eHealth Network

GUIDELINE

on

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

ePrescription and eDispensation of Authorised Medicinal Products

Release 3.1

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.

Adopted by the eHealth Network, Budapest, November 2024

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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**
Purpose	To support the processes of prescription and dispensation through the electronic exchange of supporting data for patients who are travelling inside Europe, where a patient with an ePrescription from one country (country of prescription) is retrieving medication in another Member State (country of 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.
Relevance	Benefits in both medical and economic terms can be gained from increased quality of healthcare (e. g. improved patient safety) when 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 prescribing medicines through the support of software by a health professional who is legally authorised to do so, so that the medicine can be dispensed by a pharmacy[1]; • eDispensation (eDispensing) is defined as the act of electronically retrieving a prescription and reporting on the dispensation of the medicine to the patient as indicated in the corresponding ePrescription. 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	• Personal information necessary to access ePrescription • Prescription information necessary to dispense the medication • Information about the dispensation
Participants	• Prescriber in country of prescription (Country A) • Dispenser 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 on behalf of the patient)
Functional process steps	A health professional issues a electronic prescription for the patient (in country A). The patient requires medication (in Country B). The patient visits a pharmacy (in Country B). The patient identifies himself/herself to the pharmacist/staff. Pharmacist is identified, authenticated and authorised. The patient or optionally the authorised 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).

2. Guidelines for ePrescription and 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 exchange of electronic prescriptions and dispensations between stakeholders (Member States).

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

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: Terms and Definitions

For the purpose of these guidelines, the definitions of Directive 2014/24/EU, of the eHealth Network General Guidelines and the following definitions shall apply:

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. 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

There are no additional specific requirements, a reference is made to the provisions defined in the eHealth Network General Guidelines.

Article 5: Identification, authentication and authorisation

Implementation of the ePrescription and eDispensation datasets implies that each Member State has addressed enabling activities, in addition to the provisions defined in the eHealth Network General Guidelines. such as:

1. 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.

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

Article 6: Patient safety

There are no additional specific requirements, a reference is made to the provisions defined in the eHealth Network General Guidelines.

Chapter III - Organisational and Policy 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 Country of prescription shall apply.

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

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

Article 8: Quality standards and validation

There are no additional specific requirements, a reference is made to the provisions defined in the eHealth Network General Guidelines.

Article 9: Education, training and awareness

There are no additional specific requirements, a reference is made to the provisions defined in the eHealth Network General Guidelines.

Chapter IV - Semantic Considerations

Article 10: Data

1. Section 4 shows elements for the datasets. The data elements are taken from Implementing Directive 2012/52/EU and International Standard ISO 17523:2016 as well as ISO TS 19293:2018. Reference is also made to other relevant standards, including the ISO Identification of Medicinal Products (IDMP) standards.

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

3. 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.

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 data in section 4 should be sent to the prescriber (or the prescription repository) via the relevant National Contact Point for eHealth (this should be done in real time at the time of dispensation).

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. The use case requires the ability 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 recognised that some of the code systems referenced in section 4 are not yet available, for example, identifiers for pharmaceutical products. Member States and other implementers are encouraged to implement these code systems once available.

Article 12: Controlled Lists (Value set 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.

2. That selection of concepts and its designations, organised into sets, form the Value set Catalogues, which will be 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.

Article 14: Security

For cross-border exchange, Member States shall ensure that 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 testing with health professionals to ensure the correctness and understandability of ePrescription and eDispensation data.
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 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 - General Considerations

Article 1: Objectives and scope

The guidelines aim at solving the interoperability issues inherent to ePrescriptions and eDispensations, particularly at the semantic level. 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: Terms and Definitions

It is recognised that across Europe 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 may differ across regions. In a cross-border context, the Member State rules for dispensing/ substitution must be respected.

Article 3: Concept and intended use

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

There is no specific support information, a reference is made to the provisions defined in the eHealth Network General Guidelines.

Article 5: Identification, authentication and authorisation

To be able to link patients with their 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 identifier available. In some cases, Member States have a regional patient 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

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 and Policy Considerations

Article 7: Enablers for implementation

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.

Some of the Member States allow ePrescriptions to accommodate multiple dispensations. It is the responsibility of the country of prescription (Country A) to calculate and communicate remaining dispensations in the case of multiple dispensations.

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

There is no specific support information, a reference is made to the provisions defined in the eHealth Network General Guidelines.

Chapter IV - Semantic Considerations

Article 10: Data

Semantic interoperability 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 agreement on a Europe-wide ePrescription and eDispensation datasets, in line with Implementing Directive 2012/52/EU~~€~~. The aim of the datasets is to support cross-border healthcare. However, the ability to populate 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.

Article 11: Terminology

There is no specific support information, a reference is made to the provisions defined in the eHealth Network General Guidelines.

Article 12: Controlled Lists (Value set Catalogue)

There is no specific support information, a reference is made to the provisions defined in the eHealth Network General Guidelines.

Chapter V - Technical Considerations

Article 13: Technical requirements

There is no specific support information, a reference is made to the provisions defined in the eHealth Network General Guidelines.

Article 14: Security

There is no specific support information, a reference is made to the provisions defined in the eHealth Network General Guidelines.

Article 15: Testing and audit

There is no specific support information, a reference is made to the provisions defined in the eHealth Network General Guidelines.

4. ePrescription and eDispensation Dataset

The 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 elements required or optional and number of repetitions).

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

Data elements		**Description**	**Preferred Code System**
A.1 Core data elements			
A.1.1 Patient administrative data			
A.1.1.1	Family name/surname	The family name/surname/last name of the patient [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	The given name/first name of the patient (also known as forename or first name) [ISO TS 22220:2011]. This field can contain more than one element.	
A.1.1.3	Date of birth	The date of birth of the patient [ISO TS 22220:2011]. This field may contain only the year if the day and month are not available, e.g.: 2009	ISO 8601
A.1.1.4	Personal identifier	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.1.1.6	Native language	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].	ISO 639
A.1.2 Authentication of the prescription			
A.1.2.1	Identifier of the Prescription	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	The date and optionally the time the prescription was issued.	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.	
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.1.5 Prescription information			
A.1.5.2	Quantity of prescribed product	Total quantity or volume of the medicinal product that is prescribed to the specific patient. It can be provided as number of packages, given that the pack size is sufficiently described, or it can be the overall amount in appropriate units of measure (UCUM) or units of presentation (EDQM) (ml, g, tablets, vials). Depending on national legislation, this quantity may or may not be dispensed in one dispensation.	UCUM, EDQM
A.1.5.3	Dose regimen	The regimen governing the dose quantity per single administration, the dose frequency, 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
A.1.5.4	Route of administration	The route of administration as prescribed. Example: oral intake	EDQM

A.1.5.5	Duration 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	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 medicinal product by the patient.	HL7 TimingEvent
A.1.5.8	Prescription expiry date	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
A.1.5.9	Repeats	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.	

5. REFERENCES AND EXAMPLES

This section provides examples of standards and profiles.

In eHDSI specifications on technical infrastructure and semantics have been further developed and documented at: https://webgate.ec.europa.eu/fpfis/wikis/x/Zt7zN

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 https://www.iso.org/standard/55034.html
- ISO 11238:2012 - Identification of medicinal products -- Data elements and structures for the unique identification and exchange of regulated information on substances https://www.iso.org/standard/55031.html

- ISO 11616:2012 - Identification of medicinal products -- Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information (https://www.iso.org/standard/55035.html
- 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 https://www.iso.org/standard/55032.html
- ISO 11240:2012 - Identification of medicinal products -- Data elements and structures for the unique identification and exchange of units of measurement https://www.iso.org/standard/55033.html

[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