to be made.*
- *In such cases, Country B will decide the brand name or package size to be dispensed according to their own rules of substitution*[20].

Article 12: Storage periods

There is no EU-wide agreement on minimum storage duration for ePrescription and dispensation records but the following proposals may be considered:

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

b) Data according to point a) above shall not be kept for more than 10 years, unless demanded by patients or required by law, e.g. as part of a patient electronic record, in particular for the establishment, exercise or defence of legal claims.

c) Data in the log files is to be stored for the purposes of the pilot and for litigation purposes up to a maximum of 10 years.

Chapter V – Implementation Aspects

Article 13: Evaluation and quality assurance

Each Member State is represented by a National Contact Point (NCPeH). An NCPeH is an organisation legally mandated by the appropriate authority of each Member State to act as a bidirectional technical, organisational and legal interface between the existing different national functions and infrastructures.

The NCPeH is legally competent to contract with other organisations in order to provide the necessary services needed to fulfil the cross-border use cases. The NCPeH is identifiable in both the cross-border domain and in its national domain. It acts as a communication gateway and also as a mediator for legal and regulatory aspects of delivering cross-border services. As such, an NCPeH is an active part of the cross-border

[20] As footnote 18

environment if it is in compliance with normative cross-border interfaces in terms of structure, behaviour and security policy compliance.

Similar recommendations were made by the Article 29 Data Protection Working Party, which subsequently reviewed the cross-border approach and issued a working document on cross-border health services;[21] while the party verified the appropriateness of the adopted measures, it made specific recommendations for sustainability and for reinforcing patient control and transparency.

The organisational setup and procedures for operating the NCPeH is based on the IT Infrastructure Library (ITIL) standards[22]. The selected service and support processes have been deemed a minimum requirement for operating the NCPeHs in a coherent way. It is for Member States to decide the actual implemented operating management framework, provided that the functions described are established and implemented for cooperation between Member States.

Each Member State must have its own national support organisation in place and publish information about the responsible persons. The Member States should be acquainted with the Central Service Desk for managing incidents, problems and changes and the interface between the National and Central Service Desks should be arranged.

All Member States must have ***Incident Management*** in place, including a service desk function. This service desk function may differ from country to country. Incident Management is important for the individual Member State as well as across borders; Member States should be able to contact each other in the event of technical or organisational problems.

Problem Management aims to resolve the root causes of incidents and thus to minimise the adverse impact of incidents and problems on business that are caused by errors within the IT infrastructure, and to prevent recurrence of incidents related to these errors. Member States must have organised ways to solve problems.

Change Management aims to ensure that standardised methods and procedures are used for efficient handling of all changes in the technical setup, in the organisational setup or in practical matters in a Member State. Each Member State must have a documented process for implementing changes of a technical, organisational or practical nature. The change process must include proper planning and ensure that sufficient information has been disseminated to other Member States.

In order to ensure monitoring and evaluation of cross-border services and related interoperability provisions and systems, Member States should:

- consider setting up a monitoring facility for cross-border services to monitor, benchmark and assess progress on technical and semantic interoperability for their successful implementation;
- undertake assessment activities, such as measuring the quantitative and qualitative possible benefits and risks (including economic benefits and cost-effectiveness) of services.

[21] http://ec.europa.eu/justice/data-protection/article-29/documentation/opinion-recommendation/files/2012/wp189_en.pdf

[22] http://www.itil-officialsite.com/

The semantic transformation is performed according to the translation, mapping and transcoding performed by designated competent legal entities in each Member State. The responsibility for the accuracy and integrity of the process lies with each national designated competent legal entity for such semantic processing. The issue of liability for errors in the semantic mapping will need to be considered further.

Article 14: Education and awareness raising

Member States should take steps to engage in education, training and awareness raising. Such an approach would promote the more effective use of health information as patients move between a variety of health care providers, along the continuum of care, and receive treatment and care wherever they are in the Union.

956 **ANNEX A – LIST OF ABBREVIATIONS**

Acronym	Name
CCD	Continuity of Care Document
CDA	Clinical Document Architecture
eHGI	eHealth Governance Initiative
eHN	eHealth Network
EMA	European Medicines Agency
eP	ePrescription
epSOS	European Patient Smart Open Services
HCP	Health Care Provider (i.e. an organisation)
HL7	Health Level 7
HP	Healthcare Professional (i.e. an individual)
IHE	Integrating the Healthcare Enterprise
IHTSDO	International Health Terminology Standards Developing Organisation
ISO	International Standards Organization
LSP	Large Scale Pilot
MoU	Memorandum of Understanding
MS	Member States
MTC	Master Translation/Transcoding Catalogue
MVC	Master Value Sets Catalogue
MWP	Multiannual Work Programme
NCPeH	National Contact Point
PoC	Point of Care
PPT	Pre-Production Test Environment
PS	Patient Summary
SDO	Standards Developing Organisation
STORK	Secure idenTity across-borders linKed
TFEU	Treaty on the Functioning of the European Union
Transform	Translational Research and Patient Safety in Europe
TTP	Trusted Third Party
WHO	World Health Organization

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ANNEX B – USE CASE DESCRIPTION

This section is taken from the epSOS documentation, and is intended only as background information.

It provides an outline description of the responsibilities and actions that are needed per actor (technical and human) involved in the ePrescription service. These actors may be categorised as:

Human actors (individuals):

- Patient: individual for whom the healthcare professional (HP) decides to prescribe a medicine or who requires dispensing of medicine(s) prescribed in a country participating in the epSOS project.
- Prescriber: legally authorised HP who prescribes medicine(s) to be dispensed to the patient by means of his/her prescription provider.
- Dispenser: legally authorised HP who dispenses medicine(s) to the patient fulfilling a prescription issued by a prescriber.

System actors (information system or provider such as those used to prescribe, dispense, process or convey information across borders):

- Prescribing provider: information provider used by the prescriber to identify himself or herself and to order prescriptions. This actor is a concept of a system that contains all health information and is not intended to match any physical or technical implementation as in each country these functions may be implemented in a different way.
- Dispensing provider: information provider used to identify the dispenser and to retrieve available and non-fulfilled prescriptions and to update information on the medicine(s) dispensed. This system is a logical entity and is not intended to match any physical implementation.
- National Contact Point or NCPeH. This entity deals with the following:
    - Semantics to solve the issues related to translation between different coding systems and different nomenclatures
    - Identification of patients and identification and authentication of HCPs
    - Conveying information to and from prescribing and dispensing systems and logical nodes of other countries
    - Legal aspects

    This actor is responsible for assuring the security, reliability and availability of information and for complying with national and international regulations and laws. All the information needed for the use cases is made interchangeable by means of the National Contact Points in both countries.

The following table outlines the direct interaction between human actors and technical actors in the ePrescription service:

Table 1 Human and technical relationships

System actor	Human actor
Prescribing provider	Prescriber
Dispensing provider	Dispenser
NCPeH	NA

Description of the use case and requirements

The objective of this section is to describe the use case and the requirements that will need to be fulfilled to ensure a secure interoperable scenario. This includes the knowledge required (not just data) and requirements about how to access and obtain information.

Use case: Medicine already prescribed in Country A

Sequence diagram of use case

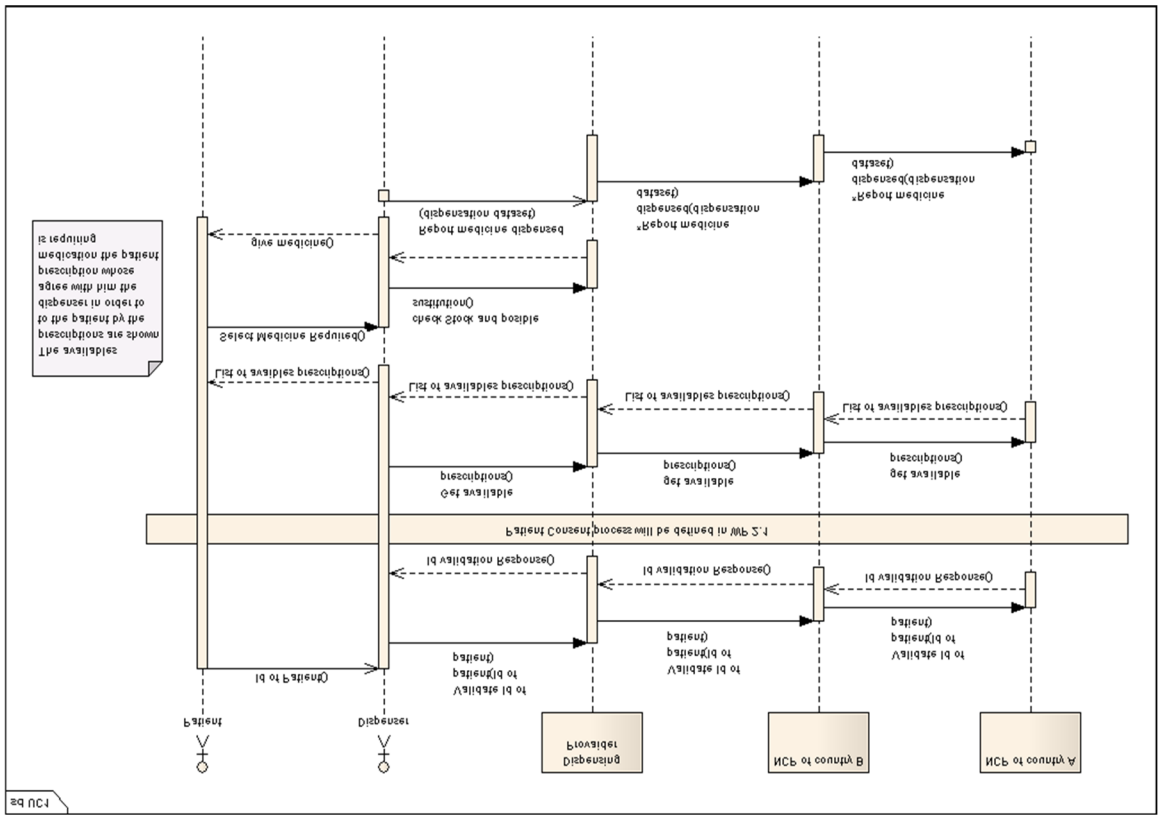


Figure 2: Sequence diagram use case

This use case describes the dispensing of medicine(s) in Country B when the medicine(s) has (have) been prescribed in a different country (Country A). In this case, Country A is also the country where the patient can be univocally identified.

In order for the use case to take place, several preconditions are needed:

- The patient has already been electronically prescribed medicine by a prescriber authorised to prescribe in Country A.

- In Country B, a mechanism to validate the identity of the patient has to be available at the pharmacy or in a hospital and the dispenser is a person legally authorised to dispense medicinal products.

In order to obtain the information required in Country B, the Prescribing Provider in Country A must make accessible at least the 'available' prescriptions to be sent or requested by another country. This implies that Country A is able to calculate the 'available' prescriptions (it has the necessary information or parameters to select the prescriptions that can be dispensed at that moment).

Country A must provide, maintain and support a logical country node (NCPeH) supporting communication of the information identified in this section with Country B and vice versa and there must be a chain of trust between system actors in this process.

If these preconditions are met, the use case can take place and the first thing the patient needs to do is to identify himself or herself to the dispenser. The dispenser has to check if this identification is valid through his or her Dispensing Provider before accessing any data. In order to avoid legal issues, it is imperative that the patient is univocally identified so that his or her identity can be assured with certainty. The appropriate method to achieve this will be specified later on in the corresponding work package.

Once the patient has been identified, the dispenser needs to obtain the patient's consent before accessing any data during this specific encounter. After the encounter, the pharmacist will need to obtain new consent to access any data about the patient.

In order to select the prescription requested by the patient, the list of, at least, 'available' (and thus, valid) prescriptions from Country A has to be presented to the dispenser and the patient. These prescriptions are provided by Country A according to the rules that apply in its health system, meaning that only a prescription that can be dispensed in Country A at that moment is available for dispensing in Country B.

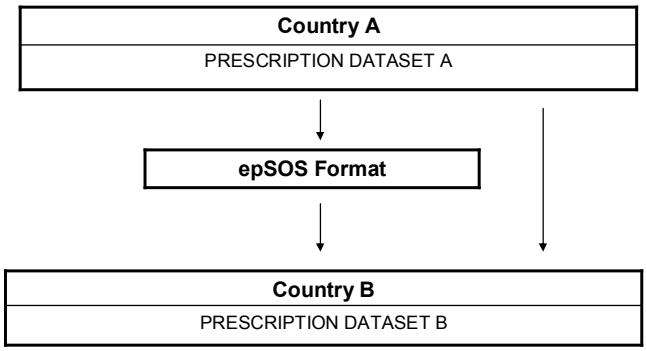
The prescription has to be valid (time validity) and also be within the permitted slot of time to collect it from the pharmacy in Country A (in some countries, mainly with long term treatments, prescriptions can only be collected from the pharmacy on specific dates to help the patient to correctly administer the medicine(s)).

Apart from the 'available' prescriptions, Country A could also send, if allowed there, the current prescriptions (this information may be contained within the Medication Summary) to the dispenser in Country B to enable him or her to consult that information (e.g. to check possible interactions).

In order to allow the dispenser to understand the information, this must be intelligible to him or her (structured, equivalent meaning and understandable), presented in his or her system as it is normally presented and contain all the information required to identify the right medicine.

As the medicinal products are not the same in the different countries, they will need to be translated identifying the active ingredient (and not the brand name) as it is the common nomenclature. The following scenario is assumed in the process of sending the prescription dataset from Country A to Country B:

Data set interoperability



The information that Country A sends to Country B will be converted to a common [epSOS] format to be sent to Country B. Country B will then receive the prescription dataset of Country A in this common format. This format will then need to be translated to a single concept in Country B (if a single prescription is issued in Country A, it is not possible to issue several prescriptions for practical reasons in Country B and one of the brand names should then be selected from all those available in Country B; the same applies to items within the prescription). As in most cases, if the same medicinal product does not exist (this document covers different brand names and/or sizes of package) in both countries, Country B will translate its single code into a medicinal product that exists there: (brand name (different from the original) + strength + pharmaceutical dose form + package size (that can be different from the original) + mode of administration (different from the original)) and that is different from the one prescribed in Country A. For security reasons, Country B must also receive the prescription dataset A in Country A format so that the original prescription is available in Country B. This "copy" of the unchanged original prescription from Country A may be used for a manual security check in Country B.

Country A medicinal product	**Country A (single concept)**	**epSOS format**	**Country B (single concept)**	**Country B medicinal product**
Termalgin 500mg **30** cap	Paracetamol 500mg 30 cap	xxx	Paracetamol 500mg 30 cap	Paracetamol **Tesco** 500mg **20** cap

A number of issues may arise when translating the medicine from Country A to Country B. The different possibilities are described:

- In Country B the exact medicine exists, meaning that the exact same following elements are found: active ingredient+strength+pharmaceutical dose form+package size. The dispenser then dispenses the medicine.
- In Country B the medicine does exist but in a different package size. The dispenser might then dispense another size (smaller or bigger) according to Country B rules or legislation. The consequence of changing the package size affects the use case at different levels:
    - The patient receives less medicine than required
    - If Country A prescribes prescriptions for long term treatments, this will affect the update of the prescription (to calculate the new credit).
    - The countries need to be able to recognise or translate the original medicine independently of the package size so it can be changed (if WP3.5 'Semantic Services' decides to codify several fields – group them – in a single code (e.g. active ingredient+strength+…=1234), the package size cannot be part of this single code to allow substitution).
- In Country B the medicine does not exist, meaning the active ingredient or strength or pharmaceutical dose form is not the same. In this case, the dispensing is not possible as substitution of any of these three elements is outside the scope of the epSOS LSP. The dispenser has to see and be aware that there is an available prescription but that it cannot be translated into a medicinal product in Country B as the active ingredient or the strength or the pharmaceutical dose form is not the same.

Once the patient and the dispenser agree on the prescription (in order to do so, both have to understand the information), it is dispensed according to Country B legislation (this is subject to the contractual agreements to be signed for the pilot operation) and the information about the medicine dispensed must be sent to Country A. This information must allow the relevant prescription to be identified so that it can be updated and must reflect factors such as package size substitution.

ANNEX C – EPRESCRIPTION DATASET

This Annex provides further information on the data items in the proposed dataset as well as a number of comments based on epSOS' experiences.

Fields	Field description	Notes from epSOS
A.1 Core data elements		
A.1.1 Identification of the patient		
A.1.1.1 Surname	Surname of the patient. The part of a name a person usually has in common with some other members of his/her family, as distinguished from his/her given names [ISO TS 22220].	
A.1.1.2 Given name	Given name of the patient (also known as first name). The subject's identifying name(s) within the family group or by which the subject is uniquely socially identified [ISO TS 22220].	
A.1.1.3 Date of birth	The date of birth of the patient [ISO TS 22220]. Information regarding the age of the patient should be noted. This can either be the date of birth and/or the actual age of the patient. Since age affects drug ADMET (absorption, distribution, metabolism, excretion and toxicity) parameters, this is important for the choice of drug and drug dosage.	
A.1.1.4 Personal identifier	A machine-readable identifier of the patient that is unique within a defined scope	
A.1.1.5 Gender	Gender is the biological distinction between male and female [ISO TS 22220]. The gender of the patient may be noted on the prescription since this can be important for gender specific effects of drugs, contra-indications etc.	Should be mandatory
A.1.2 Authentication of the prescription		
A.1.2.1 Prescription ID	A unique string generated by an EPS (Electronic Prescribing System) to uniquely identify a prescription. The prescription should receive a unique identifying code for traceability. It might additionally be used to register whether a prescription, and/or the maximum number of repeats, has already been dispensed to prevent patients from receiving medicines several times using the same prescription.	In epSOS: - Prescription item ID: mandatory - To identify each prescribed medicinal product in the eP A specific process is set up in epSOS to deal with eP with multiple items, and multiple and single eD

A.1.2.2 Issue date	The date and optionally the time the prescription was issued by the prescriber. The date and time should be known in order to be able to conduct checks on medication safety as well as reimbursement of the prescribed drug(s) and whether the prescription is still valid to trigger a dispensing event.	
A.1.3 Identification of the prescribing health professional		
A.1.3.1 Surname	The prescription should state the family name/surname/last name of the prescriber. This enables the prescriber to be traced in the event of questions or emergencies.	
A.1.3.2 Given name	The prescription should state the given name/first name of the prescriber. This enables the prescriber to be traced in the event of questions or emergencies.	[AT] In some cases only the name of the medical organisation will be used instead of the name of the health professional.
A.1.3.3 Professional qualifications	The professional title of the prescribing health professional which may be used to prove the authority of the prescriber. Note: in some countries, a nurse or midwife might not possess a professional title, but may still be entitled to prescribe (certain) drugs.	Profession: compulsory, speciality: optional
A.1.3.4 Details of direct contact	Details of direct contact could be an address and/or phone/fax number of the prescriber in order for the dispenser and/or patient to contact the prescriber. This might be necessary if problems arise with dosage, allergies, reimbursement etc.	This is optional in epSOS: hard to contact a GP in another country in real time
A.1.3.5 Work address	This is the address of the hospital or the private practice where the health professional normally works, meets patients and prescribes medication.	This is optional in epSOS. Furthermore, as expressed, it is a duplication of A.1.3.5. epSOS distinguishes between Prescriber (1.3.5) and Prescriber Organisation (1.3.6).
A.1.3.6 (Digital or electronic) signature	Most countries require by law either a handwritten signature or a digital token as proof of the authenticity of the prescriber. A digital signature is an approved authentication token necessary to comply with national laws on prescribing medicines. A prescribing message or document without this signature can only be regarded as a notice of the actual (paper) prescription.	Not supported by epSOS: it should at least be optional Business process issue – time consuming – user acceptance
A.1.3.7 Health care provider identifier (HCPI)	A unique number or code issued for the purpose of identifying a health care provider [ISO/TS 27527:2010]. A unique identification code that can be used to trace the prescriber at all times. This may be a licence or registration number that can be used to uniquely identify the prescriber. This can be used to check whether a drug was prescribed by the right person according to the law.	
A.1.4 Identification of the prescribed product		
A.1.4.1 Name of the item	An identification of the medicinal product [i.e. any substance or combination of substances that may be administered to human beings for treating or preventing	Some MS were pushing to exclude this concept because, in their view, it could increase

	disease, with a view to making a medical diagnosis or to restore, correct or modify physiological functions] that is prescribed to the patient. In addition, information may be included regarding the possibility to replace the prescribed product with an alternative equivalent product. Note: the term product includes pharmaceutical products (branded medicinal products, generic/scientific name medicinal products or pharmaceutical preparations [ISO 21549-7:2007]) or non-pharmaceutical products.	ambiguity and cause patient safety issues. Are names of medicinal products unique in Europe? Would the (additional) usage of a unique ID be better? Magistral medicinal products don't usually have "names" => problem if mandatory.
A.1.4.2 Identifier of the item	Medicinal product manufactured in a pharmacy or pharmacy department, which is based on a recipe and is intended to be used for one and only one subject of care [ISO 21549-7:2007]. Note 1: a magistral/extemporaneous medicinal product is also a pharmaceutical product. Note 2: the term extemporaneous medicinal product is not to be used, as it is more appropriate for describing a medicine processed during the administration of a medicinal product, especially when a mixture is made just before, for example, intravenous administration. Information about the constituent ingredients if the prescription concerns an extemporaneous preparation or compound medicine.	Outside scope of epSOS
A.1.4.3 Strength of the item	The content of the active substances expressed quantitatively per dosage unit, per unit of volume or weight according to the dosage form. [Article 1 of Directive 2001/83/EC] Note: strength of the medicinal product may also be derived from the element 'dose regimen'. If for example the prescription contains a statement such as 'take 10mg 3x daily for 9 days' the strength can be derived from this. In such circumstances, strength may not be provided separately.	It cannot be expressed separately from A.1.4.1 because the strength/dilution as a ratio should be provided for each active ingredient in compounds.
A.1.5 Prescription information		
A.1.5.1 Pharmaceutical formulation	The formula in which the prescribed medicinal product is/will be administered (e.g. Tablet, solution, ointment)	It should describe compounds and moiety.
A.1.5.2 Quantity	Total quantity or volume of the medicinal product that is prescribed Note 1: in some cases quantity might be derived from element 1.5.3 Dose regimen. In this case, the quantity does not need to be stated separately. Note 2: depending on national legislation, this quantity may or may not be dispensed in one dispensation.	This is a complex concept: simple in the case of pills, more complex for liquids. Very various and complex for packs of packages (e.g. 10 syringes of 1 ml).
A.1.5.3 Dose regimen	The regimen governing the dose quantity per single administration, the dose frequency, the route of administration and/or speed of administration (in the event of intravenous administration).	Few MS have it. Even less as coded element: optional in epSOS

	Note: this information may be used by the dispenser to calculate the quantity to be dispensed.	
A.1.5.4 Duration of treatment	Start and/or stop time of treatment	
A.1.5.5 Directions for use	Details about the directions for use of the prescribed medicinal product, such as 'with food' or 'before a meal') and any cautionary advice for correct use of the prescribed drug by the patient	Nearly none has this as a coded concept
A.1.5.6 Pharmaceutical preparation description	This also includes extemporaneous preparation, compounded medication and magistral preparation.	
A.2 Optional elements of prescription		
A.2.1 Identification of the patient		
A.2.1.1 Address details	The address details of the patient. In some countries (e.g. Germany) it is sometimes required that the patient's address details are included on the prescription.	
A.2.1.2 Native language [could be taken from the ISO language table (ISO 639.2 or ISO 639-3)]	The native language of the patient. This may be important for the information that is given to the patient regarding use of the prescribed product [N1228 ISO NP TS 17251]. This could be taken from the ISO language table (ISO 639.2 or ISO 639-3 for three character list of languages) or another language specification code system.	Native language of whom? The patient? The prescriber? Country of origin of the eP is mandatory, not optional
A.2.2 Patient characteristics		
A.2.2.1 Body weight	The weight of the patient. This can be important for calculating the BMI used for dosage calculation, e.g. oncology medication, or also body surface for other specific medications; this will need to specify units of measure.	
A.2.2.2 Body height	The height of the patient. This can be important for calculating the BMI used for dosage calculation, e.g. oncology medication; this will need to specify units of measure.	
A.2.2.3 Drug allergies and drug sensitivities	Information regarding allergies and sensitivities to medicinal products (e.g. certain antibiotics), drug groups and both active and non-active ingredients may be noted.	
A.2.2.4 Patient conditions	Conditions that affect the use of medicinal products, such as renal/hepatic failure, pregnancy and pharmacogenetic profile. Some medicinal products may alter fertility, harm an unborn child or affect a child via breastfeeding. This may result in another (type of) medicinal product being dispensed and/or modification of the dosage regimen. This may also be important when the person is intending to become pregnant. Note 1: in some countries a change of the medicinal product or modification of the dosage regimen does not lie within the competence of the dispenser. Note 2: in some cases the effect on fertility or pregnancy has not yet been scientifically	

	established.	
A.2.3 Prescription information		
A.2.3.1 Starting date of therapy	The time and date on which it is agreed that therapy will start	End of the therapy is also an optional item of data in epSOS
A.2.3.2 Prescription expiry date	The date and optionally time when the prescription is considered to have expired. This might be dependent on local or national policy or legislation, in accordance with the treatment plan or because the therapeutic need for the prescribed medicine has expired. In some countries (e.g. Germany) legislation is so clear that it is not necessary to include it in the prescription.	
A.2.3.3 Repeats	Whether an issued prescription allows for several repeating dispensations [5]. In some countries, when medicinal products are dispensed for the first time, the patient may only receive medication for a short period of time. When a patient starts taking medication for a chronic illness, the prescriber can issue a prescription for a longer period that is now separated by repeats. In addition, the maximum quantity (A.1.4.3) of the prescribed product that may be dispensed in one dispensation may be stated here.	
A.2.3.4 Minimum dispensing interval	If an issued prescription allows for several repeating dispensations (A.1.4.6), the minimum time interval between dispensations should be stated here [e.g. 5]. This can be important in the case of medicinal products of which patients are prone to take overdoses, e.g. opioids.	
A.2.3.5 Reason for prescription	The reason why the medicine is being prescribed, including the option to mention that the medicinal product is being prescribed for 'off label' use. The reason for the prescription gives the dispenser the opportunity to review the prescription for medication safety issues. Note: in some countries it is obligatory to state the reason for prescription on the prescription itself for some or all medicinal products. An example of this in the Netherlands is the prescription of methotrexate, since the indication for which it is used in the Netherlands (chemotherapy or rheumatoid arthritis) greatly impacts both strength and dose interval of the medication.	Conceptually fine, but extremely various and complex, and so de facto not coded hence not transferrable by anyone
A2.3.6 Substitution	Substitution handling can be recorded as a code (not a flag!) to indicate whether and to what extent substitution is allowed by the prescriber.	

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ANNEX D – EXAMPLE STANDARDS AND PROFILES

This Annex provides reference information on standards and profiles.

ISO Identification of Medicinal Products (IDMP) standards

- ISO 11615:2012 - Identification of medicinal products -- Data elements and structures for the unique identification and exchange of regulated medicinal product information (http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=55034)
- ISO 11238:2012 - Identification of medicinal products -- Data elements and structures for the unique identification and exchange of regulated information on substances (http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=55031)
- ISO 11616:2012 - Identification of medicinal products -- Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information (http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=55035)
- ISO 11239:2012 - Identification of medicinal products -- Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging (http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=55032)
- ISO 11240:2012 - Identification of medicinal products -- Data elements and structures for the unique identification and exchange of units of measurement (http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=55033)

The IHE Pharmacy ePrescription specifications may be found as follows:

ePrescription workflow:

http://www.ihe.net/uploadedFiles/Documents/Pharmacy/IHE_Pharmacy_Suppl_CMPD.pdf

ePrescription content:

http://www.ihe.net/uploadedFiles/Documents/Pharmacy/IHE_Pharmacy_Suppl_PRE.pdf

The exchange specification is based on the epSOS Common Components Specifications [4] using IHE profiles XCPD [5], XCA [6], XDR [7] and optionally XCF [8].

References

[1a] Work Package 3.9 – Appendix B1/B2 epSOS Semantic Implementation Guidelines: http://www.epsos.eu/uploads/tx_epsosfileshare/D3.9.1_Appendix_B1_B2_Implementation_v1.4_20110725.pdf

[1b] epos Deliverable 3.9.1 B1 ERRATA/CORRIGE and known issues:
https://service.projectplace.com/pp/pp.cgi/r911404315

[2] Clinical Document Architecture Release 2:
http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7

[3] IHE Patient Care Coordination Technical Framework
http://www.ihe.net/uploadedFiles/Documents/PCC/IHE_PCC_TF_Vol2.pdf

[4] Work Package 3.4 - epSOS_Common_Components_Specification_01

http://www.epsos.eu/uploads/tx_epsosfileshare/D3.4.2_epSOS_Common_Components_Specification_01.pdf

[5] IHE IT Infrastructure Technical Framework Supplement - Cross-Community Patient Discovery (XCPD)
http://www.ihe.net/Technical_Framework/upload/IHE_ITI_Suppl_XCPD.pdf

[6] IHE IT Infrastructure Technical Framework Supplement - Cross-Community Access (XCA) http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol1.pdf

[7] IHE IT Infrastructure Technical Framework - Cross-Enterprise Document Reliable Interchange (XDR)
http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol1.pdf

[8] IHE IT Infrastructure Technical Framework Supplement - Cross-Community Fetch (XCF) http://www.ihe.net/Technical_Framework/upload/IHE_ITI_Suppl_XCF_Rev1-1_TI_2011-08-19.pdf

ANNEX E – CRYPTOGRAPHIC ALGORITHMS

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 tailors the selection to 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 programmes of the Federal Government)