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GUIDELINE

on

the electronic exchange of health data under Cross-Border Directive 2011/24/EU

Release 2

ePrescriptions and eDispensations

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1. USE CASE DESCRIPTION

1.1. Cross-border ePrescription and eDispensing

The electronic prescription and dispensing of medications can have different Use Cases on different organisational scales, and each scale presents a different organisation of the process. The information below is taken from the Antilope report and relates to cross-border exchange of data.

Purpose	To support the processes of prescription and dispensation through the electronic exchange of supporting data for citizens who are travelling inside Europe, where a patient from Country A (the patient's country of affiliation) is seen in another Member State Country B (the country of treatment)
Relevance	This Use Case represents a high level of consensus on what constitutes European eHealth services, as this Use Case was described by Directive 2011/24/EU of 9 March 2011 on the application of patients' rights in cross-border healthcare. Benefits in both medical and economic terms can be gained from increased quality of care (e.g. improved patient safety) when citizens are travelling abroad and are still able to pick up (lost/forgotten/other necessary reasons) medication and to decrease the effort of gathering/exchanging health information.
Domain	Medication
Situation	Cross-border
Context	• ePrescribing is defined as a prescriber's ability to electronically send an accurate, error-free and understandable prescription directly to a pharmacy from the point-of-care (www.cms.gov). • eDispensing is defined as the act of electronically retrieving a prescription and reporting on giving the medicine to the patient as indicated in the corresponding ePrescription. • Once the medicine has been dispensed, the dispenser will report, via software, information about the dispensed medicine(s) to the prescription provider. To appropriately define the context of the Use Case relevant aspects requires consideration. These include: • The different legislative contexts in the various European countries have led to the decision that information about a newly prescribed medicine, in a country visited by a patient, will not be transferred back to the country in which the patient resides.
Information	Consent – information about patient's consent Prescription – information necessary to prescribe the medication Dispense – information about the dispensed medicine(s)
Participants	Prescriber – person responsible for the prescription of medication Dispenser – person who can hand over the medication to the patient Patient – person who gives consent and requests medication
Functional process steps	• (With the reservation that preconditions are met) • The patient visits a health professional and may give his/her consent to share his/her medical information in country A • The patient may alternatively provide his/her consent electronically in an electronic record system held in his/her country of origin

	• The patient then travels abroad where s/he requires medication in another country (B) • S/he visits a pharmacy in country B • S/he identifies himself/herself to the pharmacist/staff at the pharmacy • Pharmacist is identified, authenticated and authorised • The patient asks for his/her ePrescription. By doing so, the patient gives the dispenser/pharmacist his/her consent to access his/her personal information • The pharmacist requests the patient's ePrescription via the pharmacy's computer in a secure way • The prescription is received by country A via the eHNCP. The eHNCP checks patient consent, is translated by the semantic services and sent back to the eHNCP of country B • Pharmacist receives the ePrescription both translated into his/her own language and as an original copy of the prescription • The requested medication is then dispensed to the patient • The dispensed medicine information is sent back to country A, in real time and immediately after the medicine has been dispensed.

Table 1: General information about cross-border exchange of data (Antilope report)

2. GUIDELINES FOR EPRESCRIPTIONS AND EDISPENSATIONS

THE MEMBER STATES in the eHealth Network HAVE ADOPTED THESE supplementary clauses to the general guidelines for the electronic exchange of health data under Cross-Border Directive 2011/24/EU to support exchange of ePrescription and eDispensation data.

Chapter I – General Considerations

Article 1: Objectives 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. 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.

3. These guidelines do not cover medical devices; the guidelines do not cover non-pharmaceutical products.

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.[1]

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 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) 'Medicinal prescription' means any medicinal prescription, as defined by Article 1 (19) of Directive 2001/83/EC[2], issued by a professional person qualified to do so.

e) 'Medicinal product' means

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

[1] See supporting detail in Article 6; the aim is that the ePrescription must be updated. This should be done in real time and immediately after the medicines have been dispensed and certainly before another dispensation can take place.

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

o 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.

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.

Article 3: Concept and intended use

1. These guidelines operate within the context of the guidelines for cross-border data exchange.

Chapter II – Legal and Regulatory Considerations

Article 4: Data protection

There being no specific additional requirements, reference is made to the provisions defined in the general guidelines.

Article 5: Authorisation, authentication and identification

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

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

(b) on the health professionals/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: Patient safety

There being no specific additional requirements, reference is made to the provisions defined in the general guidelines.

Chapter III – Organisational Considerations

Article 7: Enablers for implementation

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.

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

Article 8: Quality standards and validation

1. In order to assure safe implementation, particularly patient safety and data protection and further development of cross-border 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 9: Education, training and awareness

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, healthcare professionals, health institutions, insurers and other stakeholders;

(b) consider recommendations for education and awareness raising measures targeting health policymakers and health professionals/health care providers;

(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.

Chapter IV – Semantic Considerations

Article 10: Data

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[3] published in June 2016. 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 B.4 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.

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[4]	
A.1.4.1 Name of the item [+ identifier as described in ISO IS 11615]	☐
A.1.4.2 Name of the item [+ 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	☐

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

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

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[5]	
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	

Table 2: ePrescription dataset

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 eHealth National Contact Point for the respective recipient (this should be done in real time and immediately after the medicines have been dispensed):

Identification number of the dispenser
Name of dispenser
ISO 3166 country code of the dispenser
Address of the dispenser
Personal identification number of the patient, together with the ISO 3166 country code
Identification number of the prescription
Items dispensed

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

Article 11: Terminology

1. There is a particular issue regarding the identification of medicinal products. It is expected that the coding schemes currently included within the dataset will be replaced by identifiers developed using the IDMP set of standards. The European Medicines Agency is leading work on this; further details will be provided in due course.

Article 12: Master Catalogue

There being no specific additional requirements, reference is made to the provisions defined in the general guidelines.

Chapter V – Technical Considerations

Article 14: Technical requirements

1. For cross-border exchange, the format of the document for exchange will be the CEF specification, as shown in Annex B.5. Further work will be needed to review this.

Article 15: Security

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

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

Article 16: Testing and audit

There being no specific additional requirements, reference is made to the provisions defined in the general guidelines.

Article 17: Amendments to the guidelines

The eHealth Network is responsible for updating the guidelines, which are addressed to Member States.

3. 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 general guidelines.

Chapter I – Scope and Definitions

Article 1: Objectives 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.

Article 2: Definitions

Formal definitions are provided in Article 2 in section 2 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: Concept and intended use

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 – Legal and Regulatory Considerations

Article 4: Data protection

Each query about the personal data available through cross-border services should be for a real need for access to specific information related to an ePrescription or eDispensation relating to the care or treatment to be provided.

Article 5: Authorisation, authentication and identification

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 since 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[6]) regulation adopted in July 2014.

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: Patient safety

There being no specific additional requirements, reference is made to the provisions defined in the general guidelines.

Chapter III – Organisational Considerations

Article 7: Enablers for implementation

There is no common definition, process or set of rules across Europe regarding the substitution of medication. In order to aid discussion, the following definition might be used: "Generic substitution" occurs when a different presentation 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. [7]

The Horizon 2020 OpenMedicine project is investigating the issues around substitution and is expecting to make recommendations on the topic. OpenMedicine has found no evidence of therapeutic substitution.

For the purposes of these guidelines, it is recognised that 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 need to be worked out for clarification of the 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:

- *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,*

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

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

- *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 its own rules of substitution*[8].

There is no EU-wide agreement on minimum storage duration for ePrescription and eDispensation 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 cross-border exchange and for litigation purposes up to a maximum of 10 years.

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.

Article 8: Evaluation and quality assurance

There being no specific additional requirements, reference is made to the provisions defined in the general guidelines.

Article 9: Education and awareness raising

There being no specific additional requirements, reference is made to the provisions defined in the general guidelines.

Chapter IV – Semantic Considerations

Article 10: Data

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 a Europe-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

[8] As footnote 18

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 B.4 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.

Article 11: Terminology

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")[9]: the so-called 'Article 57 database'. EMA has also suggested, in agreement with the National Regulatory Agencies, to start the aforementioned use when the ISO IDMP adoption process reaches a significant level of completion. Member States will work with the EMA and the European Commission to progress this.

Section 6 provides a possible formulation for the revised medicinal product information.

Article 12: Master Catalogue

There being no specific additional requirements, reference is made to the provisions defined in the general guidelines.

Chapter V – Technical Considerations

Article 13: Technical requirements

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.

Article 14: Security

There being no specific additional requirements, reference is made to the provisions defined in the general guidelines.

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

Article 15: Testing and audit

Member States will need to implement software to support cross-border exchange. One option would be to re-use the Open Source components maintained by the OpenNCP community under the eHDSI. These components can be adopted by participating nations and system integrators to build their own EHNCP solution.

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.

4. ePRESCRIPTION DATASET

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

Fields	Field description
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]. This can 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.
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; this unique code is needed for traceability. It might be used to register whether a prescription, and/or the maximum number of repeats, has already been dispensed.
A.1.2.2 Issue date	The date and optionally the time the prescription was issued. 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.
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.
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.

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.
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.
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]; this may be a licence or registration number which can be used to trace the prescriber and 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 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 equivalent alternative. Note: the term product includes pharmaceutical products (branded medicinal products, generic/scientific name medicinal products or pharmaceutical preparations [ISO 21549-7:2007]) and non-pharmaceutical products.
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.
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.
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)
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.
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). 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	Information 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
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
A.2.1.2 Native language [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 or another language specification code system.
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 as above.
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
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.
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.
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.

Table 3: ePrescription dataset with further information on data items in the proposed dataset including comments based on MS' experiences

5. STANDARDS AND PROFILES

This section provides reference information on standards and profiles.

Reference is made to three classes of material:

Background requirements and explanatory material

https://ec.europa.eu/cefdigital/wiki/x/30QZAg

Formal technical and semantic specifications

https://ec.europa.eu/cefdigital/wiki/x/30QZAg

Formal terminology bindings

https://ec.europa.eu/cefdigital/wiki/x/30QZAg

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)

6. POTENTIAL REFORMULATION OF MEDICINAL PRODUCT INFORMATION

A.1.4 Identification and description of the prescribed product	[10]
A.1.4.1 Pre-IDMP identification of the product as originally prescribed in the national prescription	note 1
A.1.4.1.1 Product name	
A.1.4.1.2 Substance name	
A.1.4.1.3 Strength of the item [Article 1 of Directive 2001/83/EC]	
A.1.4.1.4 Pharmaceutical dose form[11]	
A.1.4.2 IDMP identification of the product	note 2
A.1.4.2.1 Identification of the packaged product as per ISO IS 11615	
A.1.4.2.1.1 Identifier PCID (as issued by EMA) and code system	
A.1.4.2.1.2 Name	
A.1.4.2.2 Identification of the medicinal product as per ISO IS 11615	
A.1.4.2.2.1 Identifier - MPID (as issued by EMA) and code system	
A.1.4.2.2.2 Name	
A.1.4.2.3 Identification of the pharmaceutical product as per ISO IS 11616	
A.1.4.2.3.1 Identifier - PhPID (as issued by EMA) and code system	
A.1.4.2.3.2 Name	
A.1.4.2.4 Identification of the substance as per ISO IS 11238	
A.1.4.2.4.1 Substance identifier (as issued by EMA or another authority) and code system	
A.1.4.2.4.2 Name	
A.1.5 Characteristics of the product (for purposes of identification or finding equivalents, etc.)	
A.1.6 Prescription information	
A.1.6.1 Administrable dose form[12]	
A.1.6.2 Quantity	
A.1.6.3 Dose regimen 1..N	
A.1.6.4 Duration of treatment (start and/or stop time)	
A.1.6.5 Directions for use	
A.1.6.6 Pharmaceutical preparation description	

Table 4: Potential reformulation of medicinal product information

Note 1: Product name and substance should be used until such a time as the ISO IDMP identifiers are available. After the implementation of the IDMP, these identifiers may be preserved but must be complemented with the IDMP identifiers.

Note 2: At least one of the IDMP identifiers should be available. The identifier is needed and the name is optional.

[10] At least one of the IDMP identifiers MUST be available, and possibly the national identifier.

[11] This is the form in which the product is available commercially.

[12] This is the form in which the product is supposed to be administered. It may differ from the pharmaceutical dose form.