Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

ePrescription dataset and clinical document architecture standard

January 2015

About the Health Information and Quality Authority

The Health Information and Quality Authority (the Authority or HIQA) is the independent Authority established to drive high quality and safe care for people using our health and social care services. HIQA's role is to promote sustainable improvements, safeguard people using health and social care services, support informed decisions on how services are delivered, and promote person-centred care for the benefit of the public.

The Authority's mandate to date extends across the quality and safety of the public, private (within its social care function) and voluntary sectors. Reporting to the Minister for Health and the Minister for Children and Youth Affairs, the Health Information and Quality Authority has statutory responsibility for:

- **Setting Standards for Health and Social Services** – Developing person-centred standards, based on evidence and best international practice, for those health and social care services in Ireland that by law are required to be regulated by the Authority.
- **Supporting Improvement –** Supporting health and social care services to implement standards by providing education in quality improvement tools and methodologies.
- **Social Services Inspectorate** – Registering and inspecting residential centres for dependent people and inspecting children's detention schools, foster care services and child protection services.
- **Monitoring Healthcare Quality and Safety** – Monitoring the quality and safety of health and personal social care services and investigating as necessary serious concerns about the health and welfare of people who use these services.
- **Health Technology Assessment** – Ensuring the best outcome for people who use our health services and best use of resources by evaluating the clinical and cost-effectiveness of drugs, equipment, diagnostic techniques and health promotion activities.
- **Health Information** – Advising on the efficient and secure collection and sharing of health information, evaluating information resources and publishing information about the delivery and performance of Ireland's health and social care services.

Overview of the Authority's Health Information function

Healthcare is information-intensive, generating huge volumes of data every day. Health and social care workers spend a significant amount of their time handling information, collecting it, looking for it and storing it. It is therefore very important that information is managed in the most effective way possible in order to ensure a high quality, safe service.

Safe, reliable healthcare depends on access to, and the use of, information that is accurate, valid, reliable, timely, relevant, legible and complete. For example, when giving a patient a drug, a nurse needs to be sure that they are administering the appropriate dose of the correct drug to the right patient and that the patient is not allergic to it. Similarly, lack of up-to-date information can lead to the unnecessary duplication of tests. If critical diagnostic results are missing or overlooked, tests have to be repeated unnecessarily and, at best, appropriate treatment is delayed or at worst not given.

In addition, health information has a key role to play in healthcare planning decisions – where to locate a new service, whether or not to introduce a new national screening programme and decisions on best value for money in health and social care provision.

Under section (8)(1)(k) of the Health Act 2007, the Health Information and Quality Authority (the Authority) is responsible for setting standards for all aspects of health information and monitoring compliance with those standards. In addition, under section 8(1)(j), the Authority is charged with evaluating the quality of the information available on health and social care and with making recommendations to improve quality. It is also charged with filling gaps where information is needed but is not available currently.

Information and communications technology (ICT) has a critical role to play in ensuring that information to promote quality and safety in health and social care settings is available when and where it is required. For example, it can generate alerts in the event that a patient is prescribed medication to which they are allergic. Further to this, it can support a much faster, more reliable and safer referral system between the patient's general practitioner (GP) and hospitals.

Although there are a number of examples of good practice, the current ICT infrastructure in Ireland's health and social care sector is highly fragmented with major gaps and silos of information which prevents the safe and effective transfer of information. This results in service users being asked to provide the same information on multiple occasions.

Information can be lost, documentation is poor, and there is over-reliance on memory. Equally, those responsible for planning our services experience great difficulty in bringing together information in order to make informed decisions. Variability in practice leads to variability in outcomes and cost of care. Furthermore, we are all being encouraged to take more responsibility for our own health and wellbeing, yet it can be very difficult to find consistent, understandable and trustworthy information on which to base our decisions.

As a result of these deficiencies, there is a clear and pressing need to develop a coherent and integrated approach to health information, based on standards and international best practice. A strong and reliable health information environment will allow all interested and informed parties, the general public, patients and service users, health professionals and policy makers to make choices or decisions based on the best available information. This is a fundamental requirement for a high reliability healthcare system.

One of the areas currently being addressed by the health information function is the area of electronic prescribing and the electronic transfer of prescriptions. In order to electronically exchange information between the GP and community pharmacists, an ePrescribing dataset was developed which can be transformed into electronic documents using an international standard known as the Health Level 7 (HL7) Clinical Document Architecture (CDA) standard. This project defines the ePrescribing dataset and specifies the HL7 Clinical Document Architecture.

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Executive Summary

ePrescribing* was identified in the National eHealth Strategy (2013)[1] as a key priority for Ireland. The benefits of ePrescribing initiatives are well documented and an increasing number of countries have adopted ePrescribing and the electronic transfer of prescriptions. These benefits include a reduction in medication errors, prescription and transcription errors, and a corresponding improvement in patient safety.

In recent years, the Authority has undertaken multiple projects in the area of ePrescribing and electronic transfer of prescriptions. An international review by the Authority of ePrescribing and the electronic transfer of prescriptions [2] showed that in the countries reviewed, electronic transfer of prescriptions has been successfully implemented at a national level between primary care and community pharmacies.

Based on this international review, it is clear that a number of fundamental building blocks must be in place prior to developing an electronic transfer of prescriptions solution, including the development of messaging and electronic document standards to support electronic transfer of prescriptions. The international review informed the development of a work plan for the Authority's eHealth Standards Advisory Group.

In order to support the implementation of electronic transfer of prescriptions, multiple standards are required including an ePrescribing model and standard to represent and exchange clinical documents. The purpose of this project is to define an ePrescribing dataset that is used to develop a standard for the exchange of clinical documents based on an international standard known as the Health Level Seven (HL7) Clinical Document Architecture (CDA) standard.[3] The ePrescribing CDA standard is then used by software developers to create clinical documents that can be safely exchanged between multiple healthcare providers.

The implementation of an ePrescribing dataset and CDA standard can support the implementation of ePrescribing and electronic transfer of prescriptions. This brings about benefits for patients, healthcare providers, prescribers and

* In Australia, according to Department of Health and Ageing Pharmacy and Government Arrangements – Fifth Community Pharmacy Agreement,[4] an electronic prescription is a prescription electronically generated in line with a process by a prescriber, authenticated (electronically signed), securely transmitted (either directly or indirectly) for dispensing and supply, seamlessly integrated into the pharmacy dispensing software and, in the case of Pharmaceutical Benefits Scheme (PBS) prescriptions, is available to be electronically sent to Medicare Australia for claiming purposes. This definition does not preclude the use of paper-based processes to support ePrescribing activity.

organisations that fund the health and disability sector. An ePrescribing dataset and clinical document architecture standard can improve the quality and safety of patient care by standardising the way that clinical information is shared between healthcare providers, which in turn ensures that good quality health information can be reused in a meaningful way.

The HL7 clinical document architecture standard is an internationally recognised standard which is implemented in many countries. This standard facilitates the exchange and unambiguous interpretation of clinical documents such as prescriptions, referrals and discharge summaries. The Clinical document architecture standard supports a combination of free text for human readability and adds structure and coding to the document to enable machine processing. This means an electronic prescription document is both readable by clinicians and can be processed by clinical information computer systems.

The ePrescribing dataset and clinical document architecture standard was developed by the Authority in collaboration with its eHealth Standards Advisory Group (eSAG) and a technical subgroup supporting the work of the eSAG. The eSAG is a group chaired by the Authority and advises us on the development of technical standards. The subgroup was made up of representatives from the General Practitioner Information Technology Group, Irish Pharmacy Union, National Standards Authority of Ireland, School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin, and a representative community pharmacist.

The technical subgroup defined a dataset for ePrescribing. This dataset was used to inform the development of the clinical document architecture ePrescribing standard for Ireland. Several international clinical document architecture standards were researched to inform this standard. It is based primarily on a clinical document architecture standard developed by the epSOS project,[4] a large European initiative to facilitate cross-border ePrescribing.

In order to consult with important interested and informed parties, a targeted consultation was conducted by the Authority. The Authority distributed a consultation document in late 2014. Emails were sent to interested and informed parties (see Appendix 1) inviting them to participate in the consultation. Appendix 2 lists the questions that these people were asked. Overall, the ePrescribing dataset and standard was welcomed by respondents and the benefits that it can bring were recognised. Each submission was read in its entirety and informed the development of the final standard. The standard was approved by the Authority's Executive Management Team

(EMT) and the Authority's Board. It has been submitted to the Minister for Health for approval as a national standard.

1 Introduction

ePrescribing was identified in the National eHealth Strategy (2013)[1] as a key priority for Ireland. The benefits of ePrescribing initiatives are well documented and an increasing number of countries have adopted their use. In recent years, the Authority has undertaken multiple projects in the area of ePrescribing and electronic transfer of prescriptions. An international review[2] undertaken by the Authority showed that in the six jurisdictions reviewed, each has commenced implementation or already implemented ePrescribing solutions, with similarities and differences between them.

Each of the countries reviewed focused mainly on prescribing and dispensing of medication in the community, rather than from the hospital setting to the community pharmacies. This is explained as a consequence of both general practitioners (GPs) and pharmacists having similar processes across their practices and hence being able to support computerisation of the process. By contrast, hospital medication management processes are typically more complex, making standardisation and computerisation more complicated.

Each country reviewed had also undertaken processes in a phased and incremental approach, with paper systems either included as part of the solution or paper systems supported in parallel with the electronic solution.

With the exception of Northern Ireland, each solution involved the transmission of an electronic prescription document from a GP's practice management system to a message or transaction broker, where the message was stored. Each solution then allowed pharmacists to retrieve the electronic document from the transaction broker and verify a prescription prior to providing the patient with their medication.

The international review provided information and evidence to aid the development of an electronic transfer of prescriptions solution for Ireland. Based on this international review, it is clear that a number of fundamental building blocks must be in place prior to developing an electronic transfer of prescriptions solution. These include:

- introducing an individual health identifier (IHI) and an identifier for health and social care professionals and organisations
- developing an interoperability framework and supporting infrastructure to facilitate the safe and secure electronic transfer of prescriptions between prescribers and dispensers

- developing a data model to support the implementation of a national drugs reference catalogue
- developing messaging and document standards to support electronic transfer of prescriptions.

Based on the Authority's international review, a work plan for the Authority was developed. One of the items on the work plan was developing a dataset for prescriptions. The dataset is used to specify how the prescription dataset can be transformed into electronic documents using an international standard known as the Health Level Seven (HL7) Clinical Document Architecture standard.

A dataset is a formal description of the classes and attributes associated for a given use case, in this instance an electronic prescription. Datasets provide a structure for data used within information systems and provide formal definitions for the structure of the data. If a dataset is used consistently across systems then compatibility of data can be achieved.

The HL7 clinical document architecture standard is an internationally recognised standard which has been implemented in many countries. It facilitates the exchange and unambiguous interpretation of clinical documents such as prescriptions, referrals and discharge summaries. Clinical document architecture supports a combination of free text for human readability and adds structure and coding to the document to enable machine processing. It can be processed by unsophisticated applications making it easy to render in web browsers so that end users can view the clinical document. It can also be integrated into clinical information computer systems so the data can be reused.

1.1 Benefits of the electronic transfer of prescriptions

Implementing the ePrescribing clinical document architecture standard can support the introduction of electronic prescribing and the electronic transfer of prescriptions. There are many benefits of electronic transfer of prescriptions for patients, healthcare practitioners and organisations that fund the health and disability sectors.

Patients, people in care and the health and disability sectors will benefit from electronic transfer of prescriptions and ePrescribing through:

- safer care because:
  - electronic transfer of prescriptions and ePrescribing reduces manual data entry and therefore transcription errors, resulting in turn in reduced risk of a prescribed medicine not being correctly given to a patient

  - prescribed medicines descriptions are more accurate and there is improved legibility of prescription details
- having prescriptions dispensed more quickly through more efficient processes.

Healthcare practitioners who prescribe medicines will benefit from electronic transfer of prescriptions through:

- reduced interruptions from pharmacies querying prescriptions
- fewer prescriptions having to be returned to the prescriber for correction because they do not comply with legal or subsidy requirements
- better clinical decision-making, leading to safer and higher quality care, through timely access to selected health information about an individual if the electronic transfer of prescriptions solution is linked to an electronic patient record.
- the ability to receive notification whenever a patient collects prescribed medicines

Pharmacists who dispense medicines will benefit from electronic transfer of prescriptions through:

- the usage of a common list of medicines in both prescriber and pharmacy systems. This means the pharmacy can more quickly and accurately select the intended medicine for the patient
- improved quality of prescription information and therefore a reduction in time spent contacting prescribers to clarify or correct prescriptions
- the ability to download prescription details and not having to enter this manually can potentially make the process more efficient with less room for error
- reduced reliance on the individual's recollection of their medication history.

Organisations that fund the health and disability sectors will benefit from electronic transfer of prescriptions through:

- improved efficiency to health information flows and a reduction in duplicate prescribing
- potential reductions in costs from improved patient compliance and reduced hospitalisation by being able to monitor collection of prescriptions by individuals

- efficiency gains enabling pharmacists to provide other patient orientated services.
- improved consistency with the adoption of electronic transfer of prescriptions standards (and therefore better consumer understanding and control of) the policies, processes and mechanisms that are put in place to ensure the privacy of electronic healthcare records.

Furthermore, where prescribing and dispensing information is sent to electronic health records, organisations responsible for the delivery of healthcare outcomes through population-based strategies can also benefit through:

- support for optimised prescribing, such as improving the management of long-term health conditions
- being able to recall prescribing and dispensing history when seeing a different healthcare practitioner
- enabling the development of quality programmes, for instance:
  - reducing wastage by prescribing appropriate quantities of medicines
  - addressing and reducing unexplained variability in prescribing patterns among providers
  - establishing an evidence base for use of new or expensive medicines
- improved support for future permissible secondary uses of data to deliver further public benefits (when the electronic transfer of prescriptions solution is linked to a longitudinal electronic patient record) such as:
  - more targeted health initiatives
  - public health planning
  - research, education and disease detection
- when the ETP solution is linked to a longitudinal electronic patient record.

1.2 HL7 Clinical Document Architecture (CDA) Standard

The international standards organisation Health Level Seven (HL7) developed the clinical document architecture (CDA) standard to facilitate the exchange and unambiguous interpretation of clinical documents such as prescriptions, referrals and discharge summaries. Clinical document architecture supports a combination of free text for human readability and adds structure and coding to the document to enable machine processing.

HL7 defines clinical documents as historical, human-readable healthcare records that combine data and free text. The following list describes the characteristics of an electronic clinical document as defined by the CDA standard:

- Persistent – a clinical document continues to exist in an unaltered state for a period defined by local and regulatory requirements.
- Stewardship – a clinical document is maintained by an organisation entrusted with its care.
- Potential for authentication – a clinical document is a collection of information that is intended to be legally authenticated.
- Context – a clinical document establishes the default context for its content.
- Wholeness – authentication of a clinical document applies to the whole and does not apply to portions of the document without the full context of the document.
- Human readability – a clinical document is readable by humans.

Clinical document architecture allows for different levels of detail to be added to clinical documents. Level one enables implementers to develop documents that are displayed and presented to clinicians in a readable format but provides very little coded information to support machine processing of the document. More complex documents can be created that are coded for machine processing using level two and level three. Level one is considered relatively easy to implement and will ensure that clinical documents are brought up to a standard format. Over time, it is possible for implementers to add greater levels of sophistication by incrementally adding in more structure and coding to the clinical document. This feature is referred to as the 'migration path' and provides a flexible approach to implementation of clinical document architecture.

Several countries have adopted clinical document architecture as the basis for their standards-based health information exchange architecture. Countries who have undertaken CDA projects include Australia, Canada, Germany, Greece, Finland, Japan, UK and the US. Implementers can refine the generic CDA standard by defining the structure and coding requirements to meet their local requirements.

In summary, the key benefits of clinical document architecture are that they:

- are machine-computable and readable by humans
- provide a standardised display of clinical information without loss of clinical meaning
- provide assurance of clinical quality and safety more effectively than message-based interfaces, by storing and displaying the clinical data as entered by the clinician
- support legal attestation by the clinician (requiring that a document has been signed manually or electronically by the responsible individual).
- can be processed by unsophisticated applications (displayed in web browsers)
- provide a number of levels of compliance to assist with technical implementation and migration.

1.3 Methodology

The draft ePrescribing dataset and CDA standard was developed by the Authority in collaboration with a technical subgroup. The technical subgroup was made up of members from the Authority's eHealth Standards Advisory Group (eSAG) and other representatives from the General Practitioner Information Technology Group, Irish Pharmacy Union, National Standards Authority of Ireland, School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin and a community pharmacist.

The technical subgroup defined a dataset for ePrescribing based on analysis of ePrescribing datasets developed in Australia and in the European Union, and by analysing examples of prescriptions used in the Irish setting, including mandatory information for prescriptions covered by legislation. Additionally, relevant data from national clinical datasets already developed by the Authority – such as the demographic dataset and referrals and discharge summary datasets – informed the process, as did contributions from the subgroup members who were experts in the field of prescribing and dispensing.

Following development of the dataset, a CDA ePrescribing standard was developed. Several international CDA standards were researched to inform this standard. This project analysed information from the:

- HL7 Implementation Guide: CDA R2 Continuity of Care Document (CCD)[3]
- epSOS Semantic Implementation Guidelines[4]

- Integrating the Healthcare Enterprise, Patient Care Coordination Technical Framework (IHE PCC) [5]
- Australian standard on the e-Prescription CDA Implementation Guide Version 2.1.[6]

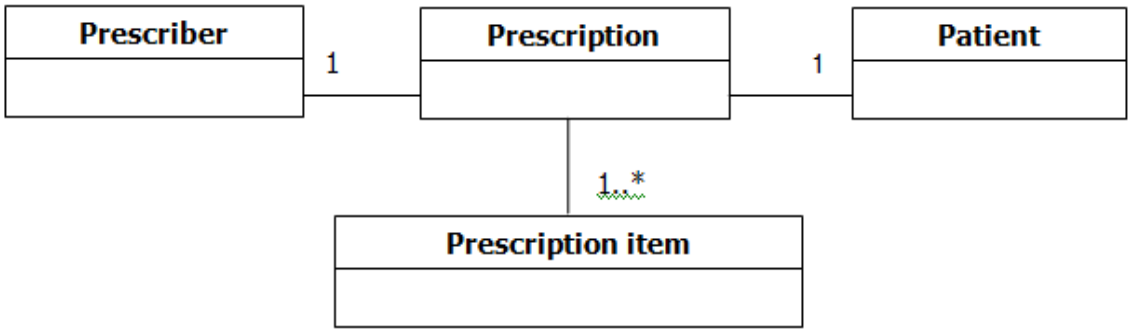
The National ePrescribing standard was based primarily on a CDA standard developed by the epSOS project. epSOS was a large European initiative to facilitate cross-border transfer of electronic patient summary documents and electronic prescriptions. The epSOS project re-used information and standards from other leading organisations who are considered experts in the area of implementation of clinical document architecture. The epSOS project reused the HL7 CDA Standard, the HL7 clinical care document (CCD) standard and the IHE PCC.

In order to consult with important interested and informed parties, a targeted consultation was conducted and the Authority distributed a consultation document, entitled the *ePrescription Dataset and Clinical Document Architecture standard (for trial use) - Draft for consultation* and the consultation feedback form. It was circulated distributed in early December 2014. Emails were sent to 25 stakeholders (see Appendix 1) inviting them to participate in the consultation. Appendix 2 lists this questions that people were asked. Overall, the ePrescribing dataset and standard was welcomed by respondents and the benefits that it can bring were recognised. Each submission was read in its entirety. Comments were reviewed and analysed and changes to the standard were made.

2 Dataset for ePrescribing

The ePrescribing dataset consists of four main classes: the patient, the prescriber, the prescription and the prescription items as illustrated in Figure 1 below. Each prescription is associated with one patient and one prescriber and multiple prescription items. The prescription items correspond to each unique item prescribed on a prescription. The classes are detailed in section 2.1 to 2.4 below. Note, the 1..* annotation in Figure 1 is used to indicate that a prescription may have multiple prescription items.

Figure 1. Dataset model for an ePrescription



In addition to the clinical dataset, the CDA standard requires information about the document identification and the owner and author of the document. These requirements are listed in sections 2.5 to 2.7 below. Each of the classes and associated attributes are described in the tables below which define the name, definition, optionality and usage of the data element.

2.1 Subject of care (the patient)

The subject of care is the person who the prescription is issued for. Table 1 illustrates the attributes in the subject of care class.

Table 1. Subject of care

Name	Definition	Optionality	Usage
1.1 Title	Coded value that contains the title relevant to the subject of care.	Optional	To be selected from a predefined list.
1.2 Forename	A patient's first name or given name(s) as recorded on their birth certificate.	Mandatory	A patient's first name or given name(s) as recorded on their birth certificate.
1.3 Surname	The second part of a patient's name which denotes their family or marital name.	Mandatory	The second part of a patient's name which denotes their family or marital name.
1.4 Address	The location to be used to contact or correspond with the patient. This would normally be the patient's usual home address.	Mandatory	The particulars of the place where the patient lives.

Name	Definition	Optionality	Usage
1.5 Date of birth	Date of birth indicating the day, month, and year when the patient was born.	Mandatory	The date of birth should be supplied in dd/mm/yyyy format.
1.6 Sex	Sex is the biological distinction between male and female. Where there is an inconsistency between anatomical and chromosomal characteristics, sex is based on anatomical characteristics.	Mandatory	Examples of sex include male and female
1.7 Health identifier	A number or code assigned to an individual to uniquely identify the individual within an organisation.	Optional	Both the code and the code type that the code relates to should be provided, for instance 0987654321 Healthcare Record Number (HcRN). When a national individual healthcare number is available, this should be carried in this attribute. Other identifiers which may be carried in this field include the General Medical Scheme, Drug Payment Scheme, Long-term Illness Scheme and Hardship Scheme identifier.

2.2 Healthcare practitioner (the prescriber)

The prescriber is the healthcare practitioner who issued the prescription. The attributes in the healthcare practitioner class are illustrated in table 2.

Table 2. Healthcare practitioner (the prescriber)

Name	Definition	Optionality	Usage
2.1 Title	Coded value that contains the title relevant to the healthcare practitioner.	Optional	To be selected from a predefined list.
2.2 Forename	First name or given name of healthcare practitioner.	Mandatory	Where the healthcare practitioner is registered with a professional body, the forename should be the forename registered with the professional body.
2.3 Surname	The second part of a healthcare practitioner's name which denotes their family or marital name.	Mandatory	Where the healthcare practitioner is registered with a professional body, the surname should be the surname registered with the professional body.
2.4 Address	The particulars of the place used to correspond with the healthcare practitioner.	Mandatory	The particulars of the place used to correspond with the healthcare practitioner.
2.5 Telephone	The telephone number of the	Mandatory	The phone number to contact the

Name	Definition	Optionality	Usage
number	healthcare practitioner.		healthcare practitioner.
2.6 Email address	A secure email address for the healthcare practitioner.	Optional	The secure email address to contact the healthcare practitioner.
2.7 Fax Number	The fax number for the healthcare practitioner.	Optional	The fax number to contact the healthcare practitioner
2.8 Health identifier	A number or code assigned to an individual to uniquely identify the individual within an organisation or professional regulatory body.	Optional	The number or code assigned to the professional by its regulatory authority or the health services' providers identifier when it is implemented.

2.3 Prescription

The prescription consists of information relating to the prescription as a whole and these are documented in Table 3 below. Table 4 in section 2.4 contains information relating to each individual medication item prescribed.

Table 3. Prescription

Name	Definition	Optionality	Usage
3.1 Date written	Date prescription was written.	Mandatory	Date field which indicates when the prescription was written. This is the same as the date the document and or prescription came into being or was created on.
3.2 Effective date	Date prescription becomes effective.	Mandatory	Date field which indicates when the prescription becomes effective. For example, the date on which the healthcare practitioner instructs the patient to begin the treatment.
3.3 Status	Status of the prescription.	Mandatory	Coded value, that is to say, 1 = active, 2= on hold, 3= completed.
3.4 Advice to dispenser	Any advice the prescriber might suggest to the dispenser.	Optional	Additional advice the prescriber may provide to the dispenser.

2.4 Prescription item

This table correlates to each of the individual items prescribed for the patient on the prescription. This section will repeat if multiple items are prescribed for the patient at the time of creating the prescription.

Table 4. Prescription item

Name	Definition	Optionality	Usage
4.1 Date written	Date prescription was written.	Mandatory	Date field which indicates when the prescription was written. This is the same as the date the document and or prescription came into being or was created on.
4.2 Effective date	Date prescription becomes effective.	Mandatory	Date field which indicates when the prescription becomes effective. For example, the date on which the healthcare practitioner instructs the patient to begin the treatment.
4.3 Status	Status of the prescription.	Mandatory	Coded value, that is to say, 1 =active 2= on hold, 3= completed
4.4 Medicinal product code	Code that identifies the medicinal product.	Mandatory	A code associated with the medicinal product.

Name	Definition	Optionality	Usage
4.5 Medicinal product	The name of the medicinal product or package. This should be sufficient for a dispenser to identify the kind of medication to dispense. It may be a trade name or a generic name.	Mandatory	A textual description associated with the medicinal product.
4.6 Medicinal product package	Size and or type of package prescribed.	Optional	When prescribing occurs at a package level, this field is used to describe the size and type of the package to dispense.
4.7 Number of packages	Number of complete packages required to fulfil the prescription.	Optional	When prescribing occurs at a package level, this field is used to describe the number of the package(s) to dispense.
4.8 Dose form (strength)	Content of the active ingredient expressed quantatively per dosage unit, per unit of volume or per unit of weight, according to the pharmaceutical dose form.	Optional	This field consists of a size value and unit, a combination of both defines the strength, for example 250 mg, 1g.

Name	Definition	Optionality	Usage
4.9 Dose form (type)	A description of the dose type.	Optional	This field describes the does type, such as tablet, vial.
4.10 Total number of dose instances	Total number of instances of the medicinal product required to fulfil the prescription.	Conditional	This field is used to describe the number of the units(s) to dispense. If 4.6 and 4.7 are populated, then this field does not need to be populated.
4.11 Dose (number of instances)	Number of instances of the medicinal product to be taken by the patient at a given time.	Optional	This field is used to describe the number of units(s) to be taken at a given time.
4.12 Frequency	How often the medication is to be administered, often expressed in number of times per day but may also include information such as 1 hour before or after meals.	Optional	This field is used to describe the frequency the dose described in 4.11 should be taken by the patient.
4.13 Duration	Duration of time for the regime to be taken.	Optional	This field is used to describe the duration the dose described in 4.11 should be taken by the patient.
4.14 Route of administration	Coded element which indicates how the medication is to be received by the patient.	Optional	A representation of the place in or on the body when the medicinal product or active ingredient is

Name	Definition	Optionality	Usage
			introduced in order to achieve the desired effect.
4.15 Advice to dispenser	Any advice the prescriber might suggest to the dispenser.	Optional	Additional advice the prescriber may provide to the dispenser.
4.16 Substitution	Used to indicate if the medication prescribed may not be substituted.	Optional	Indicates whether the prescriber does not want generic substitution to occur. This could be coded to include Do Not Substitute.
4.17 Indications	Clinical information about the reason for providing the medication.	Optional	This will be a code and description.
4.18 Repeats	This is to indicate that a prescription item can repeat or not.	Optional	This should be coded to include the values Do not Repeat (N) or Can Repeat (Y).
4.19 Number of Repeats	This is the number of times that each prescription item can repeat.	Optional	This should be a numerical value
4.20 Advice to patient	Any advice the prescriber might suggest to the patient.	Optional	Additional advice the prescriber may provide to the patient

2.5 Document identification

This section defines the document identification and data items required by the clinical document architecture (CDA) standard. This information is required by the CDA standard and is additional to the clinical dataset described in sections 2.1 to 2.4. Table 5 documents the attributes required to identify the document.

Table 5: Document information

Name	Definition	Optionality	Usage
5.1 Clinical document	The clinical document class is the entry point into the CDA R-MIM.	Mandatory	This data element is fixed and must always be included in the document. The <ClinicalDocument> XML element is the root element of a CDA document.
5.2 Type ID	This element represents the type of clinical document (such as ePrescription, eDispensation) and identifies the constraints imposed by CDA R2 on the content, essentially acting as a version identifier.	Mandatory	This data element is fixed and must always be included in the document. The @root and @extension values of this element are specified as a long fixed identifier which is in two parts: root and extension.

Name	Definition	Optionality	Usage
5.3 Template ID	Template ID is used to indicate any number of templates which might be defined at the document level, sections and clinical statement entries. Allows for the identification of templates that specify additional constraints above and beyond the base CDA R2 structure.	Mandatory	This data element is fixed and must always be included in the document.
5.4 Document ID	This is the identifier of the clinical document which uniquely identifies the document instance.	Mandatory	Each revision of a clinical document is assigned a distinct identifier.
5.5 Document title	This is the human-readable name of the clinical document.	Optional	The document title can be rendered by the browser as the caption of the document.
5.6 Date of creation	The time and date that the document came into being.	Mandatory	The time and date that the document came into being.
5.7 Date of last update of document	This element represents the last effective date when the summary content has been updated.	Optional	This element represents the last effective date when the summary content has been updated.
5.8 Clinical document code	Determines the document type.	Mandatory	A coded value. The Logical Observation Identifiers Names (LOINC) is an international classification system which

Name	Definition	Optionality	Usage
			provides appropriate values for this field.
5.9 Confidentiality code	Codes that identify how sensitive a piece of information is and or that indicate how the information may be made available or disclosed.	Mandatory	A coded value, CDA defines a limited set which can be extended as needed. The HL7 coding system contains the following codes: N-Normal/R-Restricted and V-Very restricted. Other coding systems may be used.
5.10 Legal authenticator	Legal authenticator may be a person or an organisation that is responsible for the medical content of the document.	Mandatory	Legal authenticator may be a person or an organisation that is responsible for the medical content of the document.
5.11 Document language code	Language code as defined by RFC3066.	Mandatory	The language code SHALL be in the form nn-CC. The nn portion SHALL be an ISO-639-1 language code in lower case derived by the Value Set epSOSLanguage. The CC portion SHALL be an ISO-3166 country code in upper case derived by the value Set epSOSCountry. For example: <Language Code> <COUNTRY

Name	Definition	Optionality	Usage
			CODE><languageCode code="en-GB"/>
5.12 Set ID	Identifier for a set of related documents. The original document and replacement documents versions thereof all share one and the same set ID – they all have a different and or unique document identifier (the ID attribute as present in the header).	Optional	This element is not mandatory, but you should include them if you are sending a new version of a document that has been published before. Implementers are recommended to use this attribute.
5.13 Version Number	Contains the version number of this instance and or version of the document within a set of related documents.	Mandatory	For additional information, see the description of *Other Participants: related Document:* it is used to link a later version of a document to a previous version of a document. Example: ClinicalDocument/versionNumber/ @number="1".

2.6 Author

This section defines the author data items required by the clinical document architecture (CDA) standard. This information is required by the CDA standard and is additional to the clinical data set described in sections 2.1 to 2.4. The attributes of the author class are documented in Table 6.

Table 6: Author information

Name	Definition	Optionality	Usage
6.1 Author's ID number	The identifier of the health practitioner who is responsible for creating the ePrescription.	Mandatory	The number or code assigned to the professional by its regulatory authority or the health services' providers identifier when it is implemented.
6.1 Author's title	Coded value that contains the title relevant to the author of the document.	Optional	To be selected from a predefined list.
6.2 Author's forename	The author's first or given name(s) as recorded on their birth certificate.	Mandatory	Where the Author is registered with a professional body, the forename should be the forename registered with the professional body.

Name	Definition	Optionality	Usage
6.3 Author's surname	Second part of the author's name which denotes their family or marital name.	Mandatory	Where the Author is registered with a professional body the surname should be the surname registered with the professional body.
6.4 Author's profession	Coded element that specifies the author's particular profession.	Mandatory	This value can be selected from a predefined list.
6.5 Author's telephone number	The author's telephone number.	Mandatory	The phone number to contact the author.
6.6 Author's email address	The author's email address.	Mandatory	The secure email address to contact the Author.
6.7 Author's address	The particulars of the place used to correspond with the Author.	Mandatory	The particulars of the place used to correspond with the author.

2.7 Custodian

The custodian represents the organisation that is in charge of maintaining the document. This information is required by the clinical document architecture (CDA) standard and is additional to the clinical dataset described in sections 2.1 to 2.4. Table 7 documents the attributes of the custodian class.

Table 7. Custodian information

Name	Definition	Optionality	Usage
7.1 Custodian	Defines the person or organisation responsible for the document.	Mandatory	Every CDA document has exactly one custodian.
7.2 Custodian ID	A unique identifier for the custodian	Mandatory	Unique identifier for the custodian.
7.3 Custodian's name	The name of the organisation that is responsible for maintaining the document.	Mandatory	For example, the GP practice name.
7.4 Custodian's address	The location of the organisation that is responsible for maintaining the document. This would usually be the healthcare provider's address.	Mandatory	The custodian's address.
7.5 Custodian's telephone number	The custodian's telephone number.	Mandatory	The custodian's telephone number.

7.6 Custodian's email address	The custodian's email address.	Mandatory	The custodian's email address.

3 Clinical document architecture (CDA) standard

This section defines the clinical document architecture standard for the electronic prescription and is based on the dataset defined in section 2. Sections 3.1 to 3.4 will outline some clinical document architecture rules and will provide guidance on how to interpret the ePrescribing standard. Sections 3.5 to 3.10 detail the clinical document architecture standard.

3.1 Clinical document architecture (CDA) document structure

A CDA clinical document is divided into a header and a body. The purpose of the header is to hold metadata about the clinical report which:

- sets the context for the document
- enables clinical document exchange across and within institutions
- facilitates clinical document management
- facilitates compilation of an individual patient's clinical documents into a lifetime electronic patient record.

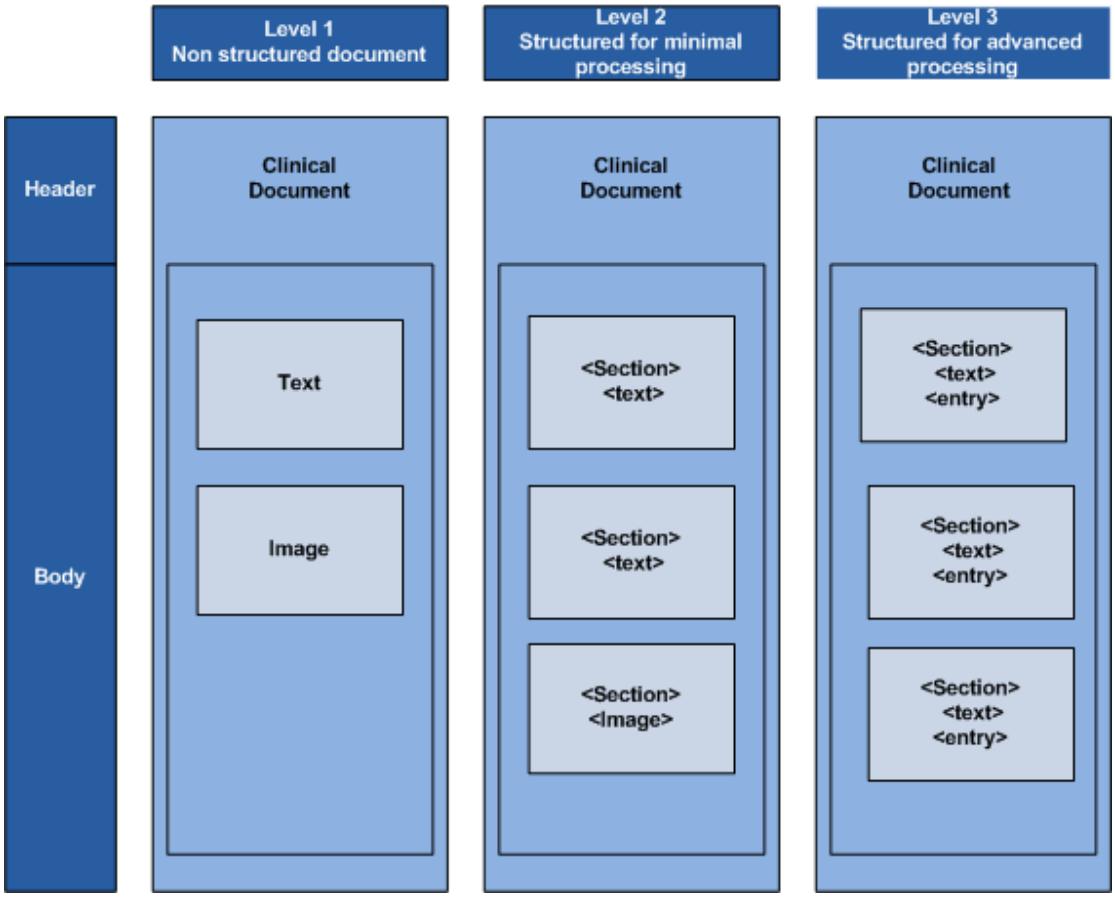
The header identifies and classifies the document and provides information on the authentication, the clinical visit, the patient, and the involved providers.

The purpose of the body of a CDA document is to carry the clinical report created by the healthcare practitioner. As previously mentioned, clinical document architecture allows for different levels of detail to be added to clinical documents (see Figure 2). Level-one implementations have a coded document header and the human-readable content is added to the body of the document as text. When implementing levels two and three, structured information is added by identifying CDA concepts known as sections and entries. Sections are used to identify headings within the clinical document and entries are used to identify lower level detail. In the context of this standard, there is one section identified – the medication section – and each prescription item is implemented as an entry.

Sections can be coded using a clinical terminologies or classifications such as Logical Observation Identifiers Names and Codes (LOINC) or the Systematized Nomenclature of Medicine--Clinical Terms (SNOMED CT). When the body of the document is structured using sections, and those sections are coded, HL7 would call that a Level 2 CDA document. A section may have a number of entries. Entries are machine-readable representations of the clinical content and constitute a Level 3 CDA document. An example of coding at the Level 3 could be for a 'prescription item'. When the body of the

document is structured using entries, and those sections are coded, HL7 would call that a Level 3 CDA document.

Figure 2. HL7 CDA document levels (adapted from epSOS)



3.2 Description of the ePrescribing standard tables

Sections 3.5 to 3.10 detail the ePrescribing CDA standard. The ePrescribing standard is defined using a table structure, as illustrated in Figure 3 below. Each purpose of each of those columns is explained in this section.

Figure 3. Attribute table for defining CDA documents, sections and entries

Num	Data element	Description	CDA Xpath expression	HL7 v3 Data Type	Card/Opt	Vocabulary

3.2.1 The 'Num' column

The Num column contains a unique number that identifies the data elements and is used for reference purposes.

3.2.2 The 'Data element' column

The data element defines the name of the field.

3.2.3 The 'Description' column

The description field gives a comprehensive description of the data element. This includes any qualifying information that needs to be included about the data element.

3.2.4 The 'CDA Xpath expression' column

The CDA Xpath expression is used to search through an XML document and locate and extracts information from the nodes (any part of the document, such as an element or attribute) in that document. This is used to help in the implementation of a CDA standard and corresponds to the XML representation required for implementation.

3.2.5 The 'HL7 v3 Data Type' column

Each data element has a datatype associated with it. This column indicates the HL7 v3 data type that must be used for the field. Information about HL7v3 data types may be found in Appendix 3.

3.2.6 The 'Optionality and Cardinality (Opt/Card)' column

The optionality, as well as the cardinality information is associated with each data elements in the table. The optionality used for this standard are based on the optionality included in the epSOS standard. The optionality descriptions and acronyms are included in Figure 4.

Figure 4. Optionality used in ePrescribing standard

Value	Meaning
R	Means Required, the mapped CDA element shall be present and shall not contain the nullFlavor attribute.
RNFA (or R use NullFlavor)	Means Required, nullFlavor Allowed, the mapped CDA element shall be present and it may contain the nullFlavor attribute. In some cases, the recommended nullFlavor value is also indicated.

O	Means Optional, the mapped CDA element may be omitted unless required by the CDA and or by the template standards.
NA	Means 'not applicable' since the data element is not applicable in the respective document.

The cardinality rules that may be used for sections and data elements are set out in Figure 5.

Figure 5. Cardinality rules

Value	Meaning
0..1	The section or data element may have zero or one instance.
1..1	The section or data element may have one and only one instance.
0..*	The section or data element may have zero or more instances.
1..*	The section or data element may have one or more instances.

For example, the cardinality of a Primary Patient Identifier is [1...1]. This is a one-to-one relationship which means that we require the Primary Patient Identifier. A cardinality of [0...*] means that there are multiple identifiers supported.

3.2.7 The 'Vocabulary' column

The vocabularies that are used throughout this standard are based on ISO, LOINC, the HL7 vocabularies, the Anatomical Therapeutic Chemical Classification System (ATC) and the European Directorate for the Quality of Medicines (see Appendix 4). The LOINC code 57833-6 is proposed code to be used for the identification of the ePrescription documents when implementing this Standard.

3.3 Templates

The HL7 CDA object model is very generic. To use the CDA model for a specific use case (such as an ePrescription document), it is necessary to use HL7 templates. HL7 templates are constraints on the CDA object model, that is they narrow the scope of the generic model. For example, a generic model for the identification of a patient may state that a patient must have one or more identifications. However, a template could be defined to state that a

patient must have exactly one national patient identifier. HL7 templates are documented in an implementation guide.

Template definitions can be generated at the document-level, section-level and entry-level such as patient identification, provider organisation or an observation entry respectively.

HL7 templates are required to have a template ID indicating that a document conforms to both the CDA generic model and the constraints specified in an implementation guide.

Templates are used throughout this standard and are taken from the epSOS project. This standard has made adaptations to the epSOS templates. There are instances where optional elements have been made stricter, for example elements which were optional in epSOS are required in this standard or elements have been added that were not originally described in the epSOS standard in order to meet the national dataset requirements. Each template has a set of metadata to describe the purpose and use of the template, allowing templates to be stored in repositories which can be queried. This makes it possible for templates to be shared internationally.

HL7 templates are required to have a template ID indicating that a document conforms to both the CDA generic model and the constraints specified in an implementation guide. Figure 6 below illustrates the template ID for the epSOS ePrescription document.

Figure 6. epSOS templateID for a prescription at document level

Document level	Template ID
epSOS ePrescription	1.3.6.1.4.1.12559.11.10.1.3.1.1.1

3.4 Local extensions

The CDA standard supports the implementation of local requirements by allowing additional XML elements and attributes (local extensions) to be included in implementation guides. These local extensions should only be included when there is no corresponding representation in the CDA standard.

3.5 Document identification

The header identifies and classifies the document and provides information on the authentication, the encounter, the patient, and the involved providers. The attributes for the document header are outlined in Table 8 below.

Table 8. Document identification

Num	Data element	Description	CDA Xpath expression	HL7 v3 data type	Card /Opt	Vocabulary
Clinical document architecture (CDA) header level template. The templateId for the document identification is 1.3.6.1.4.1.19376.1.5.3.1.1.1 (epSOS).						
1.1	Clinical document	The clinical document class is the entry point into the CDA 1..1 R-MIM, and corresponds to the <ClinicalDocument> XML element that is the root element of a CDA document.	/ClinicalDocument	CS	Fixed [1]	
1.2	Type ID	This element represents the type of clinical document (such as ePrescription, eDispensation). The	/ClinicalDocument/typeId Example :<typeId extension="POCD_HD000040" root="2.16.840.1.113883.1.3"/>	II	Fixed	

[1] A fixed or default value element must always be included in the document and entered exactly as shown to ensure conformance to the clinical document architecture 2.0.

Num	Data element	Description	CDA Xpath expression	HL7 v3 data type	Card /Opt	Vocabulary
		clinical document type ID identifies the constraints imposed by CDA R2 on the content, essentially acting as a version identifier. The @root and @extension values of this element are specified as a long-fixed identifier which is in two parts: root and extension.	which is the unique id & extension for the CDA, Release Two Hierarchical Description.			
1.3	Template ID	TemplateID is used to indicate any number of templates which might be defined at the document level, sections and clinical statement entries. Allows for the identification of templates that specify additional constraints above and beyond the base CDA R2 structure. Example: The template ID for an ePrescription	/ClinicalDocument/templateId	II	Fixed	

Num	Data element	Description	CDA Xpath expression	HL7 v3 data type	Card /Opt	Vocabulary
		document is ClinicalDocument/templateId/@root="1.3.6.1.4.1.12559.11.10.1.3.1.1.3"/.				
1.4	Document ID	This is the identifier of the clinical document. The extension typically contains the institution assigned identifier. The root is an OID that identifies the assigner of the identifier. Each revision of a clinical document is assigned a distinct identifier. Uniquely identifies the document instance. Refer to the RIM for II data types (instance identifiers). <id extension="a123" root="2.16.840.1.113883.19.2744.1.1" />.	/ClinicalDocument/id	II	R [1..1]	

Num	Data element	Description	CDA Xpath expression	HL7 v3 data type	Card /Opt	Vocabulary
1.5	Document Title	This is the human-readable name of the clinical document. The document title <title> </title>. can be rendered by the browser as the caption of the document.	/ClinicalDocument/title	ST	O[0...1]	
1.6	Date of creation	The time and date that the document came into being.	/ClinicalDocument/effectiveTime	TS	R [1..1]	
1.7	Date of last update of document	This element represents the last effective date when the summary content has been updated (even if it may happen that this instance of the CDA has been authored later.	ClinicalDocument/documentationOf/serviceEvent/effectiveTime/high	TS	O [1..1]	
1.8	Clinical document code	Determines the document type. For example 'HIQA ePrescribing Document'. This is a LOINC code that	/ClinicalDocument/code	CE	R [1..1]	

Num	Data element	Description	CDA Xpath expression	HL7 v3 data type	Card /Opt	Vocabulary
		classifies the kind of clinical document. Example: <code code="57833-6" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" displayName=" Prescription for medication " />.				
1.9	Confidentiality code	Codes that identify how sensitive a piece of information is or indicates how the information may be made available or disclosed. Example: <confidentialityCode code="N" codeSystem="2.16.840.1.113883.5.25"/>	/ClinicalDocument/confidentialityCode/@code	CE	R null flavor [1..1]	The value of @code shall be drawn from value set epSOSConfidentiality. A coded value, CDA defines a limited set which can be extended as needed. The

Num	Data element	Description	CDA Xpath expression	HL7 v3 data type	Card /Opt	Vocabulary
						HL7 coding system contains the following codes: N-Normal/R-Restricted and V-Very restricted. Other coding systems may be used.
1.10	Legal Authenticator	Legal authenticator may be a person or an organisation that is responsible for the medical content of the document.	/ClinicalDocument/legalAuthenticator/assignedEntity/assignedPerson or ClinicalDocument/legalAuthenticator/assignedEntity/representedOrganization	PN/ON	R [1..*]	
1.11	Document Language	Language Code as defined by RFC3066. <Language Code>	/ClinicalDocument/languageCode	CS	R [1..1]	The language code SHALL be in the form nn-

Num	Data element	Description	CDA Xpath expression	HL7 v3 data type	Card /Opt	Vocabulary
	Code	<COUNTRY CODE><languageCode code="en-GB"/>				CC. The nn portion SHALL be an ISO-639-1 language code in lower case derived by the Value Set epSOSLanguage. The CC portion SHALL be an ISO-3166 country code in upper case derived by the value Set epSOSCountry.
1.12	Set ID	Identifier for a set of related documents. The original document and replacement documents versions thereof all share one and the same set ID	ClinicalDocument/setID	II	O[0...1]	

Num	Data element	Description	CDA Xpath expression	HL7 v3 data type	Card /Opt	Vocabulary
		– they all have a different and unique document identifier.				
1.13	Version Number	Contains the version number of this instance or version of the document within a set of related documents. Example: ClinicalDocument/versionNumber/@number="1".	ClinicalDocument/versionNumber	INT	O[0...1]	

3.6 Author

'The author element represents the creator of the clinical document. If the role of the actor is the entry of information from his or her own knowledge or application of skills, that actor is the author. If one actor provides information to another actor who filters, reasons, or algorithmically creates new information, then that second actor is also an author, having created information from his or her own knowledge or skills.' *Source: Implementation Guide for CDA Release 2: Imaging Integration – UV Realm, March 2009.*

Table 9. Author information

Num	Data Element	Description	CDA Xpath expression	HL7 v3 Data Type	Card /Opt	Vocabulary
CDA (clinical document architecture) header level template. The templateId for Author is 1.3.6.1.4.1.19376.1.5.3.1.2.3 which is taken from the epSOS project.						
2.1	Author's ID number	User ID of individual that is clinically responsible for the ePrescription.	/ClinicalDocument/author/assignedAuthor/id	II	R [1...1]	
2.2	Author's family surname	Author's second name which denotes their family or marital name.	/ClinicalDocument/author/assignedAuthor/assignedPerson/name/family	PN	R [1...*]	
2.3	Author's given name	Author's identifying name.	/ClinicalDocument/author/assignedAuthor/assignedPerson/	PN	R [1..*]	

			name/given			
2.4	Author's prefix	Coded value that contains the title relevant to a specific family name for this Author.	/ClinicalDocument/author/assignedAuthor/assignedPerson/name/prefix	PN	O [0...*]	
2.5	Author's profession	Coded element that specifies the health practitioner's particular profession.	/ClinicalDocument/author/functionCode	CD	R [1..*]	For example, using the ISCO coding system, the code for a general practitioner is 2211, while the code for a pharmacist is 2262.
2.6	Author's telephone number	The Author's telephone number.	/ClinicalDocument/author/assignedAuthor /telecom/@value	TEL	R use nullFlavor [1..*]	
2.7	Author's email address	The Author's secure email address.	/ClinicalDocument/author/assignedAuthor /telecom/@value	TEL	O [0...*]	

2.8	Author's fax number	The Author's fax number.	/ClinicalDocument/author/assignedAuthor /telecom/@value	TEL	O [0...*]	

3.7 Custodian

The custodian is the organisation that is in charge of maintaining the document. This information is required by the CDA R2 standard and shall be recorded in the clinical document/custodian/assigned custodian/represented custodian organisation element. The data attributes for custodian are outlined in Table 10 below.

Table 10. Custodian information

Num	Data Element	Description	CDA Xpath expression	HL7 v3 Data Type	Card/ Opt	Vocabulary
CDA (clinical document architecture) header level template. The template ID for the epSOS CDA custodian is 2.16.840.1.113883.2.4.3.11.60.22.10.11 (epSOS).						
3.1	Custodian	Represents the organisation that is in charge of maintaining the document. The custodian is the steward that is entrusted with the care of the document. Every CDA document has exactly one custodian. The	/Custodian/assignedCustodian		M[1..1]	

Num	Data Element	Description	CDA Xpath expression	HL7 v3 Data Type	Card/ Opt	Vocabulary
		steward organisation is an entity scoping the role of assigned custodian.				
3.2	Custodian ID	A unique identifier for the custodian.	Custodian/assignedCustodia/representedCustodian/Organisation/id	II	M[1..1]	
3.3	Name of custodian	Practice and or organisation name. The name of the organisation that is in charge of maintaining the document.	Custodian/Organisation/name	ON	R [1..1]	
3.4	Custodian's address	The assigned Entity.addr is a mixed content element, so if the individual components of an address are not available then the entire address could be put in this element.	/ClinicalDocument/assignedCustodian/representedCustodian /Organization/addr	AD	R [1..1]	
3.5	Custodian's telephone number	The custodian's telephone number.	/ClinicalDocument/assignedCustodian/representedCustodian /Organization/addr/telecom/@val	TEL	R use nullFlavor	

Num	Data Element	Description	CDA Xpath expression	HL7 v3 Data Type	Card/ Opt	Vocabulary
			ue		[1..*]	
3.6	Custodian's email address	The custodian's secure email address.	/ClinicalDocument/assignedCustodian/representedCustodian/Organization/addr/telecom/@value	TEL	O [1..*]	

3.8 Record Target (Patient Information)

In clinical document architecture (CDA) documents, the person the clinical information relates to is known as the record target. The record target class represents the medical record that this document belongs to. A clinical document typically has exactly one record target participant. The data attributes for patient information are outlined in Table 11 below.

Table 11. Record target

Num	Data Element	Description	CDA Xpath expression	HL7 v3 Data Type	Card/ Opt	Vocabulary
Clinical document architecture (CDA) header level template. The template ID for patient information is 1.3.6.1.4.1.19376.1.5.3.1.1.1 (epSOS).						
4.1	Individual health	User ID of individual.	/ClinicalDocument/recordTarget/patientRole/id	II	0 [0...1]	

Num	Data Element	Description	CDA Xpath expression	HL7 v3 Data Type	Card/ Opt	Vocabulary
	identifier					
4.2	Family surname	Patient's second name which denotes their family or marital name.	/ClinicalDocument/recordTarget/patientRole/name/family	PN	R [1...*]	
4.3	Given name	Patient's identifying name.	/ClinicalDocument/recordTarget/patientRole/name/given	PN	R [1...*]	
4.4	Prefix	Coded value that contains the title relevant to a specific family name for this Patient.	/ClinicalDocument/recordTarget/patientRole/prefix	PN	O [0...*]	
4.5	Date of birth	The date of birth of the subject of care	/ClinicalDocument/recordTarget/patientRole/patient/birthtime	TS	R [1..1]	
4.6	Gender	Sex is the biological distinction between male and female. Where there is inconsistency between anatomical and chromosomal characteristics, sex is based on anatomical characteristics.	/ClinicalDocument/recordTarget/patientRole/patient/administrativeGenderCode	CE	R use nullFlavor = UNK [1..1]	

Num	Data Element	Description	CDA Xpath expression	HL7 v3 Data Type	Card/ Opt	Vocabulary
4.7	Address	The assignedEntity.addr is a mixed content element so if the individual components of an address are not available then the entire address could be put in this element.	/ClinicalDocument/recordTarget/ patientRole/patient /addr	AD	R [1..1]	

3.9 Prescriber

The electronic prescribing information consists of both the prescriber and the medication information. Table 12 outlines the data attributes for prescriber. Table 13 then outlines the data attributes for the medication information. Both tables are outlined below.

Table 12. Prescriber information

Num	Data Element	Description	CDA Xpath expression	HL7 v3 data type	Card/ Opt	Vocabulary
The template ID for Prescriber (Author) is 1.3.6.1.4.1.19376.1.5.3.1.2.3 (epSOS). The template ID referenced here refers to Healthcare practitoiner information in the ClinicalDocument/author/assignedAuthor/assignedPerson structure.						
5.1	Time of prescribing	The timestamp of prescribing the document. The date	/ClinicalDocument/author/time	TS	R [1...*]	

Num	Data Element	Description	CDA Xpath expression	HL7 v3 data type	Card/ Opt	Vocabulary
		and time stamp when the ePrescription was created.				
5.2	Prescriber ID number	User ID of individual that is clinically responsible for the ePrescription.	/ClinicalDocument/author/assignedAuthor/id	II	R [1...1]	
5.3	Prescriber family surname	Prescriber's second name which denotes their family or marital name.	/ClinicalDocument/author/assignedAuthor/assignedPerson/name/family	PN	R [1...*]	
5.4	Prescriber given name	Prescriber's identifying name.	/ClinicalDocument/author/assignedAuthor/assignedPerson/name/given	PN	R [1..*]	
5.5	Prescriber prefix	Coded value that contains the title relevant to a specific family name for this Author.	/ClinicalDocument/author/assignedAuthor/assignedPerson/name/prefix	PN	O [0...*]	

Num	Data Element	Description	CDA Xpath expression	HL7 v3 data type	Card/ Opt	Vocabulary
5.6	Prescriber profession	Coded element that specifies the health practitioner's particular profession.	/ClinicalDocument/author/functionCode	CD	R [1..*]	For example, using the ISCO coding system, the code for a general practitioner is 2211, while the code for a pharmacist is 2262.
5.7	Prescriber telephone number	The prescriber's telephone number.	/ClinicalDocument/author/assignedAuthor /telecom/@value	TEL	R use nullFlavor [1..*]	
5.8	Prescriber's email address	The prescriber's secure email address.	/ClinicalDocument/assignedCustodian/representedCustodian /Organization/addr/ /telecom/@value	TEL	O [0..*]	

Num	Data Element	Description	CDA Xpath expression	HL7 v3 data type	Card/ Opt	Vocabulary
5.9	Prescriber's fax number	The prescribers 's fax number	/ClinicalDocument/author/assignedAuthor /telecom/@value	TEL	O [0...*]	

3.10 Medication information (prescription)

The data attributes for the medication information for a prescription are outlined in Table 13.

Table 13: Prescription information

Num	Data Element	Description	CDA Xpath expression	HL7 v3 Data Type	Card /Opt	Vocabulary
Template id for prescription section (epSOS) = 1.3.6.1.4.1.12559.11.10.1.3.1.2.1 Template id for prescription item (epSOS) = 1.3.6.1.4.1.12559.11.10.1.3.1.3.2						
6.1	Prescription identification	Unique number which identifies the prescription.	entry/substanceAdministration[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/id	II	R [1..1]	
6.2	Prescription item identification	Unique number which identifies the prescription item.	entry/substanceAdministration[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/id	II	R [1..1]	
6.3	Effective time	Date prescription becomes effective. The date on which the healthcare practitioner instructs the patient to	entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/effectiveTime[1][@xsi:type='IVL_TS']/low/@value	II	R [1..1]	

Num	Data Element	Description	CDA Xpath expression	HL7 v3 Data Type	Card /Opt	Vocabulary
		begin the treatment.				
6.4	Date of issue of prescription	Date the prescription was issued.	entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/effectiveTime[1][@xsi:type='IVL_TS']/low/@value	TS	R [1..1]	
6.5	Medicinal product code	Code that identifies the medicinal product.	entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/consumable/manufacturedProduct/manufacturedMaterial/code	CE	R[1...*]	
6.6	Brand name	The name of the substance or product. This should be sufficient for a provider to identify the kind of medication. It may be a trade name or a generic name. This information is required in all medication entries. If the name of the medication is unknown, the type, purpose or	entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/consumable/manufacturedProduct/manufacturedMaterial/name	TXT	R [1...*]	

Num	Data Element	Description	CDA Xpath expression	HL7 v3 Data Type	Card /Opt	Vocabulary
		other description may be supplied. The name should not include packaging, strength or dosing information. Note: due to restrictions of the CDA schema, there is no way to explicitly link the name to the narrative text. This information is free text only.				
6.7	Medicinal product package size	Size of package prescribed.	entry/substanceAdministration[templateId/[@root= '1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/consumable/manufacturedProduct/manufacturedMaterial/asContent/containerPackageMedicine/formCode	CD	O [1..1]	Entry from The European Directorate for the Quality of Medicines & HealthCare vocabulary.
6.8	Number of packages	Number of packages required to fulfil the prescriptions.	entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/entryRelationship[@typeCode='COMP']/supply[@moodCode= 'RQO' and	PQ	O [1..1]	

Num	Data Element	Description	CDA Xpath expression	HL7 v3 Data Type	Card /Opt	Vocabulary
			independentInd/@value='false']/quantity			
6.9	Dose form (strength)	Content of the active ingredient expressed quantitatively per dosage unit, per unit of volume or per unit of weight, according to the pharmaceutical dose form.	entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/consumable/manufacturedProduct/manufacturedMaterial/ingredient/[@classCode='ACTI']/quantity8	PQ	O [1..1]	
6.10	Dose form (type)	Form in which a pharmaceutical product is presented in the medicinal product package as supplied by the marketing authorization holder, manufacturer or distributor.	entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/consumable/manufacturedProduct/manufacturedMaterial/formCode	CD	O[1..1]	epSOSDoseForm 1.3.6.1.4.1.12559.11.10.1.3.1.44.1
6.11	Total	Total number of instances	Not yet defined	PQ	O	

Num	Data Element	Description	CDA Xpath expression	HL7 v3 Data Type	Card /Opt	Vocabulary
	number of dose instances New requirement	of the medicinal product required to fulfil a prescription.			[0..*]	
6.12	Number of units to take	Amount of the medication given. This should be in some known and measurable unit, such as grams, milligrams or litres. It may be measured in 'administration' units (such as tablets or each), for medications where the strength is relevant. In this case, only the unit count is specified, no units are specified. It may be a range.	entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/doseQuantity/low@value entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/doseQuantity/high@value	INT	O [0..1]	If this element is expressed using measureable units, the value of the unit attribute comes from the epSOSUnits value set UCUM Code System: 2.16.840.1.113883.6.8, otherwise (administration units) the

Num	Data Element	Description	CDA Xpath expression	HL7 v3 Data Type	Card /Opt	Vocabulary
						value 1 should be used.
6.13	Frequency of intakes	Frequency indicates how often the medication is to be administered. It is often expressed as the number of times per day, but which may also include information such as one hour before or after meals, or in the morning, or evening.	entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/effectiveTime[2] For split dosing the xPath is referred to the subordinate <substanceAdministration> entry	TS IVL_TS PIVL_TS EIVL_TS SXPR_TS	O	If EIVL_TS mode is used, HL7 TimingEvent vocabulary (2.16.840.1.113883.5.139) SHALL be used.
6.14	Duration of treatment	Date (and time if available) when the medication regime began and when it is expected to finish.	entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/effectiveTime[1][@xsi:type='IVL_TS']/low/@value entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/effectiveTime[1][@	IVL_TS	O	

Num	Data Element	Description	CDA Xpath expression	HL7 v3 Data Type	Card /Opt	Vocabulary
			xsi:type='IVL_TS']/high/@value			
6.15	Route of administ-ration	Coded element which indicates how the medication is received by the patient. Examples include by mouth, intravenously or topically.	entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/routeCode	CD	O [0...*]	epSOSRoutesofAdministration 1.3.6.1.4.1.12559.11.10.1.3.1.44.1
6.16	Advice to dispenser	The prescriber might give instructions to the dispenser.	/entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/entryRelationship[@typeCode='SUBJ']/act[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.3.1']/text	TXT	O [0..1]	
6.17	Substitution allowed	Use to indicate if a substitution is allowed or prohibited.	entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/entryRelationship[@typeCode='SUBJ'][@inversionInd='true']/observation[@classCode='OBS']/value	CE	O [0..1]	epSOSSubstitutionCode 2.16.840.1.113883.5.1070
6.18	Instructions to patient	The prescriber might give instructions to the patient. They must be	entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/entryRel	TXT	O[0..1]	

Num	Data Element	Description	CDA Xpath expression	HL7 v3 Data Type	Card /Opt	Vocabulary
		presented in the original language of the patient and or of the prescriber. Example: Take only when headache. <entryRelationship> - A place to put free text comments to support additional relevant information or to deal with specialised dosing instructions. For example 'take with food' or tapered dosing.	ationship[@typeCode='SUBJ']/act[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.3']/text			
6.19	Repeats New requirement	Indicates the number of occasions the items on the prescriptions may be dispensed.	Not yet defined	INT	O [0..*]	
6.20	Status	The status of all <substanceAdministration> elements must be	Not yet defined.	CE	R [1...*	

Num	Data Element	Description	CDA Xpath expression	HL7 v3 Data Type	Card /Opt	Vocabulary
		either 'active' or 'completed'. Status of 'active' indicates a currently valid prescription, status of completed indicates a previously taken medication.			]	
6.21	Indications	A link to supporting clinical information about the reason for providing the medication (for example, a link to the relevant diagnosis). <entryRelationship>.	Not yet defined.	TXT	O [0..1]	

Reference list

(1) Department of Health. *eHealth Strategy for Ireland* . 2013. Available online from: http://health.gov.ie/wp-content/uploads/2014/03/Ireland_eHealth_Strategy.pdf Accessed on 27 November 2014

(2) Health Information and Quality Authority. 2012 *ePrescribing and electronic transfer of prescriptions: an International Review.* Available online from: http://www.hiqa.ie/healthcare/health-information/technical-standards

(3) Health Level Seven (HL7). *HL7 Clinical Document Architecture, Release 2.0*. 2004. Accessed on: 5 July 2014.

(4) European Patients Smart Open Services. *Work Package 3.9 – Appendix B1/B2 epSOS Semantic Implementation Guidelines*. 2011. Accessed on: 5 September 2014

(5) Integrating the Healthcare Enterprise. *Patient Care Coordination Technical Framework, Volume 1 and Volume 2- Revision 5*. 2013. Available online from: http://www.ihe.net/technical_frameworks/. Accessed on: 5 September 2014

(6) National eHealth Transition Authority. *e-Prescription CDA Implementation Guide Version 2.1*. 2010. Accessed on: 5 September 2014

Appendix 1 – Targeted consultation

In order to consult with interested and informed parties, a targeted consultation was conducted by the Health Information and Quality Authority. Below is the list of organisations who were invited to submit comments during the targeted consultation.

- Health Products Regularity Authority
- Irish Pharmaceutical Society of Ireland
- Irish Pharmaceutical Union
- Irish Institute of Pharmacy Practice
- Irish Pharmaceutical Healthcare Association
- Department of Health
- Health Service Executive
- Irish Medical Organisation
- School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin
- School of Pharmacy, Royal College of Surgeons in Ireland
- General Practitioner Information Technology Group
- National Standards Authority of Ireland
- Royal College of Surgeons in Ireland
- Royal College of Physicians of Ireland
- Enterprise Ireland
- Helix Health
- CompleteGP.

Appendix 2 – Consultation questions

As part of the targeted consultation conducted by the Health Information and Quality Authority, the Authority distributed a consultation document in late 2014 to interested and informed parties. Listed here in Table 14 are the questions that these people were asked.

Table 14. Consultation questions

Consultation Question 1	Are there benefits in having a standardised ePrescription dataset and clinical document architecture specification and, if so, what are the main benefits?
Consultation Question 2	Have the appropriate classes been included in the ePrescription data model?
Consultation Question 3	Have all of the appropriate data items been included in the ePrescription dataset? Would you leave out any of the data items listed? Would you suggest additional data items?
Consultation Question 4	Do the explanations provided in Tables 1 – 7 of the consultation document adequately explain each of the data items? If not, please suggest improvements?
Consultation Question 5	Are there any alterations needed for the clinical document architecture specification? If so, please suggest improvements?

Appendix 3 – HL7 v3 data types

Each data element has a data type associated with it. A description of the HL7 datatypes used in the CDA (clinical document architecture) ePrescribing is outlined below in Table 15.

Table 15. HL7 v3 Data Types

HL7 v3 Data Type	Name	Description
AD	Postal address	Home or Office address. A sequence of address parts.
ANY	Any	Defines the basic properties of every data.
CD	Concept descriptor	A concept descriptor represents any kind of concept usually by giving a code defined in a code system. A concepts descriptor can contain the original text or phrase that served as the basis of the coding and one or more translations into different coding systems.
CE	Coded with equivalents	Coded data that consists of a coded value (CV) and optionally coded values from other coding systems that identify the same concept. Used when alternative codes may exist.
CS	Coded simple value	Coded data in its simplest form, where only the code is not predetermined. The code system and code system version is fixed by the context in which the CS value occurs. CS is used for coded attributes that have a single HL7-defined value set.
ED	Encapsulated data	Data that is primarily intended for human interpretation or for further machine processing outside the scope of HL7. This includes unformatted or formatted written language, multimedia data or structured information in as defined by a different standard.

HL7 v3 Data Type	Name	Description
EN	Entity name	A name for a person, organisation, place or thing. A sequence of name parts, such as first name or family name, prefix, suffix.
II	Instance identifier	An identifier that uniquely identifies a thing or an object. Examples are object identifier for HL7 RIM objects, medical record number, order ID, service catalogue item ID. Vehicle identification number (VIN) and so on. Instance identifiers are defined based on International Standards Organisation's object identifiers.
IVL	Interval	A set of consecutive values of an ordered-based data type. Any ordered type can be the basis of an interval. It does not matter whether the base type is discrete or continuous. It the base data type is only partially ordered, all elements of the interval must be elements of a totally ordered subset of the partially ordered data type.
ON	Organisation name	A name for an organisation. A sequence of name parts.
PN	Person name	A name for a person. A sequence of name parts such as first name, family name, prefix, and suffix. A name part is a restriction of entity name part that only allows those entity name part qualifiers applicable to person names. Since the structure of entity name is mostly determined by the requirements of person name, the restriction is very minor. This data type is of mixed content.
PQ	Physical quantity	A dimensioned quantity expressing the result of measuring.
RTO	Ratio	A quantity constructed as the quotient of a numerator quantity divided by a denominator quantity. Common factors in

HL7 v3 Data Type	Name	Description
		the numerator and denominator are not automatically cancelled out. The data type supports quantities produced by laboratories that truly represent ratios.
SC	Character string with code	The character string that optionally may have a code attached. The text must always be present if a code is present. The code is often local code.
ST	Character string	The character string data type stands for text data, primarily intended for machine processing (such as sorting, querying, indexing). Used for names, symbols, and formal expressions.
TEL	Telecommunication address	A telephone number (voice or fax), email address, or other locator for a resource mediated by telecommunication equipment. The address is specified as a universal resource locator (URL) qualified by time specification and uses codes that help in deciding which address to use for a given time and purpose.
TS	Timestamp	A quantity specifying a point on the axis of natural time. A point in time is most often represented as a calendar expression. Note: An IVL TS (Interval Timestamp) has to be fully formed, whereas a regular timestamp can be shortened.

Appendix 4 – Value sets for attributes with coded data elements

Six standards, vocabularies or classification systems are used to define the allowable values for 12 of the 13 data attributes that have coded element data types. Currently, no code-value set has yet been defined or selected for the data attribute, medicinal product code. These are:

- ISO/TS 22220:2011: Health Informatics – Identification of Subject of Care
- ISO 3166-1:2013
- The International Standard Classification of Occupations
- The Anatomical Therapeutic Chemical Classification System
- European Directorate for the Quality of Medicines[‡]
- HL7 v3.0 Vocabulary Standard.

This appendix provides a list of tables that contain the code-value sets for these data attributes.

Table 16. Data attribute Name title

Name title	Abbreviation	Name Title	Abbreviation
Admiral	Adm	Master	Mstr
Bishop	Bish	Miss	Miss
Brother	Br	Mister	Mr
Canon	Canon	Missus	Mrs
Captain	Capt	Ms	Ms
Constable	Con	Pastor	Pst
Corporal	Corp	Private	Prv
Dame	Dame	Professor	Prof
Damen	Dam	Reverend	Rev
Doctor	Dr	The Right Honourable	The Rt. Hon
Father	Fthr	The Right Reverend	The Rt. Rev
General	Gen	Sergeant	Sgt

[‡] Copyright & Issuer: EDQM, info taken from D3.5.2_Appendix_D_epSOS_Master_Value_Set_Catalogue_01

Name title	Abbreviation	Name Title	Abbreviation
Herr	Herr	Sir	Sir
The Honourable	Hon	Sister	Sr
Madame	Mdm	The Venerable	The Ven

Table 17. Data attribute: street type element of street name including street type.

Code	Description	Code	Description
Ally	Alley	Gr	Grove
Arc	Arcade	Hwy	Highway
Ave	Avenue	Jnc	Junction
Bvd	Boulevard	Lane	Lane
Bypa	Bypass	Ln	Line
Crc	Circle	Link	Link
Cct	Circuit	Mews	Mews
Cl	Close	Pde	Parade
Crn	Corner	Pl	Place
Ct	Court	Ridge	Ridge
Cres	Crescent	Rd	Road
Cds	Cul-de-sac	Sq	Square
Dr	Drive	St	Street
Esp	Esplanade	Tce	Terrace
Grn	Green		
Note that this is not an exhaustive list.			

Table 18. Data attribute: electronic communications medium.

Code	Description	Alternative code
1	Telephone (excluding mobile)	T
2	Mobile (cellular) telephone	C
3	Facsimile machine	F

4	Pager	B
5	email	E
6	URL	U
8	Other	O

Table 19. Data attribute: sex

Code	Descriptor	Alternative code
1	Male	M
2	Female	F
3	Indeterminate	I
9	Not stated or inadequately described	N

Country Codes ISO 3166-1:2013

The ISO 3166-1:2013 standard is used for country codes. The full listing for this classification can be found at http://www.iso.org/iso/country_codes.htm. It is used to populate the Country Identifier data attribute.

Table 20. Data attribute: profession

The International Standard Classification of Occupations (ISCO) is used to populate the relevant professions and their codes that have been extracted from the ISCO.

Code	Profession
22	Health professionals
221	Medical doctors
2211	Generalist medical practitioners
2212	Specialist medical practitioners
222	Nursing and midwifery professionals
2221	Nursing professionals
2222	Midwifery professionals
223	Traditional and complementary medicine professionals
224	Paramedical practitioners
225	Veterinarians

Code	Profession
226	Other health professionals
2261	Dentists
2262	Pharmacists
2263	Environmental and occupational health and hygiene professionals
2264	Physiotherapists
2265	Dieticians and nutritionists
2266	Audiologists and speech therapists
2267	Optometrists and ophthalmic opticians
2269	Health professionals not elsewhere classified
32	Health associate professionals
321	Medical and pharmaceutical technicians
3211	Medical imaging and therapeutic equipment technicians
3212	Medical and pathology laboratory technicians
3213	Pharmaceutical technicians and assistants
3214	Medical and dental prosthetic technicians
322	Nursing and midwifery associate professionals
3221	Nursing associate professionals
3222	Midwifery associate professionals
323	Traditional and complementary medicine associate professionals
325	Other health associate professionals
3251	Dental assistants and therapists
3252	Medical records and health information technicians
3253	Community health workers
3254	Dispensing opticians
3255	Physiotherapy technicians and assistants
3256	Medical assistants
3257	Environmental and occupational health inspectors and associates

Code	Profession
3258	Ambulance workers
3259	Health associate professionals not elsewhere classified

Data attribute: ATC codes

The Anatomical Therapeutic Chemical Classification System (WHO/ATC) is used for this. A searchable online database can be available at http://www.whocc.no/atc_ddd_index/ which contains the allowable values for the data attribute active ingredient code.

Data attribute: Medicinal product package.

The European Directorate for the Quality of Medicines (EDQM) has been used for medicinal product package values.

Table 21. Medicinal product package – data attribute[§]

Code	Description
30000500	Administration system
30001000	Ampoule
30002000	Applicator
30004000	Bag
30006000	Barrel
30007000	Blister
30008000	Bottle
30009000	Box
30010000	Brush
30011000	Brush applicator
30012000	Cannula
30013000	Cap
30014000	Cartridge
30015000	Child-resistant closure

[§] Taken from https://decor.nictiz.nl/epsos/epsos-html-20131203T170006/voc-1.3.6.1.4.1.12559.11.10.1.3.1.42.3-2013-06-03T000000.html.

Code	Description
30016000	Cup
30017000	Dabbing applicator
30019000	Dredging applicator
30020000	Dredging container
30022000	Dropper applicator
30023000	Dropper container
30023005	Fixed cryogenic vessel
30024000	Gas cylinder
30025000	High-pressure transdermal delivery device
30026000	Implanter
30026500	Inhaler
30027000	In-ovo injection device
30028000	Injection needle
30029000	Injection syringe
30031000	Intramammary syringe
30032000	Jar
30033000	Measuring device
30034000	Measuring spoon
30035000	Metering pump
30036000	Metering valve
30036005	Mobile cryogenic vessel
30037000	Mouthpiece
30038000	Multidose container
30039000	Multidose container with airless pump
30040000	Multipuncturer
30041000	Nasal applicator
30042000	Nebuliser
30043000	Needle applicator
30044000	Nozzle

Code	Description
30045000	Oral syringe
30046000	Pipette
30047000	Pipette applicator
30048000	Pour-on container
30049000	Pre-filled gastroenteral tube
30050000	Pre-filled pen
30051000	Pre-filled syringe
30052000	Pressurised container
30053000	Prick test applicator
30053500	Roll-on container
30054000	Sachet
30055000	Scarifier
30056000	Screw cap
30057000	Single-dose container
30058000	Spatula
30059000	Spot-on applicator
30060000	Spray container
30061000	Spray pump
30062000	Spray valve
30063000	Stab vaccinator
30064000	Stopper
30064500	Straw
30065000	Strip
30066000	Tablet container
30067000	Tube
30069000	Vial

Table 22. Data attribute: Pharmaceutical dose form**

Code	Description
10101000	Oral drops, solution
10102000	Oral drops, suspension
10103000	Oral drops, emulsion
10104000	Oral liquid
10105000	Oral solution
10106000	Oral suspension
10107000	Oral emulsion
10108000	Oral gel
10109000	Oral paste
10110000	Powder for oral solution
10111000	Powder for oral suspension
10112000	Granules for oral solution
10113000	Granules for oral suspension
10114000	Powder and solvent for oral solution
10115000	Powder and solvent for oral suspension
10116000	Lyophilisate for suspension
10117000	Syrup
10118000	Powder for syrup
10119000	Granules for syrup
10120000	Soluble tablet
10121000	Dispersible tablet
10122000	Herbal tea
10201000	Oral powder
10202000	Instant herbal tea
10203000	Effervescent powder
10204000	Granules

** Taken from https://decor.nictiz.nl/epsos/epsos-html-20131203T170006/voc-1.3.6.1.4.1.12559.11.10.1.3.1.42.2-2013-06-03T000000.html

Code	Description
10205000	Effervescent granules
10206000	Gastro-resistant granules
10207000	Prolonged-release granules
10208000	Modified-release granules
10209000	Cachet
10210000	Capsule, hard
10211000	Capsule, soft
10212000	Gastro-resistant capsule, hard
10213000	Gastro-resistant capsule, soft
10214000	Chewable capsule, soft
10215000	Prolonged-release capsule, hard
10216000	Prolonged-release capsule, soft
10217000	Modified-release capsule, hard
10218000	Modified-release capsule, soft
10219000	Tablet
10220000	Coated tablet
10221000	Film-coated tablet
10222000	Effervescent tablet
10223000	Orodispersible tablet
10224000	Oral lyophilisate
10225000	Gastro-resistant tablet
10226000	Prolonged-release tablet
10227000	Modified-release tablet
10228000	Chewable tablet
10229000	Medicated chewing-gum
10230000	Oral gum
10231000	Pillules
10236100	Orodispersible film
10301000	Gargle

Code	Description
10302000	Concentrate for gargle
10303000	Gargle, powder for solution
10304000	Gargle, tablet for solution
10305000	Oromucosal solution
10306000	Oromucosal suspension
10307000	Oromucosal drops
10308000	Oromucosal spray
10309000	Sublingual spray
10310000	Mouthwash
10311000	Mouthwash, tablet for solution
10312000	Gingival solution
10313000	Oromucosal gel
10314000	Oromucosal paste
10314005	Oromucosal ointment
10314010	Oromucosal cream
10314011	Buccal film
10315000	Gingival gel
10316000	Gingival paste
10317000	Oromucosal capsule
10318000	Sublingual tablet
10319000	Muco-adhesive buccal tablet
10320000	Buccal tablet
10321000	Lozenge
10322000	Compressed lozenge
10323000	Pastille
10401000	Periodontal powder
10402000	Dental gel
10403000	Dental stick
10404000	Dental insert

Code	Description
10405000	Dental powder
10406000	Dental solution
10407000	Dental suspension
10408000	Dental emulsion
10409000	Toothpaste
10410000	Periodontal gel
10411000	Periodontal insert
10501000	Bath additive
10502000	Cream
10503000	Gel
10504000	Ointment
10505000	Cutaneous paste
10506000	Medicated plaster
10507000	Cutaneous foam
10508000	Shampoo
10509000	Cutaneous spray, solution
10510000	Cutaneous spray, suspension
10511000	Cutaneous spray, powder
10512000	Cutaneous liquid
10513000	Cutaneous solution
10514000	Concentrate for cutaneous solution
10515000	Cutaneous suspension
10516000	Cutaneous emulsion
10517000	Cutaneous powder
10517500	Cutaneous patch
10518000	Solution for iontophoresis
10519000	Transdermal patch
10520000	Collodion
10521000	Medicated nail lacquer

Code	Description
10521500	Nail solution
10522000	Poultice
10523000	Cutaneous stick
10524000	Cutaneous sponge
10525000	Impregnated dressing
10539500	Scrub
10546500	Transdermal spray, solution
10547000	Transdermal system
10548000	Solution for skin-prick test
10549000	Solution for skin-scratch test
10550000	Plaster for provocation test
10601000	Eye cream
10602000	Eye gel
10603000	Eye ointment
10604000	Eye drops, solution
10604500	Eye drops, emulsion
10605000	Eye drops, suspension
10606000	Eye drops, powder and solvent for solution
10607000	Eye drops, powder and solvent for suspension
10608000	Eye drops, solvent for reconstitution
10609000	Eye drops, prolonged-release
10610000	Eye lotion
10611000	Eye lotion, solvent for reconstitution
10612000	Ophthalmic insert
10613000	Ophthalmic strip
10701000	Ear cream
10702000	Ear gel
10703000	Ear ointment
10704000	Ear drops, solution

Code	Description
10705000	Ear drops, suspension
10706000	Ear drops, emulsion
10707000	Ear drops, powder and solvent for suspension
10708000	Ear powder
10709000	Ear spray, solution
10710000	Ear spray, suspension
10711000	Ear spray, emulsion
10712000	Ear wash, solution
10713000	Ear wash, emulsion
10714000	Ear tampon
10715000	Ear stick
10801000	Nasal cream
10802000	Nasal gel
10803000	Nasal ointment
10804000	Nasal drops, solution
10805000	Nasal drops, suspension
10806000	Nasal drops, emulsion
10807000	Nasal powder
10808000	Nasal spray, solution
10809000	Nasal spray, suspension
10810000	Nasal spray, emulsion
10811000	Nasal wash
10812000	Nasal stick
10900500	Intravaginal ring
10901000	Vaginal cream
10902000	Vaginal gel
10903000	Vaginal ointment
10904000	Vaginal foam
10905000	Vaginal solution

Code	Description
10906000	Vaginal suspension
10907000	Vaginal emulsion
10908000	Tablet for vaginal solution
10909000	Pessary
10910000	Vaginal capsule, hard
10911000	Vaginal capsule, soft
10912000	Vaginal tablet
10913000	Effervescent vaginal tablet
10914000	Medicated vaginal tampon
10915000	Vaginal delivery system
10916000	Vaginal sponge
11001000	Rectal cream
11002000	Rectal gel
11003000	Rectal ointment
11004000	Rectal foam
11005000	Rectal solution
11006000	Rectal suspension
11007000	Rectal emulsion
11008000	Concentrate for rectal solution
11009000	Powder for rectal solution
11010	Oral drops
11010000	Powder for rectal suspension
11011000	Tablet for rectal solution
11012000	Tablet for rectal suspension
11013000	Suppository
11014000	Rectal capsule
11015000	Rectal tampon
11050	Oral liquid
11101000	Nebuliser solution

Code	Description
11102000	Nebuliser suspension
11103000	Powder for nebuliser suspension
11104000	Powder for nebuliser solution
11105000	Nebuliser emulsion
11106000	Pressurised inhalation, solution
11107000	Pressurised inhalation, suspension
11108000	Pressurised inhalation, emulsion
11109000	Inhalation powder
11110000	Inhalation powder, hard capsule
11111000	Inhalation powder, pre-dispensed
11112000	Inhalation vapour, powder
11113000	Inhalation vapour, capsule
11114000	Inhalation vapour, solution
11115000	Inhalation vapour, tablet
11116000	Inhalation vapour, ointment
11117000	Inhalation vapour, liquid
11118000	Inhalation gas
11201000	Solution for injection
11202000	Suspension for injection
11203000	Emulsion for injection
11204000	Gel for injection
11205000	Powder for solution for injection
11206000	Powder for suspension for injection
11207000	Powder and solvent for solution for injection
11208000	Powder and solvent for suspension for injection
11209000	Concentrate for solution for injection
11210000	Solution for infusion
11210500	Solution for infusion in administration system
11211000	Emulsion for infusion

Code	Description
11212000	Powder for solution for infusion
11213000	Concentrate for solution for infusion
11214000	Powder and solvent for solution for infusion
11214500	Lyophilisate and solvent for solution for injection
11215000	Lyophilisate for solution for infusion
11216000	Solvent for parenteral use
11217000	Lyophilisate for solution for injection
11218000	Lyophilisate for suspension for injection
11301000	Implant
11302000	Implantation tablet
11303000	Implantation chain
11303500	Implantation suspension
11304000	Powder and solvent for implantation paste
11401000	Solution for peritoneal dialysis
11402000	Solution for haemofiltration
11403000	Solution for haemodiafiltration
11404000	Solution for haemodialysis
11405000	Concentrate for haemodialysis solution
11501000	Solution for intravesical use
11502000	Bladder irrigation
11503000	Powder for bladder irrigation
11504000	Urethral gel
11505000	Urethral stick
11601000	Endotracheopulmonary instillation, solution
11602000	Endotracheopulmonary instillation, powder for solution
11603000	Endotracheopulmonary instillation, suspension
11604000	Endotracheopulmonary instillation, powder and solvent for solution
11701000	Endocervical gel
11702000	Powder and solvent for endocervical gel

Code	Description
11901000	Intrauterine delivery system
11902000	Intrauterine solution
11903000	Intrauterine suspension
11904000	Intrauterine emulsion
11905000	Intrauterine tablet
11906000	Intrauterine capsule
12004000	Nebulisation solution
12100	Capsule
12100500	Absorbable coated sponge
12101000	Denture lacquer
12102000	Anticoagulant and preservative solution for blood
12103000	Solution for blood fraction modification
12104000	Wound stick
12105000	Radiopharmaceutical precursor
12106000	Radionuclide generator
12107000	Kit for radiopharmaceutical preparation
12108000	Gastroenteral solution
12109000	Dispersion
12109500	Fibrin sealant-powder and solvent for fibrin sealant
12110000	Gastroenteral suspension
12111000	Gastroenteral emulsion
12112000	Solution for organ preservation
12113000	Irrigation solution
12114000	Stomach irrigation
12115000	Sealant
12115500	Solution of perfusion of organs
12116000	Powder and solvent for sealant
12117000	Impregnated pad
12118000	Living tissue equivalent

Code	Description
12119000	Medicated sponge
12120	Gastro-resistant capsule
12120000	Intestinal gel
12130000	Medicated thread
12131000	Solution for provocation test
12150	Prolonged-release capsule
12200	Tablet
12301000	Medicinal gas, compressed
12302000	Medicinal gas, cryogenic
12303000	Medicinal gas, liquefied
13050	Oromucosal liquid
13220	Lozenge
14050	Dental liquid
15090	Cutaneous spray
15130	Cutaneous liquid
16040	Eye drops
17040	Ear drops
17090	Ear spray
17120	Ear wash
18040	Nasal drops
18080	Nasal spray
19050	Vaginal liquid
19100	Vaginal capsule
20050	Enema
21010	Nebuliser liquid
21060	Pressurised inhalation
21100	Inhalation powder
21140	Inhalation vapour
22010	Injection

Code	Description
22050	Powder for injection
22090	Sterile concentrate
22100	Infusion
22120	Powder for infusion
26010	Endotracheopulmonary instillation
29020	Intrauterine liquid
30047500	Pouch
31030	Blood fraction modifier
31080	Gastroenteral liquid
50001000	Chewable/dispersible tablet
50001250	Coated granules in sachet
50001500	Concentrate and diluent for solution for infusion
50002000	Concentrate and solvent for concentrate for solution for infusion
50003000	Concentrate and solvent for cutaneous solution
50004000	Concentrate and solvent for cutaneous use
50005000	Concentrate and solvent for injection
50006000	Concentrate and solvent for solution for infusion
50007000	Concentrate and solvent for solution for injection
50008000	Concentrate and solvent for suspension for injection
50009000	Concentrate for cutaneous spray, emulsion
50009300	Concentrate for dispersion for infusion
50009500	Concentrate for emulsion for infusion
50010000	Concentrate for oral solution
50011000	Concentrate for oral/rectal solution
50012000	Concentrate for peritoneal dialysis solution
50013000	Concentrate for solution for intravesical use
50013500	Concentrate for spray emulsion
50014000	Concentrate for suspension for infusion
50015000	Cutaneous and nasal ointment

Code	Description
50015300	Cutaneous/oromucosal/oral solution
50015400	Cutaneous/oromucosal spray
50015500	Cutaneous spray, emulsion
50016000	Cutaneous spray, ointment
50017000	Dental paste
50018000	Ear/eye drops, solution
50019000	Ear/eye oinment
50020000	Ear/eye/nose drops, solution
50020500	Effervescent buccal tablet
50021000	Emulsion for injection/infusion
50021500	Emulsion and suspension for emulsion for injection
50022000	Endosinusial wash, suspension
50023000	Eye drops, solution in single-dose container
50023500	Film coated gastro-resistant tablet
50024000	Gargle/mouthwash
50025000	Gastro-resistant coated tablet
50026000	Gastro-resistant granules for oral suspension
50026250	Gastro-resistant prolonged-release tablet
50026500	Granules and solvent for oral suspension
50027000	Granules and solvent for suspension for injection
50028000	Granules for oral and rectal suspension
50029000	Granules for oral drops, solution
50029250	Granules for use in drinking water
50029500	Granules for vaginal solution
50029600	Hard capsule with gastro-resistant pellets
50029700	Herbal tea in bag
50030000	Inhalation powder, tablet
50031000	Inhalation vapour, effervescent tablet
50032000	Inhalation vapour, emulsion

Code	Description
50033000	Inhalation vapour, impregnated pad
50033300	Intrauterine foam
50033500	Intravitreal implant in applicator
50034000	Liquefied gas for dental use
50035000	Modified-release film-coated tablet
50036000	Modified-release granules for oral suspension
50036100	Muco-adhesive buccal prolonged-release tablet
50036500	Nasal/oromucosal solution
50037000	Nasal spray and oromucosal solution
50037250	Nasal spray, solution in single-dose container
50037750	Oral drops, liquid
50038000	Oral/rectal suspension
50038500	Oral solution/concentrate for nebuliser solution
50039000	Oromucosal patch
50039300	Oromucosal powder in pouch
50039500	Oromucosal/laryngopharyngeal solution
50040000	Oromucosal/laryngopharyngeal solution/spray
50041000	Pillules in single-dose container
50041500	Powder and solution for solution for injection
50042000	Powder and solvent for concentrate for solution for infusion
50043000	Powder for concentrate for solution for infusion
50044000	Powder and solvent for cutaneous solution
50044500	Powder and solvent for dispersion for injection
50045000	Powder and solvent for endosinusial solution
50045500	Powder and solvent for epilesional solution
50046000	Powder and solvent for gingival gel
50047000	Powder and solvent for instillation solution for intraocular use
50047500	Powder and solvent for intravesical solution
50047700	Powder and solvent for nebuliser solution

Code	Description
50048000	Powder and solvent for prolonged-release suspension for injection
50048250	Powder and solvent for solution for injection in pre-filled syringe
50048300	Powder and solvent for suspension for injection in pre-filled syringe
50048500	Powder and suspension for suspension for injection
50048600	Powder, dispersion and solvent for concentrate for dispersion for injection
50048750	Powder for concentrate for dispersion for infusion
50049000	Powder for concentrate for haemodialysis solution
50049100	Powder for concentrate for intravesical suspension
50049250	Powder for concentrate for solution for injection/infusion
50049270	Powder for dental solution
50049300	Powder for epilesional solution
50049500	Powder for implantation suspension
50050000	Powder for intravesical solution
50051000	Powder for intravesical suspension
50051100	Powder for mouth wash
50052000	Powder for oral/rectal suspension
50053000	Powder for solution for injection or infusion
50053500	Powder for solution for injection/infusion
50054000	Powder for solution for intravesical use
50055000	Powder for solution for nasal spray
50055500	Prolonged-release film-coated tablet
50056000	Prolonged-release granules for oral suspension
50056500	Radiopharmaceutical precursor, solution
50057000	Solution for haemodialysis/haemofiltration
50058000	Solution for infusion and oral solution
50059000	Solution for injection/concentrate for solution for infusion
50060000	Solution for injection/infusion
50060100	Solution for injection in cartridge

Code	Description
50060200	Solution for injection in pre-filled pen
50060300	Solution for injection in pre-filled syringe
50060400	Solution for injection in pre-filled syringe with automatic needle guard
50060500	Solution for injection/infusion in pre-filled syringe
50061000	Solution for intraperitoneal use
50061300	Solution for use in drinking water
50061500	Solution for sealant
50061600	Solvent for nasal use
50062000	Suspension and effervescent granules for oral suspension
50062500	Suspension and solution for spray
50063000	Suspension for infusion
50063100	Suspension for injection in cartridge
50063200	Suspension for injection in pre-filled pen
50063300	Suspension for injection in pre-filled syringe
50063500	Suspension for use in drinking water
50064000	Tablet and solvent for rectal suspension
50065000	Tablet and powder for oral solution
50066000	Tablet for oral suspension
50070000	Oral suspension for use in drinking water
50071000	Powder and solvent for dental gel
50072000	Powder for use in drinking water
50073000	Powder for solution for intraocular irrigation
50074000	Solvent for solution for intraocular irrigation
50076000	Solvent for solution for infusion
50077000	Dispersion for injection
50078000	Gas and solvent for dispersion for injection/infusion
50079000	Concentrate for solution for injection/infusion
50080000	Powder and solvent for solution for injection/infusion

Code	Description
50081000	Inhalation solution
50082000	Oral drops, powder for suspension

Table 23. Data attribute: Route of administration.

Code	Description
20001000	Auricular use
20002500	Buccal use
20003000	Cutaneous use
20004000	Dental use
20006000	Endocervical use
20007000	Endosinusial use
20008000	Endotracheopulmonary use
20009000	Epidural use
20010000	Epilesional use
20011000	Extraamniotic use
20011500	Extracorporeal use
20013000	Gastroenteral use
20013500	Gastric use
20014000	Gingival use
20015000	Hemodialysis
20015500	Implantation
20020000	Inhalation use
20021000	Intestinal use
20022000	Intra-amniotic use
20023000	Intra-arterial use
20024000	Intra-articular use
20025000	Intrabursal use
20026000	Intracardiac use

Code	Description
20026500	Intracartilaginous use
20027000	Intracavernous use
20027010	Intracerebral use
20028000	Intracervical use
20028500	Intracisternal use
20029000	Intracoronary use
20030000	Intradermal use
20031000	Intradiscal use
20031500	Intraepidermal use
20032000	Intralesional use
20033000	Intralymphatic use
20035000	Intramuscular use
20036000	Intraocular use
20036500	Intraosseous use
20037000	Intrapericardial use
20038000	Intraperitoneal use
20039000	Intrapleural use
20039500	Intraprostatic use
20041000	Intrasternal use
20042000	Intrathecal use
20043000	Intratumoral use
20044000	Intrauterine use
20045000	Intravenous use
20046000	Intravesical use
20047000	Intravitreal use
20047500	Iontophoresis
20048000	Laryngopharyngeal use
20049000	Nasal use
20050000	Nebulisation use

Code	Description
20051000	Ocular use
20053000	Oral use
20054000	Oromucosal use
20055000	Oropharyngeal use
20056000	Paravertebral use
20057000	Periarticular use
20058000	Perineural use
20059000	Periodontal use
20059300	Periosseous use
20059500	Posterior juxtascleral use
20061000	Rectal use
20061500	Retrobulbar use
20062000	Route of administration not applicable
20063000	Skin scarification
20065000	Subconjunctival use
20066000	Subcutaneous use
20067000	Sublingual use
20067500	Submucosal use
20070000	Transdermal use
20071000	Urethral use
20072000	Vaginal use

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