eHealth Network

GUIDELINE

on

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

Release ~~2~~
~~ePrescriptions~~3

ePrescription and ~~eDispensations~~

eDispensation
of Authorised Medicinal Products

The eHealth Network is a voluntary network, set up under article 14 of Directive 2011/24/EU. It provides a platform of Member States' competent authorities dealing with eHealth.

For eHealth Network adoption, Paris, 1 June 2022

eHealth Network guidelines

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- 1) 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.

(2)

1. Use Case Description

This use case represents a high level of consensus on what constitutes European eHealth services necessary to facilitate the recognition of electronic prescriptions in cross-border scenarios, as this use case was described by Directive 2011/24/EU of 9 March 2011 and Implementing Directive 2012/52/EU of 20 December 2012.

Use case description:

Title	ePrescription and eDispensation on a cross-border scale
(3) Purpose	(4) To support the processes of prescription and dispensation through the electronic exchange of supporting data for ~~citizens~~patients who are travelling inside Europe, where a patient with an ePrescription from ~~Country A (the patient's~~ one country (country of ~~affiliation~~prescription) is ~~seen~~retrieving medication in another Member State ~~Country B (the~~ (country of ~~treatment)~~dispensation). As information sharing is not limited to the cross-border use case, Member States could also use these guidelines for national and regional level interoperability to ensure consistency as well as avoid fragmentation and duplication of efforts.
(5) 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.~~ (6) Benefits in both medical and economic terms can be gained from increased quality of ~~care~~healthcare (e. g. improved patient safety) when ~~citizens are travelling abroad~~patients move within the European Union 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 (potentially inter-regional or national)
Context	• ePrescribing is defined as ~~a prescriber's ability~~prescribing medicines through the support of software by a health professional who is legally authorised to ~~electronically send an~~ • ~~accurate, error-free and understandable prescription directly to~~do so, so that the medicine can be dispensed by a pharmacy[1] ~~from the point of care ().~~; • eDispensation (eDispensing) is defined as the act of electronically retrieving a prescription and reporting on ~~giving~~the dispensation of 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.~~In Release 3 of this guideline additions were made to fill in existing gaps and to address progress made in the implementation of ISO IDMP as well as adding preferred code systems (see section 4). Lessons learned from national implementations of ePrescriptions and from cross-border settings are that a great variety of data standards is in place in Europe. This guideline is therefore seen as an approach to provide a high level conceptual structuration of data which supports a data exchange for ePrescription as the future goal for cross-border health care. It is to be acknowledged though, that not all preferred code systems are fully in place yet.
Information	~~Consent – information about patient's consent~~ • ~~Prescription~~ Personal information necessary to ~~prescribe~~access ePrescription • Prescription information necessary to dispense the medication • ~~Dispense~~ Information about the ~~dispensed medicine(s)~~dispensation
Participants	• Prescriber ~~– person responsible for the~~ in country of prescription ~~of medication~~ (Country A) • Dispenser ~~– person who can hand over~~in country of dispensation (Country B) • Patient • (optional) Authorised third party (such as the guardian of a minor, or another person authorised to purchase the medication ~~to~~on behalf of the patient ~~Patient – person who gives consent and requests medication~~)
Functional process steps	• ~~(With the reservation that preconditions are met)~~ ~~The patient visits a~~ A health professional ~~and may give his/her consent to share~~issues a electronic prescription for the patient (in country A). ~~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 (~~Country B~~)~~).

s/heThe patient visits a pharmacy (in Country B). s/heThe patient identifies himself/herself to the pharmacist/staff at. Pharmacist is identified, authenticated and authorised. The patient or optionally the pharmacyauthorised party asks for his/her ePrescriptions. By doing so, the patient gives the dispenser/pharmacist his/her authorisation to access his/her electronic prescriptions. The pharmacist requests the patient's ePrescriptions via the pharmacy's dispensation system in a secure way.   - The ePrescription is received (from Country A).   - The ePrescription is translated by a semantic service.   - Pharmacist receives the ePrescription either translated into his/her own language or English, and a copy of the original information in the prescription.   Pharmacist decides on dispensing. The requested medication is then dispensed to the patient. Information about the dispense act and dispensed medicine is tracked in a dispense record and should be sent back to an ePrescription system in the country of prescription (Country A).

- 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~~**ePrescription** and ~~eDispensations~~**eDispensation**

The Member States in the eHealth Network have adopted these supplementary clauses to the eHealth Network General Guidelines for the electronic exchange of health data under Cross-Border Directive 2011/24/EU and Implementing Directive 2012/52/EU to support the exchange of ePrescription and eDispensation data. These guidelines add use case specific guidelines and do supplement the eHealth Network General Guidelines.

Chapter I – General Considerations

Article 1: Objectives and scope

1. These guidelines are addressed to the Member States of the European Union (and the European Economic Area) and apply to the implementation of interoperable electronic prescription services across Member States, in order to facilitate the ~~recognition and delivery~~exchange of electronic prescriptions ~~issued in another~~ and dispensations between stakeholders (Member ~~State.~~States).

2. In particular, while the non-exhaustive list of elements to be included in ~~medical~~electronic 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.~~, of the prescription, of the dispensing health professional, of the dispensation information and of the authorised medicinal product (on different levels).

1. ~~These guidelines do not cover medical devices; the guidelines do not cover nonpharmaceutical products.~~

3. These guidelines are applicable to authorised medicinal products. Out of scope are extemporaneous / magistral pharmaceutical preparations. These guidelines do not cover medical devices, non-pharmaceuticals and shall not apply to medicinal products subject to special medical prescription provided for in Article 71(2) of Directive 2001/83/EC.

4. These guidelines could serve as a guiding principle for the development and implementation of national systems for ePrescription and eDispensation.

5. The use of electronic prescriptions and dispensations in the cross-border context provides support to patients exercising their right of free movement. It also allows for the portability of data, which is one of the rights embedded in several legislative acts, such as GDPR.

Article 2: Definitions

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For the purpose of these guidelines, the definitions of ~~the directives cited within the recitals of these~~Directive 2014/24/EU, of the eHealth Network General 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~~

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

~~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.~~

Term	**Definition**
Prescription	means a prescription for a medicinal product 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, as defined by Article 3 (k) of Directive 2011/24/EU[2].
ePrescription	means a medicinal prescription issued and transmitted electronically, as defined in point 3 (f) of Commission Recommendation on cross-border interoperability of electronic health records[3].
Medicinal product	means 1. any substance or combination of substances presented as having properties for treating or preventing disease in human beings or

	2. 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, as defined by Article 1 (2) of Directive 2001/83/EC[4].
eDispensation	is defined as the act of electronically retrieving a prescription and reporting on giving out the medicine to the patient as indicated in the corresponding ePrescription[5].
Authorised medicinal product	is a medicinal product for which a marketing authorisation has been issued by the competent authorities of Member States in accordance with Directive [2001/83/EC] or an authorisation has been granted in accordance with Regulation (EC) No 726/2004, read in conjunction with Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and Regulation (EC) No 1394/2007, as defined in Article 6 (1) of Directive 2001/83/EC.
Generic prescription	means the prescription of medication by a health professional using the generic name of a substance. This allows the dispensing pharmacist to choose between generic equivalent products of different brands.
Substitution	means the replacement of a prescribed (branded) product by another product with equivalent qualitative and quantitative composition, pharmaceutical form and route of administration. Substitution can be either "generic substitution" entitling the pharmacist to choose between products with the same active substance(s) or "therapeutic substitution" entitling the pharmacist to replace the prescribed branded or generic product by a product containing a chemically different substance within the same therapeutic group. Generic substitution applies to local substitution or reimbursement rules and may be limited to a given set of substances or connected with rules considering galenic particularities (f. ex. modified release formulations).
Unit of presentation	is a qualitative term describing the discrete countable entity in which a pharmaceutical product or manufactured item is presented, in cases where strength or quantity is expressed referring to one instance of this countable entity (Source: EDQM Standard Terms).
Route of administration	means the path by which the pharmaceutical product is taken into or makes contact with the body (Source: EDQM Standard Terms)

Article 3: Concept and intended use

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

1.   The provisions in the 'eHealth Network GUIDELINE on the electronic exchange of health data under Cross-Border Directive 2011/24/EU - General guidelines' apply.

2.   The aim of the use case is to help to facilitate the safe and unambiguous exchange of electronic medical prescriptions and dispensing process across regions and reuse of data.

Chapter II – Legal and Regulatory Considerations

Article 4: Data protection

Data transferred in ePrescriptions and eDispensation records are a special category of personal data within the meaning of Art. 9 of the General Data Protection Regulation and therefore Member States will need to ensure that processing and storage are in line with applicable data protection requirements.

Article 5: Identification, authentication and authorisation

Implementation of the ePrescription and eDispensation datasets implies that each Member State has addressed enabling activities such as:

1.   Providing an official health ID number. For cross-border purposes, a unique patient identifier is a necessary requirement for each individual patient to be linked to the electronic prescriptions in the country of prescription.

2.   Maintaining electronic registers of health professionals, including information:

   a) on the health professionals who are entitled (according to national law) to prescribe medicinal products

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

3.   Agree on levels of authorisation for certain healthcare roles, for example prescriber and dispenser.

Article 6: Patient safety

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

Article 1:   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 2:   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

The information contained in an ePrescription document needs to be comprehensive to enable safe and secure dispensation in regional, national and in cross-border context.

1. For issuing an ePrescription the rules of the ~~dispensing Member State~~Country of prescription shall apply~~; hence~~.

2. For eDispensation the rules of the country of dispensation shall apply.

~~1.~~3.   Member States are responsible for application of their rules regarding substitution. It is acknowledged that the rules for substitution are ~~outwith~~outside the ~~remit~~realm of the eHealth Network.

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

Article 8: *Quality standards and validation*

In order to ~~assure~~ensure safe implementation, particularly patient safety and data protection and further development of cross-border services, in particular ePrescriptions, Member States should:

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

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

3. aim to align with "preferred code systems" for the data elements in this guideline. The ePrescription and eDispensation guideline introduces the concept of "preferred code systems" for some of the data elements in the datasets as agreed by the eHealth Network.

   o The purpose of such guideline is to promote convergence towards code systems used internationally, officially maintained, using FAIR-principles, available in several languages as well as possible to transcode to other relevant code systems. Therefore, in this context, the word "preferred" should be understood as a guiding principle and not as an obligation.

   o The convergent use of code systems should contribute to ensure clear understanding and preserve the meaning of the information present in the ePrescription and eDispensation documents, by tackling the variability of coding practices.

   o The convergent use of code systems should also contribute to the increase of quality of health data collection as well as facilitate benchmarking and evaluation initiatives.

   o When convergent use of standards is not achievable in practice, solutions should be found to enable the exchange of existing information without compromising patient safety.

The above provisions shall ultimately contribute to reinforce patient safety and increase the overall quality of the continuity of care process.

Article 9: *Education, training and awareness*

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

1. initiate appropriate, easy to understand information and awareness raising measures for all individuals, in particular patients;

1.2.   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. This should include awareness of the need to foster the interoperability of technical systems among producers and vendors of information and communication technologies, health care providers, ~~healthcare~~ health professionals, health institutions, insurers and other stakeholders;

2.3.   consider recommendations for education and awareness raising measures targeting health policymakers and health professionals/health care providers;

3.4.   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;.

~~(a)   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~~Section 4 shows ~~fields~~elements for the ~~dataset~~datasets. The data elements are taken from Implementing Directive 2012/52/EU and ~~Draft~~ International Standard ~~DIS~~ISO 17523[3] ~~published in June~~ :2016 as well as ISO TS 19293:2018. 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~~section 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	

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

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	⊟
A.1.5.4 Duration of treatment (start and/or stop time)	
A.1.5.5 Directions for use	

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[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.1.5.6 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.

3. ~~Member States of treatment~~It is the responsibility of the Member State to provide data in compliance with these guidelines. Member States are encouraged to align their future considerations on national ePrescription and eDispensation datasets according to the datasets structure given in section 4.

~~3.~~4. Member States of dispensing act 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 in section 4 should be sent to the prescriber (or the prescription repository) via the relevant ~~eHealth~~ National Contact Point for ~~the respective recipient~~ eHealth (this should be done in real time ~~and immediately after~~at the ~~medicines have been dispensed):~~time of dispensation).

1. Identification number of the dispenser	
2. Name of dispenser	
3. ISO 3166 country code of the dispenser	
4. Address of the dispenser	
5. Personal identification number of the patient, together with the ISO 3166 country code	
6. Identification number of the prescription	
7. Items dispensed	

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

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5. For a given ePrescription, some of the elements (in section 4) might be empty as no data would be applicable or available; such situations should be communicated differently. Cardinality (i.e., repetition and optionality) of individual data elements or groups of data elements are not part of this document and can be defined in detailed implementation guides.

6. In cross-border setting, the structured and coded content of the ePrescription datasets is received in two languages, Country A language and a translation to Country B language. If Country B language is unavailable for a datasets, English can be used.

7. In cross-border setting, when the available coded information in one Member State cannot be transcoded into the selected preferred code system currently, the information should, as an interim solution, be transferred encoded, preferably in English, and/or in narrative form.

Article 11: Terminology

1. There is a particular issue regardingThe use case requires the identificationability to convey both meaning and context in the ePrescription to enable safe, high-quality healthcare. For that purpose, along with the datasets structure, preferred code systems provide concepts that will be understood by both, the prescriber and the dispenser of the ePrescription.

2. Different code systems are used by Member States. The strategic goal is to gradually reduce fragmentation and converge on the use of international code systems across Europe also considering, in the future, the expected wider use of new and emerging international standards such as the ISO Identification of Medicinal Products (IDMP) suite of standards, which should be used for medicinal products. identification, as soon as made available by the EMA and National Competent Authorities joint SPOR (Substances, Products, Organisations, Referentials) Project.

3. Member States wishing to engage in cross-border communication are encouraged to use for that communication the preferred code systems as described in the datasets in section 4. It is expected that the coding schemes currently included within the dataset will be replaced by recognised that some of the code systems referenced in section 4 are not yet available, for example, identifiers developed using the IDMPfor pharmaceutical products. Member States and other implementers are encouraged to implement these code systems once available.

Article 12: Controlled Lists (Value set of standards. The European Medicines Agency is leading work on this; further details*Catalogues)*

1. An agreed selection of sets of concepts from the preferred code systems is necessary to facilitate the understanding of the information exchanged in the ePrescription by the pharmacy receiving it.

1.2.   That selection of concepts and its designations, organised into sets, form the Value set Catalogues, which will be ~~provided in due course~~based on international code systems whenever possible.

3. It is considered essential to evaluate on a regular basis the selection of concepts and the code systems used. For historical health data preservation, Value set Catalogues should maintain previous versions of the code systems.

4. A suggested general policy is to adopt the latest version of a code system. If this is not possible, at a minimum the adoption of critical concepts should be considered (e. g. the new concepts released for the COVID-19 pandemic).

5. There might be one or multiple Value set Catalogues depending on the scope of each specific implementation. Relevant Value set Catalogues should be easily available for implementers. Ideally, Value set Catalogues should create a network of EU Value set Catalogues accessible and interoperable across Europe with a harmonised maintenance process.

Chapter V – Technical Considerations

Article 13: Technical requirements

For cross-border exchange~~,~~ the format of the document for exchange shall be based on standards and profiles as agreed by the eHealth Network for the particular technical infrastructure. The cross-border specifications of eHDSI are described in section 5 as an example, which also refers to supporting requirements and other relevant documentation.

~~will be the CEF specification, as shown in Annex B.5. Further work will be needed to review this.~~

Article 14: Security

For cross-border exchange, Member States shall ensure that ~~communication of identifiable personal health data is subject to secure communication and~~ they are fully compliant with the cross-border Security Policy.

Article 15: Testing and audit

It is recommended that implementers of the ePrescription and eDispensation guidelines should perform tests and provide audit trails, mainly:

1. Perform end-to-end ~~security measures~~testing with health professionals to ensure the correctness and understandability of ePrescription and eDispensation data.

1. 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 14:   Testing and audit

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

Article 15:   Amendments to the guidelines

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

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2. Ensure that audit trails are recorded to support the monitoring and verification of events related with ePrescription and eDispensation information (e. g. access, transfer).

3. Demonstrate compliance with semantic and technical interoperability specifications in the scope of the implementation project.

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~~recommendations, and follows the same structure as the general guidelines. This chapter can be taken as inspiration for any initiative aiming at implementing interoperable ePrescription and eDispensation systems.

The main goal of this chapter is to disseminate common practices for initiatives implementing the exchange of ePrescriptions and eDispensations and it is highly inspired by the lessons learnt in the MyHealth@EU implementation of these guidelines.

The material in this chapter has built on earlier ePrescription experiences, but cites follow-on work in Horizon 2020 projects like OpenMedicine, eStandards, VALUeHEALTH, UNICOM and the joint EU/US Trillium Bridge and Trillium II projects.

Chapter I ~~– Scope and Definitions~~ – General Considerations

Article 1: Objectives and scope

The guidelines ~~will take a gradual approach to~~aim at solving the interoperability issues inherent to ePrescriptions and eDispensations, particularly at the semantic level ~~(identification of drugs,~~. This revision aims to align with similar entities between the current revision of the eHealth Network guidelines on Patient Summary, in particular for patient administrative data and medication description. Further, this revision incorporates input from the UNICOM project as well as from the EMA and the eP Cluster of eHDSI.

Article 2: Definitions

There is no specific support 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 1:   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~~local rules for prescribing (for example prescriptions by mid-wives, specialised nurses or repetitive prescriptions) and for dispensing (substitution rules) apply and definitions and concepts ~~apply; examples include "primary care prescribing" and "~~may differ across regions. In a cross-border

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context, the Member State rules for dispensing/ substitution" (e.g. therapeutic, economic). must be respected.

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.

These guidelines are non-binding and Member States are considered to have the right to choose freely their way of implementing national ePrescription and eDispensation datasets. The ePrescription and eDispensation guidelines focus on the content issues and the description of possible ways to produce this content for cross-border exchange, taking existing national implementations into consideration.

These guidelines do not define if certain data elements are mandatory or optional. This is up to each implementation initiative to determine according to the use cases purposes.

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.~~

~~Authorisation~~Pursuant to GDPR, legal basis for data processing shall comply with Art 6 and 9. Member States may introduce further conditions/limitations with regards to the processing of ePrescriptions and eDispensation receipts as set forth in Art 9.4 GDPR.

Article 5: Identification, authentication and ~~identification~~authorisation

~~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~~ePrescription and eDispensation 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~~identifier available. In some cases, Member States have a regional patient ~~identification number~~identifier.

Member States should consider identification of health professionals who are entitled to prescribe and dispense medicinal products. These activities should be in line with the eHAction deliverable for a common eID for healthcare in Europe[6].

Article 6: Patient safety

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

~~http://ec.europa.eu/digital-agenda/en/trust-services-and-eid~~

It has to be noted that for an adequate dispensing and substitution decision of the dispensing pharmacy the availability of meaningful and interpretable data is essential for unambiguous identification of the medicinal product and for the substitution decision. In addition to the data transferred via the ePrescription there is often additional information regarding the prescribed product necessary to clearly identify the properties of the prescribed medicinal product and support the substitution decision, which is to be retrieved in the Summary of Product Characteristics (SPC) or Patient Information Leaflet (PIL), for example restrictions regarding the age of the patient, contraindications, allergies, pregnancy status, body weight for dosage checking. For the sake of patient safety and unambiguous substitution decisions, the dispenser should have access to the SPC and PIL. It should be noted that electronic product information (ePI), including SPC and PIL, for EU medicines in the EU ePI Common Standard might be used to enable access to this information when ePI implementation reaches a significant level of completion.

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 substitution 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,*

- *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

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

[8] As footnote 18

~~up to a maximum of 10 years.~~

~~Most~~Some of the Member States allow ePrescriptions to accommodate multiple dispensations ~~for~~. It is the responsibility of the country of prescription (Country A) to calculate and communicate remaining dispensations in the case of multiple ~~drugs. There is, however, a gap in code systems able to represent medications with multiple active ingredients~~dispensations.

~~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.~~

Some of the Member States allow ePrescriptions to accommodate multiple medicinal products. For the cross-border use case, if for technical reasons the ePrescription is split up into multiple single-product ePrescriptions, information on the joint prescription should be provided so that the dispenser can dispense the medications jointly when deemed necessary by the country of prescription (Country A).

Article 8: Quality standards and validation

Member States should work together to build a convergent use of code systems. Mappings should be done as shared activities when more Member States are affected. This will reduce the burden of the workload, support capacity building and also foster the EU pathway towards a harmonised way forward. This may be facilitated by the European Commission.

Article 9: Education, training and awareness ~~raising~~

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

Chapter IV – Semantic Considerations

Article 10: Data

Semantic interoperability ~~requires~~is a way of 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~~ePrescription and ~~dispensation dataset, aligned~~Dispensation datasets, in line with Implementing Directive 2012/52/~~EC~~EU~~C~~. The aim of the ~~dataset~~datasets is to support cross-border ~~care~~healthcare. However, the ability to populate ~~this dataset~~these datasets 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 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.

*Master*There is no specific supporting information.

Article 12: Controlled Lists (Value set *Catalogue*)

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

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.

There is no specific supporting information.

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

Article 14: *Security*

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

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.~~

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There is no specific supporting information.

4. ePrescription and eDispensation Dataset

This section provides further informationThe datasets indicated in the following tables are considered relevant for patient safety and the provision of adequate level of healthcare both at cross-border and national level.

It is up to each implementation project to decide on the conformity and cardinality (i.e. data items in the proposed dataset as well as aelements required or optional and number of comments based on MS' experiencesrepetitions).

The indicated "Preferred Code Systems" are inspired by the eHealth Digital Service Infrastructure implementation and the HL7 IPS implementations.

FieldsData elements		Field descriptionDescription	Preferred Code System
A.1 Core data elements			
A.1.1 Identification of the patientPatient administrative data			
A.1.1.1 Surname	Family name/surname	SurnameThe family name/surname/last name 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].:2011]. This field can contain more than one element or multiple data elements could be present.	
A.1.1.2 Given name	Given name	(7)The given name/first name of the patient (also known as forename or first name). The subject's identifying name(s) within the family group or by which the subject is uniquely socially identified) [ISO TS 22220].:2011]. This field can contain more than one element.	
A.1.1.3 Date of birth	Date of birth	(8) The date of birth of the patient [ISO TS 22220]. :2011]. This can befield may contain only the date of birth and/oryear if 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.day and month are not available, e.g.: 2009	ISO 8601
A.1.1.4	A.1.1.4Personal identifier	A machine-readable identifier of the patient that is unique within a defined scope.Country ID, unique to the patient in that country. Example: ID for a Portuguese patient, national healthcare patient ID. Multiple identifiers could be provided.	

| A.1.1.5 | Gender | This field must contain a recognised valid value for "administrative gender". If different, "physiological sex" could be communicated elsewhere. | HL7 Administrative Gender |
| A.1.1.5 ~~Gender~~6 | Native language | ~~(9) Gender is the biological distinction between male and female [ISO TS 22220].~~ The ~~gender~~native language of the patient. This may be ~~noted on the prescription since this can be~~ important for ~~gender specific effects~~the information that is given to the patient regarding use of ~~drugs, contra-indications etc.~~the prescribed product [N1228 ISO NP TS 17251]. | ISO 639 |

A.1.2 Authentication of the prescription

| A.1.2.1 | ~~A.1.2.1~~Identifier of the 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. The identifier can consist of a root and an extension [ISO 21090:2011]. | |
| A.1.2.2 ~~Issue date~~ | 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.~~ | ISO 8601 |

A.1.3 Identification of the prescribing health professional

A.1.3.1	Family name	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 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.	
A.1.3.4	Details for direct contact	Details for direct contact could be an email 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 practice, etc. where the health professional normally works, meets patients and prescribes medication. Minimally, the country should be specified.	
A.1.3.6	Signature	Digital signature or token as proof of the authenticity of the prescriber.	

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A.1.3.7	Health care provider identifier	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 medicinal product was prescribed by the right person according to the law of the prescribing country.	
A1.4 Identification of the prescribed product			
A.1.4.1	Name of the medicinal product	Brand name of the authorised medicinal product. It has to be noted, that according to Implementing Directive 2012/52/EU additional requirements may apply. *[not applicable for generic prescriptions]*	
A.1.4.2	Identifier of the medicinal product	Identifier of a medicinal product refers to the product inside the package, not the packaged item as such. It could be MPID according to ISO 11615, EMA PMS ID and/or a national identifier. *[not applicable for generic prescriptions]*	EMA PMS
A.1.4.2.1	Identifier(s) of the pharmaceutical product	Identifier of a pharmaceutical product refers to unique PhPID according to ISO 11616. This could be a part of a description of a specific medicinal product or an attribute of a generic prescription. *[not applicable for generic prescriptions]*	EMA PMS
A.1.4.2.2	Identifier(s) of the packaged medicinal product	Identifier of a packaged medicinal product refers to a specific pack size of a specific product. It could be PCID according to ISO 11615 and/or its national equivalent. *[not applicable for generic prescriptions]*	EMA PMS
A.1.4.3	Marketing authorisation holder	Organisation that holds the marketing authorisation of the prescribed product. *[not applicable for generic prescriptions]*	
A.1.4.4	Active substance(s)	All active substances according to ISO 11238. Referred to by "common name" in implementing directive 2012/52/EU.	EMA SMS
A.1.4.4.1	Strength of the active substance(s)	Presentation and/or concentration strength of the active substances. In addition, reference strength could be provided (Article 1 of Directive 2001/83/EC).	UCUM; EDQM

A.1.4.5	Product classification	WHO ATC code of the product	ATC
A.1.4.6	Pharmaceutical dose form(s)	Dose form of a product could be either authorised dose form (includes EDQM combination pack dose forms), administrable dose form or manufactured item dose form. It must be made clear which type of dose forms are provided. For example, for the same product several different dose forms can be provided: 'powder and solvent for solution for injection' as authorised dose form, 'solution for injection' as administrable dose form, and 'powder' and 'solvent' as the dose forms for the manufactured items in the inner packaging. Referred to by "pharmaceutical formulation" in implementing directive 2012/52/EU.	EDQM
A.1.4.7	Unit of presentation(s)	Unit of presentation is used as a unit when describing the strength, but according to ISO IDMP it is also a separate attribute of the pharmaceutical product and manufactured item.	EDQM
A.1.4.8	Package type	Type of the container Examples: bottle, blister, box	EDQM
A.1.4.9	Pack size	Typically, the pack size is the number of unit of presentations in the package. It could also be presented using units of measurement (ml, g). In some cases, there is a need to refine the package size that it describes the amounts of different manufactured items in more than one inner packages. However, the overall amount of a prescribed product must be calculable from the pack size description.	UCUM; EDQM

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	A.1.5.2 Quantity of prescribed product	Total quantity or volume of the medicinal product that is prescribed Note 1: in some cases quantity might to the specific patient. It can be derived from element 1.5.3 Dose regimen. In this case, the quantity does not need to provided as number of packages, given that the pack size is sufficiently described, or it can be stated separately.the overall amount in appropriate units of measure (UCUM) or units of presentation (EDQM) (ml, g, tablets, vials). Note 2: Depending on national legislation, this quantity may or may not be dispensed in one dispensation.	UCUM, EDQM
A.1.5.3	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.1.5.3.1	Number of units per intake	The number of units per intake that the patient is taking. Example: 1 tablet	UCUM, EDQM
A.1.5.3.2	Frequency of intakes	Frequency of intakes per hour/day/week/month. Example: every 24 hours	UCUM, HL7 TimingEvent

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A.1.5.4	Route of administration	The route of administration as prescribed. Example: oral intake	EDQM
A.1.5.5	~~A.1.5.4~~ Duration of treatment	~~Start and/or stop time of treatment~~ The duration of the treatment as indicated by the Prescriber. Example: 14 days. Can be left blank for long-term therapies.	UCUM
A.1.5.6	Starting date of therapy	The time and date on which it is agreed that therapy will start.	ISO 8601
A.1.5.7	~~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~~ medicinal product by the patient.	HL7 TimingEvent
~~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~~ 5.8	Prescription expiry date	~~The address details of the patient~~ 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.	ISO 8601

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A.~~2~~.1.~~2~~ Native language [~~from the ISO language table (ISO 639.2 or ISO 639-3)~~]5.9	Repeats	~~(10) 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.~~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. Decision on dispensability is made in the country of prescription.	
A.1.5.10	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.	
A.1.5.11	Substitution	Substitution handling can be recorded to indicate whether and to what extent substitution is allowed by the prescriber.	
B.1 Dispensation information (provided by the dispensing pharmacy)			
B.1.1	Identifier of the dispenser	A unique number or code issued for the purpose of identifying a dispenser [ISO/TS 27527:2010]; this may be a licence or registration number which can be used to trace the dispenser and to check whether a medicinal product was dispensed by the right person according to the law of the dispensing country.	
B.1.2	Family name of the dispenser	The family name/surname/last name of the dispenser. This enables the dispenser to be traced in the event of questions or emergencies.	

B.1.3	Given name of the dispenser	The given name/first name of the dispenser. This enables the dispenser to be traced in the event of questions or emergencies.	
B.1.4	Identifier of the pharmacy	A unique number or code issued for the purpose of identifying a pharmacy [ISO/TS 27527:2010]; this may be a licence or registration number which can be used to trace the dispensing pharmacy.	
B.1.5	Address of the pharmacy	Minimally, the country should be specified.	
B.1.6	Details of direct contact	Details of direct contact could be an email address and/or phone/fax number of the dispensing pharmacy.	
B.1.7	Identifier of the prescription	As described in A.1.2.	
B.1.8	Medicinal product	Information about the dispensed product as described in A.1.4. The cardinality of the data elements in the product description may differ between ePrescription and eDispensation.	
B.1.9	Dispensed quantity	The package size should be clear from the medicinal product data and the overall amount should be automatically calculable. The dispensed quantity may differ from the prescribed quantity.	UCUM, EDQM
B.1.10	Dispensation date	The date and optionally the time of dispensation.	ISO 8601
B.1.11	Substitution	Information whether and why the substitution took place.	

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.

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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

H   Co-funded by the Health Programme of the European Union

4.   Standards and profiles

5. REFERENCES AND EXAMPLES

This section provides ~~reference information on~~examples of standards and profiles.

~~Reference is made to three classes of material:~~

~~Background requirements and explanatory material~~

~~Formal technical and semantic specifications~~

~~Formal terminology bindings~~

In eHDSI specifications on technical infrastructure and semantics have been further developed and documented at: EHDSI:My Health @EU - eHealth Digital Service Infrastructure (eHDSI) Home

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)

[1] https://usecase-repository.ihe-europe.net/content/e-prescription-and-e-dispensing-cross-border-scale

[2] https://eur-lex.europa.eu/legal-content/DE/ALL/?uri=celex%3A32011L0024

[3] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008H0594&from=GA

[4] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02001L0083-20210526

[5]   https://usecase-repository.ihe-europe.net/content/e-prescription-and-e-dispensing-cross-border-scale

[6]   http://ehaction.eu/wp-content/uploads/2021/06/eHAction-D8.2.4-Common-eID-Approach-for-Health-in-the-EU-_-for-adoption_19th-eHN.pdf

[7]   https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2014.257.01.0073.01.ENG

[8]   https://www.ema.europa.eu/en/human-regulatory/research-development/data-medicines-iso-idmp-standards/spor-master-data/substance-product-data-management-services

5. 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[10][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

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[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.

identifiers.

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