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Health informatics — Requirements for electronic prescriptions

Informatique de santé — Exigences applicables aux prescriptions électroniques

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 215, *Health informatics*.

Introduction

Modern healthcare is rapidly advancing and relying on electronic communications. Many countries already have or are in the process of developing electronic systems to contain and distribute personal data regarding healthcare, among which is exchange of electronic prescriptions. Therefore, it becomes increasingly important to set up International Standards that in the end will facilitate safe and reliable dispensing and administration of the prescribed product to the patient. Also, since international travelling has become integrated into daily life, it is important that electronic communications regarding prescriptions can somehow be synchronized between prescribers and dispensers in different jurisdictions.

The most important question regarding electronic prescriptions is which information is required to accompany the electronic prescription in order to have exactly the intended medicine dispensed to the patient, including all relevant information with regard to its correct and safe use. This International Standard provides the basic set of information requirements to support electronic prescription.

While the organization of healthcare is national, the development and production of medicinal products on the other hand is truly international. The market authorization is strictly legislated in jurisdictional specific directives and laws. Part of this legislation regulates prescribing and dispensing of medicinal products. Information systems in healthcare must be designed so that end-users comply with this legislation (preferably without needing to pay too much attention). An International Standard on electronic prescriptions may support the implementation of (international) legislation on medicinal products in health informatics. For instance, the definition of the term “electronic prescription” has to comply with that of national legislations and multinational directives.

The prescription written on paper has a deeply rooted cultural history for both healthcare professionals and patients. Using an electronic prescription instead of paper is a change that must be guided to ensure society’s trust in healthcare professionals. Requirements for the processing of electronic prescriptions can fulfil this need. An example of use in practice of this specification is the following: a general practitioner prescribes a medicinal product for a patient with the aid of an information system and sends the electronic prescription to the local pharmacy where the patient picks up the medication a short while thereafter.

The benefit of an International Standard on the requirements of an electronic prescription is that it can serve as a starting point and reference for all kinds of records and messages related to electronic prescriptions, facilitating the communication between stakeholders and information systems.

The intended audience for this International Standard is made up of the developers of standards and information systems, so that in using their products, end-users (healthcare professionals) comply with legislation, regulations and expectations of society relating to the prescribing and dispensing of medicinal products. Specifically, this International Standard provides a basis for a common understanding of the data elements contained in an electronic prescription across legislations.

Health informatics — Requirements for electronic prescriptions

1 Scope

This International Standard specifies the requirements that apply to electronic prescriptions. It describes generic principles that are considered important for all electronic prescriptions.

The scope of this International Standard is constrained to the content of the electronic prescription itself, the digital document which is issued by a prescribing healthcare professional and received by a dispensing healthcare professional. The prescribed medicinal product is to be dispensed through an authorized healthcare professional with the aim of being administered to a human patient. Other messages, roles and scenarios (e.g. validation of a prescription, administration, medication charts, EHR of the patient, reimbursement of care and dispensed products) are out of scope of this International Standard, because they are more or less country or region specific, due to differences in culture and in legislation of healthcare. However, requirements and content of electronic prescriptions within the context of jurisdictions have a relationship with these scenarios. The way in which electronic prescriptions are made available or exchanged also fall outside the scope of this International Standard.

This International Standard is applicable to electronic prescriptions of medicinal products. Although other kinds of products (e.g. medical devices, wound care products) can be ordered by means of an electronic prescription, the requirements in this International Standard are aimed at medicinal products that have a market authorization and at pharmaceutical preparations which are compounded in a pharmacy. An electronic prescription is an information object that authorizes a healthcare professional to legally dispense a medicinal product.

This International Standard specifies a list of data elements that can be considered as essential for electronic prescriptions, depending on jurisdiction or clinical setting (primary healthcare, hospital, etc.).

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

ISO 11238, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on substances*

ISO 11239, *Health informatics — 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*

ISO 11240, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of units of measurement*

ISO 11615, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal product information*

ISO 11616, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information*

ISO 17090-1, *Health informatics — Public key infrastructure — Part 1: Overview of digital certificate services*

ISO/TS 16791, *Health informatics — Requirements for international machine-readable coding of medicinal product package identifiers*

ISO/TS 22220, *Health informatics — Identification of subjects of health care*

ISO/TS 27527, *Health informatics — Provider identification*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
dispenser
healthcare professional authorized to dispense medicinal products

3.2
dispensing
process of validation of the electronic prescription, preparation of the medicinal product, labelling, informing and handing the medication to the patient or administering healthcare professional

3.3
electronic prescription
e-prescription
prescription (issued by electronic means) that complies with this International Standard

3.4
digital signature
signature based upon cryptographic methods of originator authentication, computed by using a set of rules and a set of parameters such that the identity of the signer and the integrity of the data can be verified

Note 1 to entry: Digital signatures employ a type of asymmetric cryptography. For messages sent through an insecure channel, a properly implemented digital signature gives the receiver reason to believe the message was sent by the claimed sender.

3.5
prescriber
healthcare professional authorized to issue electronic prescriptions

3.6
prescribing
process in which an authorized healthcare professional, the prescriber, issues a prescription information object

Note 1 to entry: Typically, the healthcare professional is a medical specialist or a general practitioner but this differs across legislations. In some countries, pharmacists or nurse practitioners are also authorized to prescribe.

3.7
prescription
set of values of attributes that is produced as the output of a prescription act

Note 1 to entry: A prescription is a set of instructions written by a prescriber that authorizes a medicinal product or treatment to be given to a patient. It is a) an instruction by an authorized healthcare professional, b) a request to dispense by an authorized healthcare professional and c) advice to a patient on his/her medication treatment or d) an instruction to administer by an authorized healthcare professional.

Note 2 to entry: The word "prescription" is sometimes used when referring to the act of prescribing, "prescription process". To avoid confusion with the term "prescription" as an information object, throughout this International Standard, the word "prescription" is reserved for the information object. For the act of prescribing, the term "prescribing" is used.

3.8
medicinal product
substance or combination of substances, which can be administered to human beings for treating or preventing disease, making a medical diagnosis or to restore, correct or modify physiological functions

3.9
authentication
formalized process of verification that, if successful, results in an authenticated identity for an entity

Note 1 to entry: The authentication process involves tests by a verifier of one or more identity attributes provided by an entity to determine, with the required level of assurance, their correctness.

Note 2 to entry: Authentication typically involves the use of a policy to specify a required level of assurance for the result of a successful completion.

Note 3 to entry: Identification is usually done as authentication to obtain a specific level of assurance in the result.

[SOURCE: ISO/IEC 24760-1:2011, 3.3.1, modified]

3.10
authorization
granting of rights, which includes the granting of access based on access rights

[SOURCE: ISO 7498-2:1989, 3.3.10]

3.11
identification
process of recognizing an entity in a particular domain as distinct from other entities

Note 1 to entry: The process of identification applies verification to claimed or observed attributes.

Note 2 to entry: Identification typically is part of the interactions between an entity and the services in a domain and to access resources. Identification can occur multiple times while the entity is known in the domain.

[SOURCE: ISO/IEC 24760-1:2011, 3.2.1, modified]

3.12
identity information
set of values of attributes that differentiate one entity from others

Note 1 to entry: In an information and communication technology system, an identity is present as identity information.

[SOURCE: ISO/IEC 24760-1:2011, 3.2.4, modified]

4 Conformance

4.1 Generic conformance

An electronic prescription is conformant to this International Standard when it fulfils all detailed requirements in Clause 6.

4.2 Data element conformance

An electronic prescription is conformant to Annex A when it fulfils the requirements described in Clause 6 by using data elements from Annex A.

NOTE Data element conformance implies generic conformance.

5 General information

5.1 Structure of this International Standard

This International Standard provides the requirements for electronic prescriptions. Clause 6 describes the generic requirements considered important for any electronic prescription, regardless of the data elements presented in the electronic prescription. Annex A lists a selection of data elements and their definition that should be used to fulfil the requirements as specified in Clause 6. Annex B has three parts: B.1 lists examples of electronic prescription implementations in other countries; B.2 provides an overview of data structures and standards; B.3 lists examples and code snippets belonging to either the core or optional elements.

5.2 Usage of this International Standard

This International Standard provides a basis for a common understanding of the data elements contained in an electronic prescription within and across jurisdictions to achieve interoperability. This International Standard is therefore intended to be used in the process of development of standards and information systems handling electronic prescription information. Healthcare system designers should specify which data elements are supported by their implementation. The chosen subset may vary based on their intended use, regulatory background, and other aspects that condition the local requirements. However, data elements used have to fulfil the requirements of Annex A.

5.3 Use cases, actors, processes

This International Standard intends to specify the requirements for the information object that is to be created when a system issues a prescription. While an electronic prescription can appear in a wide range of processes, the intended scope of this International Standard is for a simple use case:

A physician enters prescription information for medication. The prescription information may then be reviewed by another professional before dispensing and the medication is then dispensed. After the dispense, the medication is expected to be administered.

NOTE 1 In a cross-border setting, the use case can be described as follows: A physician enters prescription information for medication in country A. The prescription information may then be reviewed by another professional before dispensing, and the medication is then dispensed in country B. After the dispense, the medication is expected to be administered. Extended information on cross-border requirements of electronic prescriptions can, e.g. be found in the Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare.[7] Article 11 (2-b) of the Directive defines the need for supporting the Member States in developing the interoperability of electronic prescriptions. The "Guidelines on eprescriptions dataset for electronic exchange under cross-border directive 2011/24/EU" [8] is aiming to facilitate this.

NOTE 2 Review, dispense, and administration processes use the prescription information. These processes might lead to the creation of new additional information possibly including parts of the prescription information or referring to it. The review, dispense and administration processes are considered only in so far as they impose additional requirements on the prescription information. The information created by those processes is not subject of this International Standard.

This International Standard only addresses the requirements that are necessary for the electronic prescription. However, this use case may trigger the following acts.

Prescribing: the intellectual process of deciding on a medication, related to medication treatment plans, decision support, etc. All considerations that lead to defining the information to be entered are considered to be prior to the prescription entry.

Prescription review: to check prescription information against pharmaceutical knowledge and regulations, e.g. drug interaction checking.

In order to fulfil this task, the reviewer should have access to information concerning the current treatment of the patient and medication already dispensed. For a prescription to be validated, a prescription review (or several) may be needed. The conditions for this are not relevant for this International Standard.

During the review process, there can arise a need to contact the prescriber.

NOTE 3 Prescription review is also known as medication order review or pharmaceutical review.

Dispense of medication: to dispense the physical medication, based on the (previously validated) prescription information assigning (giving) the medication to a particular patient, including the necessary actions that lead to that dispensing. The dispenser may be entitled to diverge from the initial prescription (e.g. change the brand of the medication) or to reject the prescription and inform the prescriber on this rejection.

One prescription may lead to more than one dispense action, such as repeat prescriptions for chronic diseases. Differences may exist between healthcare settings. In some settings, repeat dispenses require repeat prescriptions, yielding a 1:1 relationship between prescriptions and dispenses; in other settings multiple dispenses per prescription are allowed.

Administration: the prescribed medication is intended to be administered to the patient by a person who may be the patient or another person.

Additional acts can be triggered by the prescription, like those related to reimbursement (eligibility, reimbursement requests) or secondary uses (adding to the patient history).

The use case leads to the following requirements:

a) the patient shall be unambiguously identifiable by all the healthcare professionals (see 6.1);

b) the healthcare professional that enters the prescription shall be identifiable for legal and auditing reasons and in order to be contacted by the other participants (see 6.2);

c) the prescription information entry is a professional activity of the responsible prescribing person, potentially causing patient safety issues and also liability issues in subsequent process steps (see 6.7). Therefore there shall be an appropriate level of assurance that the prescription information entry accurately and unambiguously captures the intention of the prescriber (see 6.3);

d) the medicinal product(s) that is the object of the prescription shall be clearly and unambiguously identifiable by all actors (see 6.3 and 6.4);

e) the contextual information of the prescription that is relevant for the dispensing or administration shall also be available. This may include access to specific patient information or instructions (see 6.5);

f) the content shall convey the legal authorization to dispense a medicinal product (see 6.6);

g) since the prescription is a trigger for a process, the data for these processes (validity, identification, conditions for dispense or others like reimbursement) should be available (see 6.7);

h) the data that are available (or are permitted) may differ across clinical cases, across regulatory frameworks, or across different products. Therefore, the standard mechanisms should not limit or enforce any specific set of data (see 6.7).

5.4 Information objects

5.4.1 Prescription

The prescription shall describe the medication that the prescriber wants to be administered to or used by the patient. It may serve as input to the prescription review and dispense process. Variations in the content of the prescription can occur, varying from country to country, depending upon regulations, responsibilities, and standards.

5.4.2 Related information objects

Mentioned here in order to clarify requirements on the prescription information object are the following:

a) the dispensed medication information shall contain what medication has actually been dispensed. The prescription that resulted in a dispense shall be traceable from the dispense. There can be, in general, multiple dispenses originating from one prescription;

b) the prescription review documentation object shall contain the observations and actions of the pharmacist in the prescription review process. The possible outcome shall be documented as either prescription unchanged, prescription modified (e.g. substitution), or prescription cancelled. The review documentation shall be traceable to the prescription. A defined status of the prescription shall be implied at any point in time;

c) the administration documentation object shall describe the administration event (primarily in hospitals). These events shall be traceable to the prescription, they may be sent along with the prescription information or managed in some other way, independently from the prescription information.

6 Requirements for electronic prescriptions

6.1 Identification of the patient

A patient is a person in the role of a patient. Data content shall support reliable long-term identification, provide contact information (e.g. location or telecom).

The patient shall be able to identify him/herself using an identification method that is legal in the country of the prescriber. The identity information shall state contact information to be able to track the patient in case of emergency, such as a misprescribed drug or dose.

In cases where the identity of the patient cannot be revealed to the dispenser (e.g. in special healthcare situations due to national legislation), the prescriber shall provide pseudonymized identity information with sufficient information for re-identification on his behalf.

Pseudonymization or any constraints on patient identification can bring risks, namely patient safety risks. There shall be a reliable way to unambiguously and clearly re-identify the patient, in such cases, in order to mitigate those risks.

6.2 Identity information of the prescribing healthcare professional

A prescriber shall be a healthcare professional, i.e. a person who is involved in or associated with the delivery of healthcare to a subject of care or caring for the well-being of a subject of care (ISO/TS 27527). A prescriber is a healthcare professional authorized to issue prescriptions (ISO 21549-7). Data content shall support testing the legitimate use (identification, authentication, authorization), traceability/auditing, and non-repudiation.

6.3 Identification of the prescribed medicinal product

The information provided on the electronic prescription shall result in reliable identification of the prescribed medicinal product (or medicinal appliance) for the dispenser. Preferably and in the case of a medicinal product, the information should be derived from a medicinal product dictionary [(ISO/DTS 19256 (under development)]. If this is not available or if a product other than a medicinal product is prescribed, enough information shall be given on the electronic prescription for the dispenser to dispense the correct product.

6.4 Compliance to medicinal product dictionaries

Electronic prescriptions created, exchanged, and filled according to this International Standard shall comply with the ISO IDMP standards to realize the unique and unambiguous identification of medicinal products in electronic prescriptions. During the transitional period between implementation of the electronic prescription standard and availability of ISO IDMP terminology for production use, current medicinal product dictionaries and related identifiers should be used in electronic prescriptions. Examples of current medicinal product dictionaries are as follows:

— national medicinal product dictionaries;

— European Medicinal Product Dictionary, known as Art57-XEVMPD dictionary implemented by the European Medicines Agency;

— FDA medicinal product dictionaries.

6.5 Product use information

The electronic prescription shall supply the information that is required to instruct the patient on the use and administration of the prescribed product. This shall include data on the route of administration, strength, the dose regimen quantity, directions of use. When this information is relevant in order to dispense the correct amount of the prescribed product (e.g. number of tablets), it shall also be available to the dispenser.

6.6 Authentication of the electronic prescription

Authentication includes testing the integrity of the electronic prescription, testing the authentication and authorization of the prescribing professional, and testing the commitment of the prescriber to the content. Therefore, a prescription should bear a signature of the prescribing healthcare professional. An electronic prescription shall contain a digital signature that provides the potential for authentication of the prescription information.

6.7 Data elements

An electronic prescription shall contain a subset of the data elements listed in Annex A. This subset depends on the use case. Data elements used shall fulfil the requirements of Annex A.

Annex A
(normative)

Data elements

A.1 Identity information of the patient

A.1.1 Surname

Surname of the patient. The part of a name a person usually has in common with some other members of his/her family, as distinguished from his/her given names (see ISO/TS 22220).

A.1.2 Given names

Given names of the patient (also known as first name and middle names). The subject's identifying name(s) within the family group or by which the subject is uniquely socially identified (see ISO/TS 22220).

A.1.3 Date of birth

The date of birth of the patient (see ISO/TS 22220). Information regarding the age of the patient should be noted. This can either be the date of birth and/or the actual age of the patient at the time the prescription is issued. Since age is affecting drug ADMET (absorption, distribution, metabolism, excretion and toxicity) parameters, this is important for the choice of the drug and drug dosing.

A.1.4 Personal identifier

A machine-readable identifier of the patient that is unique within a defined scope.

NOTE Depending on jurisdiction, this can be, for instance, a healthcare-specific personal identifier (e.g. insurance number) or a national personal identifier (e.g. social security number).

A.1.5 Address details

The address details of the patient. In some countries (e.g. Germany), it is sometimes required that the patient's address details are included on the electronic prescription.

A.1.6 Sex

Sex is the biological distinction between male and female. The sex of the patient may be noted on the electronic prescription since this can be important for sex-specific effects of drugs, contra-indications, etc. Sex may be noted as unknown.

NOTE 1 Instead of sex, the term gender is sometimes used.

NOTE 2 The gender might not match the biological sex as determined by genetics or the individual's preferred gender identity.

A.1.7 Patient language

The preferred language of the patient. This is important for the information that is given to the patient regarding use of the prescribed product and the printed label on the product.

This should be taken from the ISO language table (ISO 639-2 or ISO 639-3 for three character list of languages). Other language specification code systems may be used.

A.1.8 Body weight

The weight of the patient. This can be important for deriving body mass index or body surface area which may be used in medicine dose calculations.[9]

A.1.9 Body height

The height of the patient. This can be important for deriving body mass index or body surface area which may be used in medicine dose calculations.[9]

A.1.10 Drug allergies and drug intolerances

Information regarding allergies and sensitivities to medicinal products (e.g. certain antibiotics), drug groups and active, as well as non-active, ingredients may be noted.

A.1.11 Patient conditions

Conditions that affect the use of medicinal products, such as renal/hepatic failure, pregnancy, pharmacogenetic profile. For instance, some medicinal products can alter fertility, harm the unborn child or affect the child via breastfeeding. This can result in the dispense of another medicinal product and/or modification of the dosage regimen. This can also be important when the person has the intention to become pregnant.

NOTE In some jurisdictions, the dispenser is not allowed to change the medicinal product or modify the dosage regimen.

A.1.12 Relevant pathology test results

Relevant pathology test results, e.g. creatinine clearance, eGFR, etc. are important for dose calculations, e.g. nephrotoxic drugs.

A.2 Electronic prescription information

A.2.1 Electronic prescription identifier

A value to uniquely identify an electronic prescription. The electronic prescription should receive a globally unique identifying code for traceability, e.g. by making use of information object definitions. It may additionally be used to register whether an electronic prescription and/or the maximum number of repeats was already dispensed or not to prevent that patients retrieve medicines several times using the same electronic prescription.[9]

A.2.2 Issue date

The date and optionally the time the electronic prescription was issued by the prescriber. The issue date of the prescription can be important for reimbursement of the prescribed drug(s) and whether the electronic prescription is still valid to trigger a dispense event. Date shall be stated as described in ISO 8601.

A.2.3 Electronic prescription expiry date

Date and optionally time when the electronic prescription is considered to be expired. This can be dependent on local or national policy or legislation, in accordance with treatment plan or because the therapeutic need for the prescribed medicine is expired. In some countries (e.g. Germany), legislation is so clear that it is not necessary to put in on the electronic prescription.

A.2.4 Repeats

Whether an issued electronic prescription allows for several repeating dispensations.[9] In some countries, when medicinal products are dispensed for the first time, the patient can only receive medication for a short period of time. In the case of starting chronic medication, the prescriber may issue an electronic prescription for a longer period that is constituted by repeats.

NOTE The term refill is used in some countries instead of repeats. In this International Standard, it carries the same meaning.

A.2.5 Minimum dispensing interval

If an issued electronic prescription allows for several repeating dispensations (see A.4.4), the minimum time interval between dispensations shall be stated here (e.g. Reference [9]). This can be important in the case of medicinal products that are prone to be overdosed, e.g. opioids.

The minimum dispensing interval can differ since repeating dispensations can differ in the amount compared to the first dispensation. If that is the case, this shall be stated here as well.

A.2.6 Reason for prescription

The reason for prescribing, including the possibility of mentioning that the prescribed medicinal product is being applied for 'off label' use. The reason for prescribing should give the opportunity for the dispenser to review the electronic prescription for medication safety issues.

NOTE In some countries, it is obligatory to state the reason for electronic prescription on the electronic prescription itself for some or all medicinal products. An example of this in the Netherlands is an electronic prescription of methotrexate, since the indication for which it is used in the Netherlands (chemotherapy or rheumatoid arthritis) greatly impacts both strength and dose interval of the medication.

A.3 Identity information of the prescribing healthcare professional

A.3.1 Surname

The electronic prescription should state the family name/surname/last name of the prescriber. This enables the possibility to trace the prescriber in case of questions or emergencies.

A.3.2 Given name

The electronic prescription should state the given name/first name of the prescriber. This enables the traceability of the prescriber in case of questions or emergencies.

A.3.3 Professional qualification

The professional credential of the prescribing healthcare professional which may be used to prove the authority of the prescriber.

In some countries, a nurse or midwife might not possess a professional title; however, might still be entitled to prescribe (certain) drugs. This might also be true for other healthcare professionals. In all cases, the professional credential shall be present on the electronic prescription.

A.3.4 Details for direct contact

Details for direct contact may include a street address, mailing address, e-mail address, or phone/fax number of the prescriber in order for the dispenser and/or patient to contact the prescriber. This can be necessary in case problems arise with dosage, allergies, reimbursement, etc.

A.3.5 Work address

This is the address of the hospital, the private practice where the healthcare professional is normally working, meeting patients and prescribing medications.

A.3.6 Digital 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 to these national laws for prescribing. A prescribing message or document without this digital signature can only be regarded as a notice of the actual (paper) electronic prescription (see ISO/TS 17090-1).

NOTE A digital token is bound to a specific prescription and includes the prescribed medication. In order to prevent fraud it cannot be transferred to other documents. A scanned handwritten signature is not a digital signature.

A.3.7 Healthcare professional identifier (HCPI)

A unique number or code issued for the purpose of uniquely identifying a healthcare professional (ISO/TS 27527). A unique identifier that can be used to trace back the prescriber at all times. This can be, for example, a licence or registration number which can be used to uniquely identify the prescriber. This can be used to check whether a drug was prescribed by the right person according to the law.

HCPI is issued within a certain jurisdiction. When the electronic prescription is received in another jurisdiction/country, the HCPI is unique when combined with the designation of the country of origin.

A.3.8 Academic institution

The name of the academic institution which gave the professional credential to the healthcare professional. In some countries such as Mexico, this is a required data element in electronic prescriptions.

A.3.9 Work place identifier

A unique code identifying the work place of the healthcare professional. In some countries such as Sweden, the work place of the healthcare professional has a unique code.

A.4 Identity information of the prescribed product

A.4.1 Name of the medicinal product

Textual description of the medicinal product or medicinal appliance that is prescribed to the patient as entered or chosen by the prescriber (e.g. as in the IDMP standards). Information may be included regarding the possibility to substitute the prescribed product with an equivalent product.

NOTE Some medicinal products are prescribed as a combination of a medicinal product and a medical device.

In many countries, it is possible for a prescriber to state that the product shall not be substituted, due to absence of scientific bio-equivalent or pharmaco-equivalent studies or otherwise.

A.4.2 Reimbursement information

Information provided by the prescriber related to reimbursement.

NOTE Although reimbursement is out of scope, such information can be relevant for the review or dispense process. This can include information on the urgency of the prescription (e.g. “noctu”) or whether or not the prescribed product will be reimbursed. Details depend on jurisdiction.

A.4.3 Prescribed product identifier

A national or international unique identifier of the prescribed medicinal product which can be used in the prescription corresponding to a specific and unique product (see ISO/TS 16791).

A.4.4 Strength of the medicinal product

The content of the active substances expressed quantitatively per dosage unit, per unit of volume or weight according to the dosage form (see Directive 2001/83/EC, Article 1).

NOTE Strength of the medicinal product can also be derivable from the element 'dose regimen'. If, for example, the electronic prescription contains a statement such as "use 3× daily 10 mg for 9 d", strength can not be provided separately.

A.5 Product use information

A.5.1 Pharmaceutical dose form

The physical characteristics in which the prescribed medicinal product shall be administered (e.g. tablet, solution, ointment).

A.5.2 Quantity

Total quantity or volume of the medicinal product that is prescribed.[10]

NOTE 1 In some cases, quantity might be derived from A.5.3. In that case, it is not necessary to state quantity separately.

NOTE 2 Depending on national legislation, this quantity may or may not be dispensed in one dispensation.

A.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 case of intravenous administration).

NOTE This information can be used by the dispenser to calculate the quantity to be dispensed.

A.5.4 Duration of treatment

Start and/or stop date and/or time of the treatment.

A.5.5 Directions for use

Details about the directions for use of the prescribed medicinal product, such as "with food" or "before a meal" and any cautionary advice for correct use of the prescribed drug by the patient. This includes conditional use such as "use in case of allergic reaction".

A.5.6 Pharmaceutical preparation description

Information about the constituent ingredients, if the electronic prescription concerns a medicinal product manufactured in a pharmacy or a 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).

NOTE 1 Synonym also includes extemporaneous preparation, compounded medication and magistral preparation.

NOTE 2 The term extemporaneous medicinal product is not to be used, as it is more appropriate in describing a medicine processed during the administration of a medicinal product, especially when a mixture is made just before, e.g. intravenous administration.

A.6 Schematic representation of electronic prescription contents

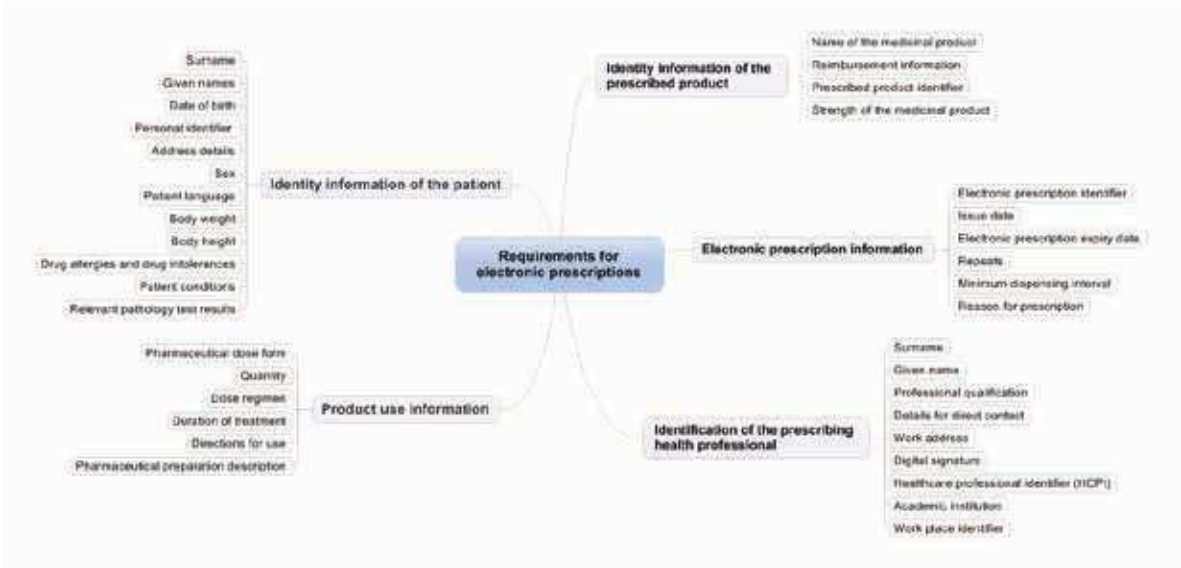

Figure A.1 — Schematic representation based on Reference [10], article 9 in Reference [8] and ISO 21549-7:2007

Annex B
(informative)

Examples of elements and implementations of electronic prescription

B.1 References to implementations of electronic prescription

B.1.1 England

The NHS England Electronic Prescription Service (EPS) is described at http://systems.hscic.gov.uk/eps.

B.1.2 Europe

European cross-border prescription, based on epSOS.

B.1.3 Netherlands

NEN 7503:2011 nl, *Medische informatica — Berichtenverkeer — Elektronische uitwisseling van recept- en verstrekkingsberichten*.

B.1.4 Denmark

The Danish electronic prescription format is described at:

http://svn.medcom.dk/svn/releases/Standarder/Den%20gode%20recept/XML/Dokumentation/XPRE01.pdf (in Danish) Lægemiddelstyrelsen/MedCom, (2009). Den gode xml recept, Electronic prescription, VersionCode XLMS016.

B.1.5 Norway

The Norwegian ePrescription solution is described at:

http://www.helsedirektoratet.no/it-helse/eresept/leverandor/dokumentarkiv/Sider/default.aspx

B.1.6 Australia

http://www.nehta.gov.au/

B.1.7 USA

https://www.ncpdp.org/

B.1.8 Canada

https://www.infoway-inforoute.ca/en/solutions/clinicians-e-services/e-prescribing

B.2 Data structures and standards

B.2.1 Danish healthcare datanet

http://www.medcom.dk/wm109991 (in English)

B.2.2 HL7

HL7 published CDA specifications, also HL7 V3 messages, in particular the HL7 v3 Medication Order Topic from Pharmacy Domain in the May 2014 ballot.

B.2.3 IHE Pharmacy

IHE published profiles for Medication Workflow in Hospitals and Community Settings.

B.2.4 EN ISO 13606

EXAMPLE The Spanish Ministry of Health, Social Services, and Equality has published an official set of ISO 13606 archetypes and derived artefacts for the communication of EHR among the regions of Spain. These archetypes have been developed by the UPV based on the official "Clinical Report Minimum Data Set" (CMDIC - Conjunto Minimo de Datos de Informes Clinicos). One is about electronic prescription of medication.

https://www.msssi.gob.es/profesionales/hcdsns/areaRecursosSem/Rec_mod_clinico_arquetipos.htm

B.3 Examples of data elements

B.3.1 Machine readable codes (A.1.4)

Implementation of this element would look as follows through the Person and Patient Common Message Element Types "Universal" in Health Level 7 v3 (where family qualifier is for surname, given is for given name and birth time is for date of birth in ISO (ISO/TS 22220) format (yyyymmddhhmm):

This is an example generated by HL7v3:

```
<subject typeCode="SBJ">
 <patient classCode="PAT">
  <!- Item: Personal Identifier →
  <id root="2.16.840.1.113883.2.4.99.23444.1.2.3.1.1.1.4.1"  extension="1234567"/>
  <!- Item - Adress→
  <addr>
   <postalCode>1200 AA</postalCode>
  </addr>
  <statusCode code="active"/>
  <patientPerson classCode="PSN" determinerCode="INSTANCE">
   <!- Item: - Name Patient →
   <name use="L">
   <given>Francis</given>
   <given qualifier="IN">F.C.M.</given>
   <prefix qualifier="VV SP">van den </prefix>
   <family qualifier="SP">Hurk</family>
   <delimiter>-</delimiter>
   <prefix qualifier="VV BR">van </prefix>
   <family qualifier="BR">Bramen</family>
  </name>
  <name use="OR">
   <given>Francis Clara Maria</given>
   <prefix qualifier="VV BR">van </prefix>
   <family qualifier="BR">Bramen</family>
  </name>
  <!- Item: - Date of Birth →
  <birthTime value="19830721"/>
 </patientPerson>
 </patient>
</subject>
```

B.3.2 Digital signature (A.3.6)

The implementation of a digital signature in the Dutch national health system: A token consists of relevant selected parts of the electronic prescription, such as prescription identifier, prescriber, patient, medication and quantity. These are hashed with a private key according to a certain algorithm into a digital signature. The receiver compares the digital signature with the outcome of the reproduced

formula using a public key with (the same parts of) the received electronic prescription to prove that the electronic prescription has not been tampered and that the prescriber is authentic. The authentication token usually resides on the outer layer of the electronic prescription or message.

This is an example generated by HL7v3:

```
<overseer typeCode="RESP">
  <AssignedPerson>
    <id extension="012345678" root="2.16.528.1.1007.3.1"/>
    <id extension="03004256" root="2.16.840.1.113883.2.4.6.1"/>
    <code code="01.015" codeSystem="2.16.840.1.113883.2.4.15.111" displayName="General
Practitioner"/>
    <assignedPrincipalChoiceList>
    <assignedPerson>
    <name>
       <prefix qualifier="AC">Dr. </prefix>
     <given>Thomas</given>
      <family>Young</family>
    </name>
    <telecom value="tel:+49125463726"/>
   </assignedPerson>
 </assignedPrincipalChoiceList>
  <Organization>
   <id extension="01234567" root="2.16.528.1.1007.3.3"/>
   <id extension="06005465" root="2.16.840.1.113883.2.4.6.1"/>
   <code code="V4" codeSystem="2.16.840.1.113883.2.4.15.1060"    displayName="Hospital "/>
   <name> Medical Centre East</name>
   ≤addr≥
      <city>East London</city>
   </addr>
  </Organization>
 </AssignedPerson>
</oversee>
```

B.3.3 Address details (A.1.5)

HL7 v3 based message as presented below to illustrate how this can be implemented.

```
<add
r>
   <streetName>Purmersteenweg</streetName>
   <houseNumber>42</houseNumber>
   <postalCode>1441 DM</postalCode>
   <city>Purmerend</city>
</addr>
```

B.3.4 Sex (A.1.6)

Content for sex in an electronic prescription message could be presented as below:

This is an example generated by HL7v3, where the term “gender” is used.

```
<!- Item: gender →
<administrativeGenderCode code="M" codeSystem="2.16.840.1.113883.5.1"/>
```

where M = male and F = Female. Other codes might apply.

B.3.5 Body weight (A.1.8)

Content for weight in an electronic prescription message could be presented as below:

This is an example generated by HL7v3

```
<observation classCode="OBS" moodCode="EVN">
   <code code="3141-9" displaytext="Body weight Measured" "codeSys-
tem="2.16.840.1.113883.6.1"/>
   <value xsi:type="PQ" value="81" unit="kg"/>
</observation>
```

B.3.6 Body height (A.1.9)

Content for height in an electronic prescription message could be presented as below:

This is an example generated by HL7v3

```
<observation classCode="OBS" moodCode="EVN">
<code code="248334005 " displayName="length of body" "codeSys-
tem="2.16.840.1.113883.6.96"/>
<value xsi:type="PQ" value="171" unit="cm"/>
</observation>
```

Bibliography

[1] ISO 639-2, *Codes for the representation of names of languages — Part 2: Alpha-3 code*

[2] ISO 639-3, *Codes for the representation of names of languages — Part 3: Alpha-3 code for comprehensive coverage of languages*

[3] ISO 7498-2:1989, *Information processing systems — Open Systems Interconnection — Basic Reference Model — Part 2: Security Architecture*

[4] ISO 21549-7, *Health informatics — Patient healthcard data — Part 7: Medication data*

[5] ISO/IEC 2382:2015, *Information technology — Vocabulary*

[6] ISO/IEC 24760-1:2011, *Information technology — Security techniques — A framework for identity management — Part 1: Terminology and concepts*

[7] Directive EU 2011/24/EU Directive of the European Parliament and of the Council of 9 mar 2011 on the application of patients' rights in cross-border healthcare

[8] Guidelines on eprescriptions dataset for electronic exchange under cross-border directive 2011/24/EU release 1 (18 Nov 2014)

[9] NEHTA Electronic prescription Structured Document Template v. 3.1; 17 dec 2010

[10] Commission implementing directive 2012/52/EU and Annex (non-exhaustive list of elements to be included in medical electronic prescriptions)

[11] Directive EU 2001/83/EU on the community code relating to medicinal products for human use

ICS 35.240.80

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