Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Draft Standard for eDispensing Dataset and Clinical Document Architecture (for trial use) - Draft for consultation

September 2016

About the Health Information and Quality Authority

The Health Information and Quality Authority (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 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 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 imperative 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) has responsibility 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 making recommendations in relation to improving the quality and filling in gaps where information is needed but is not currently available.

Information and communications technology (ICT) has a critical role to play in ensuring that information to drive 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, 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 robust health information environment will allow all stakeholders, 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 through this work programme is the need to standardise the information shared between general practitioners and hospital consultant and administrative staff. This has been achieved through a General Practice Messaging Standard .The Authority's GPMS is based on the international Health Level Seven (HL7) version 2.4 messaging standard. Version 1.0 of the GPMS was published in April 2010 and approved by the then Minister for Health and Children in May 2010. Version 2.0 of the GPMS was developed in 2011 to incorporate new requirements identified by stakeholders. Version 3.0 has been developed to include the messaging requirements for the electronic transfer of prescriptions between both the GP and out-patient departments to community pharmacists. The draft eDispensing Dataset and Clinical Document Architecture Standard (for trial use) is an extension of this work and will support the implementation of the electronic transfer of prescriptions in Ireland.

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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. These benefits include a reduction in medication errors, prescription and transcription errors with a corresponding improvement in patient safety.

In recent years, HIQA has undertaken multiple projects in the area of ePrescribing and the electronic transfer of prescriptions and has published two Standards in this regard. Firslty, a *Data model for an electronic medicinal product reference catalogue – a National Standard* which outlines a data model for a medicinal product reference catalogue, and secondly an *ePrescription dataset and clinical document architecture standard* which is a dataset and technical specification for electronic prescriptions. This draft standard should be read in conjuntion with these standards.

An international review[2] was also undertaken by HIQA and 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 i.e. the medication is dispensed.

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.

This draft standard uses the HL7 clinical document architecture which is an internationally recognised standard that 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.

In order to support the implementation of the electronic transfer of prescriptions, multiple standards are required including the data model standard and the ePrescribing standard published by HIQA in 2015. In addition, HIQA's general practice messaging standard (Version 3.0) was revised and information was included to describe the messaging standards for the electronic transfer of prescriptions. They included the messaging requirements for the electronic

transfer of prescriptions between GP's and community pharmacy and included scenarios, clinical examples, message flows and use cases relevant to the ETP in the community (See Appendix 1).

1.1 Purpose

The development of an eDispensing standard is a key enabler for the effective and accurate exchange of information and ultimately for increasing patient safety. The purpose of this draft eDispensing standard is to record in electronic format the medications dispensed. This is a minimum dataset that covers a dispense record that may be used in community pharmacy. The standard will outline the structure and content needed for a dispening report/note at the time of dispensing medication to the patient.

1.2 Defintion

According to the World Health Organization 'drug dispensing is a process that ends with a client leaving a drug outlet with a defined quantity of medication(s) and instructions on how to use it (them)'.[(2)] The type of information that dispensers require to dispense medication may include:

- drug(s) prescribed
- dose(s) prescribed
- average number of items per prescription
- percentage of items prescribed that were actually supplied (an indicator of availability)
- percentage of drugs adequately labelled
- quantity of medications dispensed
- cost of each item or prescription.

This data can be obtained from records kept at the community pharmacy either in electronic or manual form. Electronic dispensing or eDispensing is defined as:

'eDispensing is defined as the act of electronically retrieving a prescription and administering medicine to the patient as indicated in the corresponding ePrescription. Once the medicine is administered, the dispenser sends an electronic report on the dispensed medicine(s)'.

1.3 Benefits of the electronic transfer of prescriptions (ETP)

The implementation of the ePrescribing CDA specification can support the implementation of electronic prescribing and the electronic transfer of prescriptions (ETP). There are many benefits of ETP for patients, healthcare practitioners and organisations that fund the health and disability sector.

Patients, people in care and the health and disability sector will benefit from ETP and ePrescribing through:

- safer care because ETP and ePrescribing reduces manual data entry and therefore transcription errors resulting in reduced risk of a prescribed medicine not being correctly dispensed
- safer care because prescribed medicines descriptions are more accurate and there is improved legibility of prescription details
- fewer hospital admissions or unwanted adverse effects because prescribers and dispensers can monitor patient compliance with prescribed medicines
- having prescriptions dispensed more quickly through more efficient processes.

Healthcare practitioners who prescribe medicines will benefit from ETP through:

- the ability to receive notification when a patient collects prescribed medicines enables patient compliance and patient follow-up
- 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 ETP solution is linked to an electronic patient record.

Pharmacists who dispense medicines will benefit from ETP 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 sector will benefit from ETP 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 ETP 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.

Further, 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, e.g. 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, e.g. 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 and/or potentially expensive medicines.
- improved support for future permissible secondary uses of data to deliver further public benefits, 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.

1.4 Approach

The draft eDispensing standard is being developed as trial for use. It was developed by HIQA 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:

- General Practioner Information Technology Group
- Irish Pharmacy Union

- National Standards Authority of Ireland
- School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin
- Subject matter expert in Pharmacy
- Health Service Executive National ePharmacy Programme

The technical subgroup defined a dataset for eDispensing based on analysis of eDispensing specifications and standards developed in other jurisdictions (Australian standards, EU, HL7 FIHR). Also relevant data from national clinical datasets already developed by HIQA such as the demographic dataset, referrals and discharge summary datasets informed the standards development process, as did contributions from the subgroup members acting as subject matter experts in the field of pharmacy.

Following development of the dataset, a CDA eDispensing standard was developed. Several international CDA implementation guides were researched to inform this specification which are listed below:

- 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 eDispensing CDA Implementation Guide Version 2.1[6]

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

1.4.1 Next Steps

There will be a five week consultation on the *Draft eDispensing Dataset and Clinical Document Architecture Standard (for trial use) - Draft for consultation* which will take place from 09 September 2016 to 14 October 2016. All submissions from the consultation will be reviewed and will inform the development of the final draft of the standard. Following the targeted consultation, the draft standard will then be reviewed by the eHealth Standards

Advisory Group, HIQA's Executive Management Team and the Board of HIQA. Finally, the standard will be sent to the Minister for Health for mandate.

1.4.2 Targeted Consultation

This document presents for targeted consultation the proposed *Draft Standard for eDispensing Dataset and Clinical Document Architecture Standard (for trial use)* for use in health and social care settings in Ireland for a period of five weeks. HIQA will consider and review all submissions received during the consultation process. Following this process, HIQA will finalise the standards.

The closing date for receipt of submissions is 14 October 2016 at 5 pm.

How to make a submission

A number of consultation questions have been prepared for your consideration when reviewing the standards. These questions are grouped together in the consultation feedback form. They are not intended, in any way, to limit feedback, and any other comments are welcome. There are three ways to tell us what you think:

- Complete the online consultation feedback form by clicking here. This will bring you to an online version of the consultation feedback form.
- Your comments can be submitted by downloading and completing the consultation feedback form available here and emailing your completed forms to technicalstandards@hiqa.ie.
- You can print off a copy of the feedback form at http://www.hiqa.ie and post it to us at:

Health Information and Quality Authority
Draft National eDispensing Standard
George's Court
George's Lane
Smithfield
Dublin 7, D07 E984.

For further information or if you have any questions you can talk to the consultation team by calling (01) 8147685.

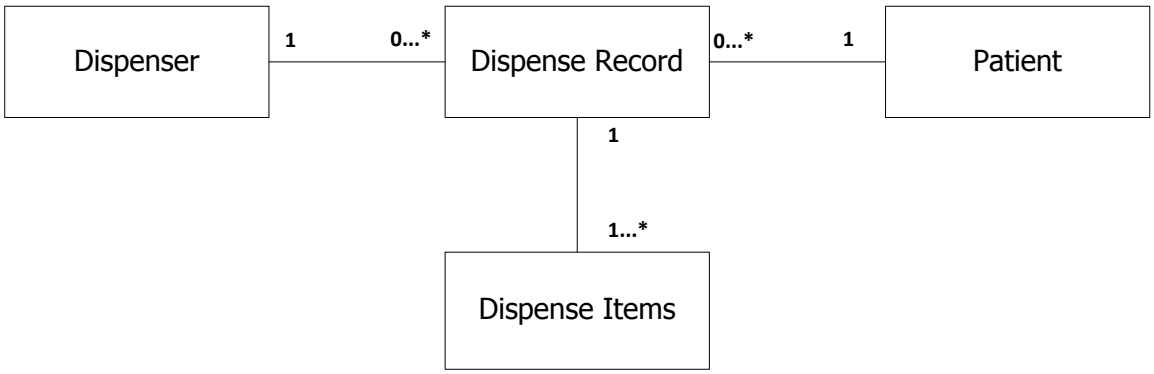
How we will use your comments

Following the consultation, the Authority will analyse the submissions and as a result may make further amendments to the document. We will present the main amendments in a separate statement of outcomes document which we will publish. This is your opportunity to participate in the development of standards. We wish to thank you in advance for taking the time to submit your comments.

2 Dataset for eDispensing

Figure 1 below indicates at a high level the class model for the clinical aspect of the eDispensing dataset. The Dispenser is associated with the dispense record. Each dispesnse record is associated with multiple dispensed items. The dispensed items correspond to each unique entry in a dispense record.

Figure 1: Model for a Dispense Record



The dataset for eDispensing includes information for the subject of care (Patient), healthcare practitioner (Dispenser), dispense record and dispense items.

Tables 1 defines the clinical dataset to be supported by this draft standard. In addition to the clinical dataset the CDA standard requires information about the document identification and the custodian and author of the document. These requirements are listed in Appendix 3 and Appedix 4.

Each of the classes and associated attributes are described in the tables below which define the name, definition, optionality and usage of the data elements.

2.1 Dispense Record Dataset

Data Element	Definition	Optionality	Usage
1.1 Date	The date (and optionally time) when an authorised pharmacist or dispenser dispensed a prescribed item(s) to the patient.	Mandatory	Date field which indicates when the prescription was dispensed.
1.2 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.
1.3 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.
1.4 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
1.5 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.	Conditional	This field consists of a size value and unit, a combination of both defines the strength, for example 250 mg, 1g. If 1.3 and 1.4 are populated, then this field does not need to be populated.
1.6 Dose Form (type)	A description of the dose type.	Conditional	This field describes the does type, such as tablet,

			vial. If 1.3 and 1.4 are populated, then this field does not need to be populated.
1.7 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 1.3 and 1.4 are populated, then this field does not need to be populated.
1.8 Label Instruction	Dispenser instructions to the subject of care concerning the medication.	Mandatory	A textual description associated with instructions to the subject of care.
1.9 Comments	Any additional information that may be needed to ensure the continuity of supply, proper use, or appropriate medication management.	Optional	A textual description associated with additional information.

Table 1: Dispense Record

3 CDA standard

This draft CDA standard for electronic dispensing is based on the dataset described in Section 2. The eDispensing document contains a list of dispensed items for a patient and has a human prescriber as the document author. This section (3.1 – 3.4) will outline some CDA rules and will provide some guidance on how to interpret the draft CDA eDispensing standard. Table 2 below outlines the draft CDA eDispensing standard .

3.1 CDA Document Structure

A CDA clinical document is divided into a header and a body. The purpose of the CDA header is to set the context for the document as a whole, enable clinical document exchange across and within institutions, facilitate clinical document management, and facilitate compilation of an individual patient's clinical documents into a lifetime electronic patient record. The CDA document header is consistent across all CDA documents regardless of document type.

The header identifies and classifies the document and provides information on the authentication, the encounter, the patient, and the involved providers. The CDA ePrescribing specification for Ireland defines a clinical document header which includes header attributes and participations. They include the author, custodian and the patient's information. The body of a CDA document contains the clinical report, and can be structured text or a combination of both structured text and structured data.

CDA has three levels of document definition from level one to level three. Level one has a structured header and no coding of clinical information. An example of a level one constraint on a document could be an 'eDispensing Document'. Level two adds some coding of the clinical information. An example of a level two is coding of a 'Dispensing section'. Level three provides additional constraints on the document at the entry level of the document. An example of coding at the level 3 could be for a 'dispensing item'. The eDispensing standard aims to make use of CDA Document Levels 2 and 3.

3.2 Description of the eDispensing standard tables

The eDispensing CDA standard is defined using a table structure as illustrated in figure 2 below.

Figure 2: Attribute Table for defining CDA Documents, Sections and Entries

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

Each of the columns including the number, data element, description, CDA Xpath expression, HL7v3 data type, cardinality/optionality and vocabulary are described below.

- **Num**

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

- **Data element**

The data element defines the name of the field.

- **Description**

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.

- **CDA Xpath expression**

The CDA xpath expression is used to search through an XML document and locates 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 specification and corresponds to the XML representation required for implementation.

- **HL7 v3 Data Type**

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 2.

- **Optionality and Cardinality (Opt/Card)**

The optionality, as well as the cardinality information is associated with the data elements in the table (and not the XPath expression). The optionality used for

this specification are based on the optionality included in the epSOS specification. The optionality descriptions and acronyms are included in figure 3:

Figure 3: Optionality used in eDispensing standard

R	means required, the mapped CDA element shall be present and shall not contain the nullFlavor attribute.
RNFA (or R use NullFlavor)	means Required, Null Flavor 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 specifications.
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:

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 that there are optionally many (more than one) additional identifiers.

- **Vocabulary**

The vocabularies that are used throughout this specification are based on ISO, LOINC, the HL7 vocabularies. The LOINC code proposed for the identification of the documents for this standard is:

Figure 4: LOINC codes for eDispensing

Document	LOINC code	LOINC description
eDispensing	60590-7	Dispensing medication

3.3 Templates

HL7 templates are constraints (additional validation) on the CDA R2 object model. Constraints specify how CDA can be used for particular purposes and specific use cases. Template definitions can be generated at the document-level (See figure 5), section-level and entry-level such as patient identification, provider organisation or an observation entry respectively.

HL7 templates are required to have a templateID indicating that a CDA instance (document), conforms to both the CDA specification and the constraints specified in an implementation guide. The templateID, which could be an OID or locally defined, is used to indicate which template is being used.

Templates are used throughout this specification and are taken from the epSOS project. This specification has made adaptations or is a specialisation of the epSOS templates because there are instances where optional elements have been made more strict e.g. (0..1 → 1..1) and elements have been added that were not originally described in the epSOS specification in order to meet the 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.

Figure 5:epSOS templateID for a dispensing record at document level

Document	Template id
epsos eDispensation	1.3.6.1.4.1.12559.11.10.1.3.1.1.2

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 the there is no corresponding representation in the CDA specification.

3.5 Dispense Record

The CDA data attributes for the dispense record is outlined below.

Num	Data Element	Description	CDA xpath Expression	HL7 V3 Data Type	Card /Opt	Vocab
Dispensation Section 1.3.6.1.4.1.12559.11.10.1.3.1.2.2 Dispensed Medicine Entry Content Module 1.3.6.1.4.1.12559.11.10.1.3.1.3.3						
1.1	Date of Dispense	The date (and optionally time) when an authorised pharmacist or dispenser dispensed a prescribed item (s) to a patient.	entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.3']/effectiveTime[1][@xsi:type='IVL_TS']/low/@value	TS	R [1..1]	
1.2	Dispensed Medicine ID	A string generated by an EDS (Electronic Prescribing System) to uniquely identify an action of dispensing a medication.	entry/supply[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.3']/product/manufacturedProduct/manufacturedMaterial/id	II (Instance Identifier).	R[1..1]	
1.3	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.	entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.3']/consumable/manufacturedProduct/manufacturedMaterial/name	TXT	R [1...*]	
1.4	Medicinal product package	Size and or type of package prescribed.	entry/supply[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.3']/product/manufacturedProdu	CD	RNFA [1..1]	epSOSPackage 1.3.6.1.4

			ct/manufacturedMaterial/asContent/containerPackageMedicine/formCode			.1.12559.11.10.1.3.1.44.1
1.5	Number of packages	Number of complete packages required to fulfil the prescription.	1.3.6.1.4.1.12559.11.10.1.3.1.3.3 entry/supply[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.3']/quantity	PQ, PQ	0[1..*]	
1.6	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/supply[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.3']/product/manufacturedProduct/manufacturedMaterial/ingredient/[@classCode='ACTI']/quantity	PQ, PQ	R[1..1]	
1.7	Dose form (type)	Form in which a pharmaceutical product is presented in the medicinal product package as supplied by the marketing authorization holder, manufacturer and/or distributor.	entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.3']/consumable/manufacturedProduct/manufacturedMaterial/formCode	CD	R[1..1]	epSOSDoseForm 1.3.6.1.4.1.12559.11.10.1.3.1.44.1
1.8	Total number of dose instances	Total number of instances of the medicinal product required to fulfil the prescription.	1.3.6.1.4.1.12559.11.10.1.3.1.3.3 entry/supply[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.3']/quantity	PQ, PQ	0[1..1]	
1.9	Label Instruction	Dispenser instructions to the subject of care concerning the medication.	<text><reference value='#comment'/></text>	ST	R[1..1]	
1.10	Comments	Any additional information that	<text><reference	ST	O[0..*]	

		may be needed to ensure the continuity of supply, proper use, or appropriate medication management	value='#comment'/></text>			
1.11	Prescription ID	A link back to the original prescription identifier.	/ClinicalDocument/component/structuredBody/component/section[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.2.1']/id	II (Instance Identifier).	R[1..1]	

Table 2 : Dispense Record

Appendix 1 - ETP use cases and message flows

Figure 6 below illustrates the use cases in scope for the electronic transfer of prescriptions. Relevant scenarios for each of the use cases are subsequently provided along with messages flows.

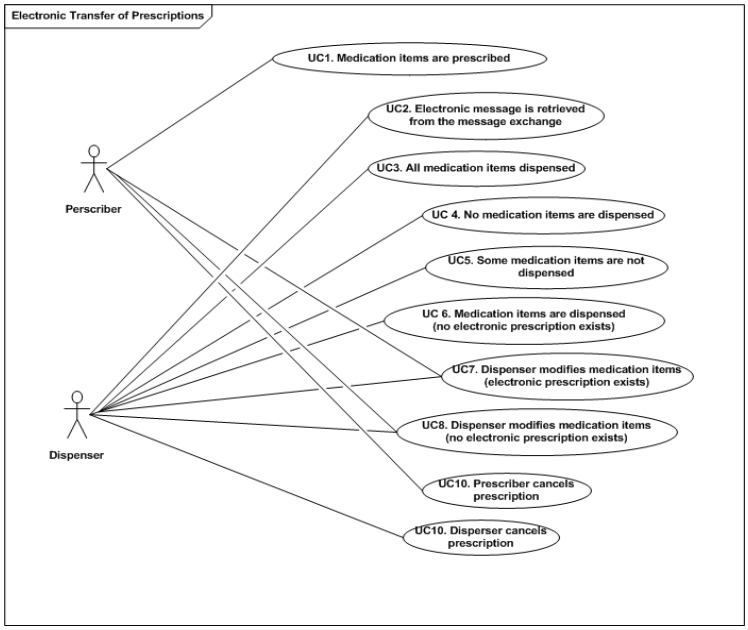


Figure 6 Electronic Transfer of Prescriptions

2.1 Scenario 1

A patient attends a prescriber who generates an electronic prescription which is sent and stored at the message exchange (Healthlink). The patient subsequently attends a dispenser and provides the dispenser with a bar coded paper prescription which allows the dispenser to identify and retrieve the prescription from the message exchange. The dispenser then dispenses the prescribed medication in accordance with the prescription information.

Finally, if no medications are dispensed for the prescription and the dispenser indicates this by returning the unfulfilled items in a message back to the message exchange.

The use cases (UCs) to support this scenario are depicted in Figure 2 below.

2.1.1 Clinical examples to inform use cases

- The patient attends a prescriber and is prescribed medication (UC 1)

- A patient may contact a prescriber requesting that a repeat prescription is issued. (UC 1)
- A next of kin or carer may request a prescription to be issued for a patient (UC 1)
- The patient or a person on their behalf attends the pharmacy of his/her choice in order to have medication items dispensed. The dispenser retrieves the electronic prescription from the message exchange. (UC 2)
- A prescription is presented to a dispenser, the person the prescription relates to may present in person or another person may collect the prescription on their behalf. The dispenser retrieves the electronic message from the message exchange. The dispenser is able to dispense all medication items on the prescription (UC 2 and UC 3).
- The patient receives a prescription from a prescriber and decides to have the price checked at the pharmacy without any of the prescribed medication items being dispensed. (UC 2 and UC 4)
- The patient attends the pharmacy of his/her choice but the pharmacy does not have the required medication in stock and no medication items are dispensed (UC 2 and UC 4).

2.1.2 Message flows

Figure 7 below illustrates the message flows generated when a patient attends a prescriber and subsequently attends a dispenser.

On generation of a paper prescription, the prescriber's practice management system creates an electronic version of the prescription which is sent to a message exchange.

On receipt of the paper prescription, which contains a unique identifier for the electronic prescription, the dispenser retrieves the electronic prescription from the message exchange and subsequently notifies the message exchange that the prescription has been dispensed.

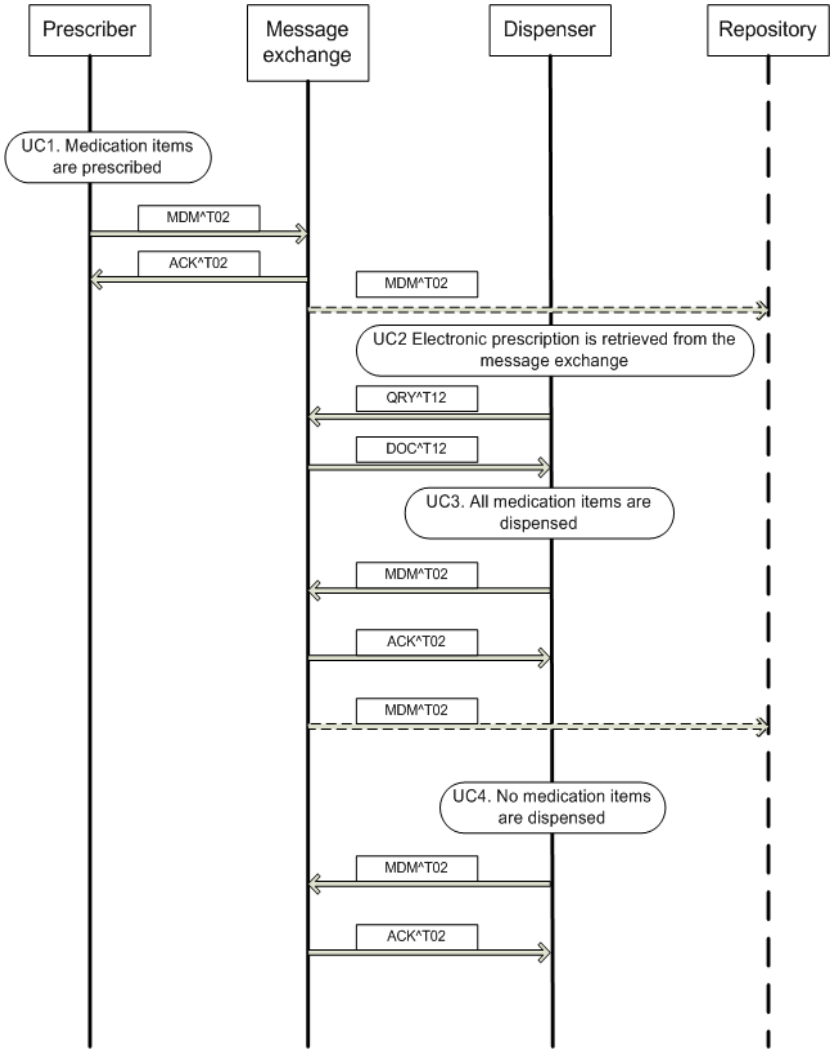


Figure 7. Electronic prescribing and dispensing of an electronic prescription

Use case 1 – Medication items are prescribed

The message type used for the electronic prescription is MDM^T02 with a MIME encapsulated Clinical Document Architecture (CDA) prescription document carried in the OBX segment. For the purpose of this standard the MDM^T02 contains the following segments:

MSH Message Header
EVN Event Type
PID Patient Identification
PV1 Patient Visit
TXA Document Notification
OBX Observation/Result.

For the purpose of this standard the acknowledgement response to receiving an electronic prescription is ACK^T02. It consists of the following segments:

MSH Message Header
MSA Message Acknowledgement
ERR Error Information. Use case

Use case 2 – Electronic prescription is retrieved from the message exchange

The message type used to query the message exchange and retrieve the electronic prescription is QRY^T12. For the purpose of this standard the QRY^T12 contains the following segments:

MSH Message Header
QRD Query Definition
QRF Query Filter.

The message type used to return the relevant document for the query is DOC^T12. For the purpose of this standard the acknowledgement response to receiving an electronic prescription is DOC^T12.

MSH Message Header
MSA Message Acknowledgement
ERR Error Segment
QRD Query Definition
EVN Event Segment
PID Patient Identification
PV1 Event Type/Patient Visit
OBX Observation Response.

Use case 3 – All medication items dispensed

The message type used for the electronic prescription is MDM^T02 with a MIME encapsulated Clinical Document Architecture (CDA) prescription document carried in the OBX segment.

For the purpose of this standard the acknowledgement response to receiving an electronic prescription is ACK^T02.

Use case 4 – No medication items dispensed

The message type used for the electronic prescription is MDM^T02 with a MIME encapsulated Clinical Document Architecture (CDA) prescription document carried in the OBX segment.

For the purpose of this standard the acknowledgement response to receiving an electronic prescription is ACK^T02.

2.2 Scenario 2

The dispenser is able to prescribe some of the items prescribed. After the patient collects the medication the dispenser updates the message exchange of medications dispensed. If certain medications are not dispensed then the dispenser updates the medication exchange to indicate this.

2.2.1 Clinical examples

- The patient attends a prescriber and receives a prescription for one or more medication items. The pharmacist does not have all medications in stock but dispenses some of the medication items prescribed. (Use case 5).
- The patient attends the GP and receives a prescription for more than one medication. The patient decides to collect only part of the prescription; therefore some of the medication items are dispensed (Use case 5).
- A GMS patient attends the GP and receives a prescription for more than one medication item. Some medications are not covered under the GMS scheme and are therefore not dispensed (Use case 5).

2.1.2 Message flows

Figure 8 below illustrates message flows generated when a patient attends a dispenser and only some of the items on the prescription are dispensed.

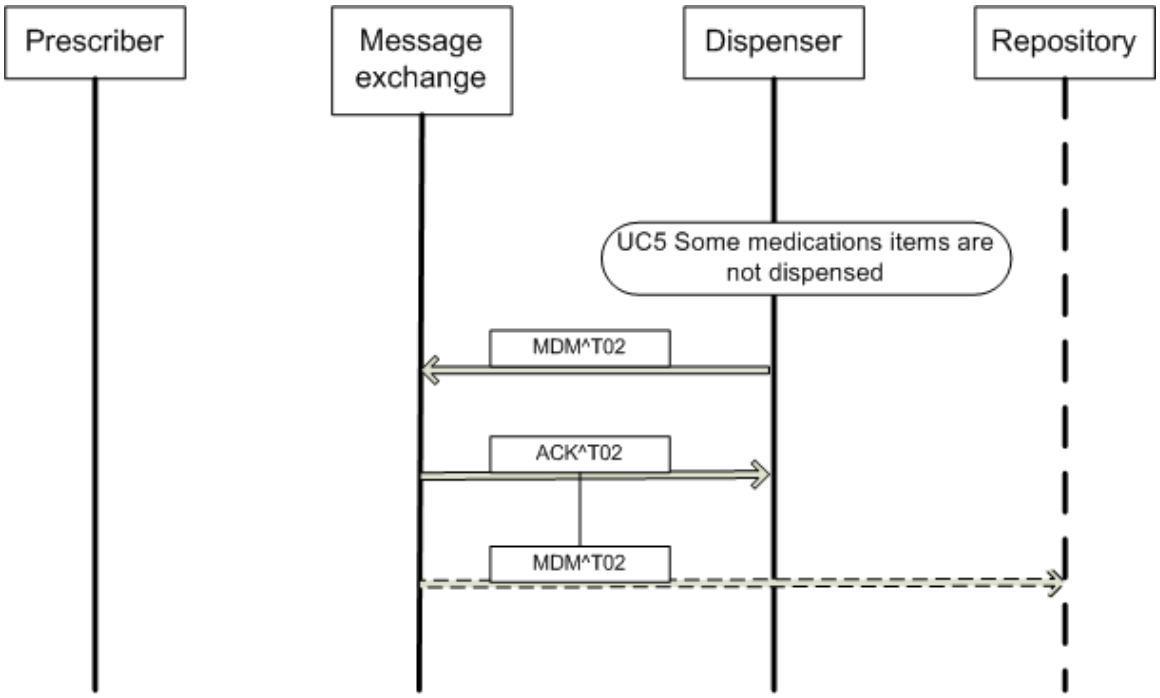


Figure 8. Some medications are not dispensed

Use case 5 – Some medication items are not dispensed

The message type used for the electronic prescription is MDM^T02 with a MIME encapsulated Clinical Document Architecture (CDA) prescription document carried in the OBX segment.

For the purpose of this standard the acknowledgement response to receiving an electronic prescription is ACK^T02.

2.3 Scenario 3

A patient attends a dispenser with a paper prescription. The pharmacist dispenses the medication items to the patient and records this on their computer system. No electronic prescription record exists for the prescription from the prescriber.

2.3.1 Clinical examples

- A patient attends a prescriber who has yet to computerise processes and is given a handwritten, typed or printed prescription (Use case 6).
- Information systems are not functioning and the prescriber must revert to manual processes and prescribe using a paper handwritten prescription (Use case 6).
- A patient is reviewed by a prescriber during a home visit and the prescriber writes a paper prescription.
- A patient is reviewed by a prescriber out of hours and the prescriber creates a paper prescription.

2.3.2 Message flows

Figure 9 below illustrates the message flows generated when a patient attends dispenser with a paper prescription and there is no electronic version of the prescription.

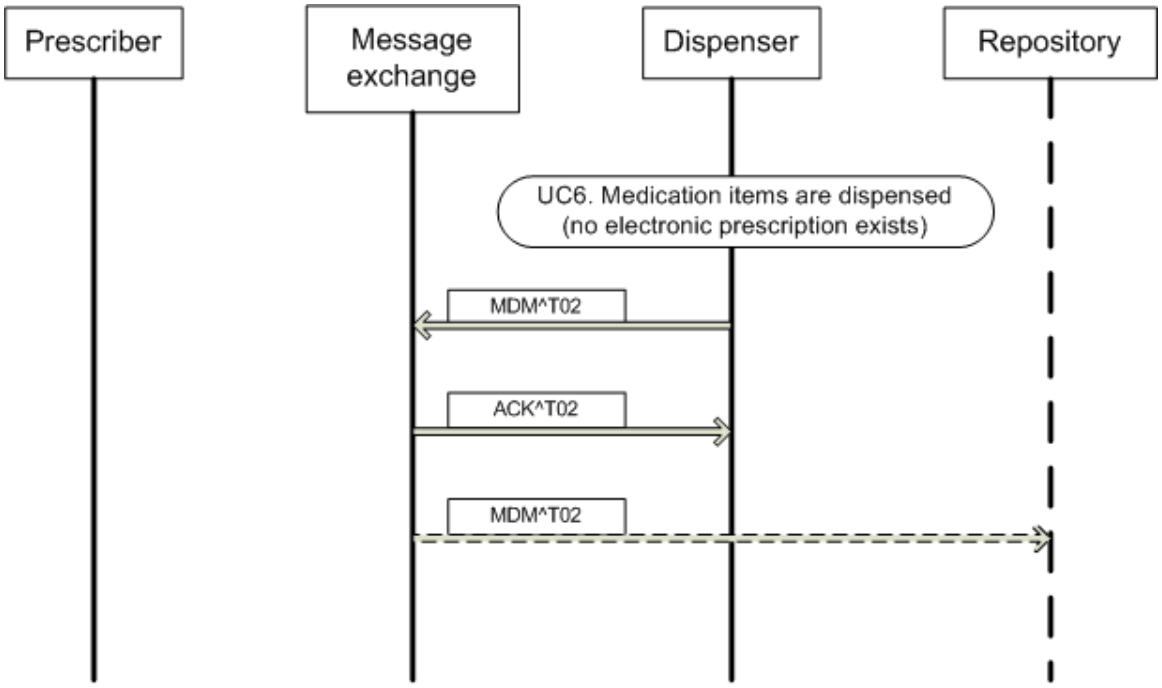


Figure 9. Medications are dispensed where no electronic prescription ever existed

Use case 6 – Medication items are dispensed (no electronic prescription exists)

The message type used for the electronic prescription is MDM^T02 with a MIME encapsulated Clinical Document Architecture (CDA) prescription document carried in the OBX segment.

For the purpose of this standard the acknowledgement response to receiving an electronic prescription is ACK^T02.

Note: if an electronic repository exists the message exchange broker may forward the MDM^T02 message to it. The electronic repository responds with ACK^T02.

2.4 Scenario 4

A patient attends a prescriber and is prescribed medication items. The patient visits a dispenser to have the medication items dispensed. Prior to dispensing a medication item, the dispenser decides a substitution is to be made for one of the medication

items which requires authorisation by the prescriber. The authorisation to change the medication items is obtained and a prescriber subsequently issues an updated prescription.

2.4.1 Clinical examples

- It may occur that the dispenser feels it is necessary to change the dose of a medication due to an error on the prescription or other clinical factors (Use case 7).
- The duration that the medication is to be taken may require a change (Use case 7).
- The route of administration of the medication may need to be changed (Use case 7).
- The dispenser may have knowledge of an allergy that requires substitution for a different type of medication (Use case 7)

2.4.2 Message flows

Figure 10 below illustrates the message flows generated when a patient attends dispenser who modifies prescription items requiring authorisation from the perscriber.

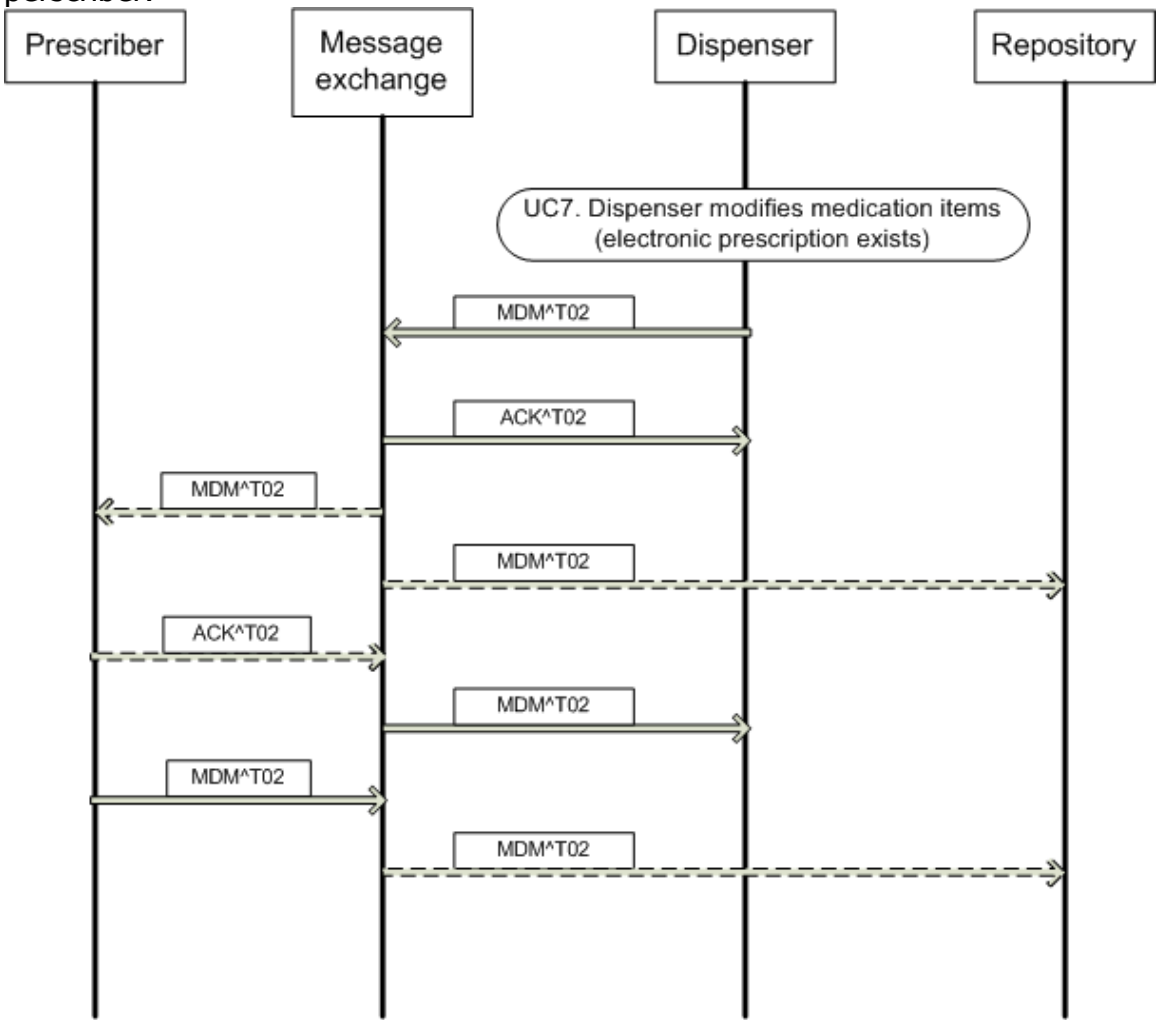


Figure 10 Dispenser modifies prescription item and this requires authorisation from the prescriber

Use case 7 – Dispenser modifies some medication items (electronic prescription exists)

A message is sent from the dispenser to the message exchange after substitution of a prescribed medication item. The message type used to indicate the medication items which were substituted is MDM^T02 and is sent from the dispenser to the message exchange. For the purpose of this standard, the acknowledgement response to receiving an electronic prescription is ACK^T02. This message may be sent back to the original prescriber.

The prescriber may update the original prescription to note the updated content. The message type used to indicate certain prescribed medications items were changed is MDM^T02 with a MIME encapsulated Clinical Document Architecture (CDA) prescription document carried in the OBX segment.
For the purpose of this standard the acknowledgement response to the indication of medications dispensed is ACK^T02. The message is sent to the message exchange and may be forwarded from there to an electronic repository.

2.5 Scenario 5

A patient attends a doctor and is prescribed medication items on a paper prescription. The patient visits a pharmacy to have the medication items dispensed. Prior to dispensing medication a substitution is made for one of the medication items which requires authorisation by the doctor. The authorisation is obtained and a doctor sends another paper prescription to the pharmacy.

2.5.1 Clinical examples

- It may occur that the pharmacist feels it is necessary to change the dose of a medication due to an error on the prescription or other clinical factors (Use case 8).
- The duration that the medication is to be taken may require a change (Use case 8).
- The route of administration of the medication may need to be changed (Use case 8).
- The pharmacist may have knowledge of an allergy that requires substitution for a different type of medication (Use case 8).

2.5.2 Message flows

Figure 11 below illustrates the message flows generated when a patient attends dispenser who modifies prescription items requiring authorisation from the prescriber. In this instance no electronic prescription existed.

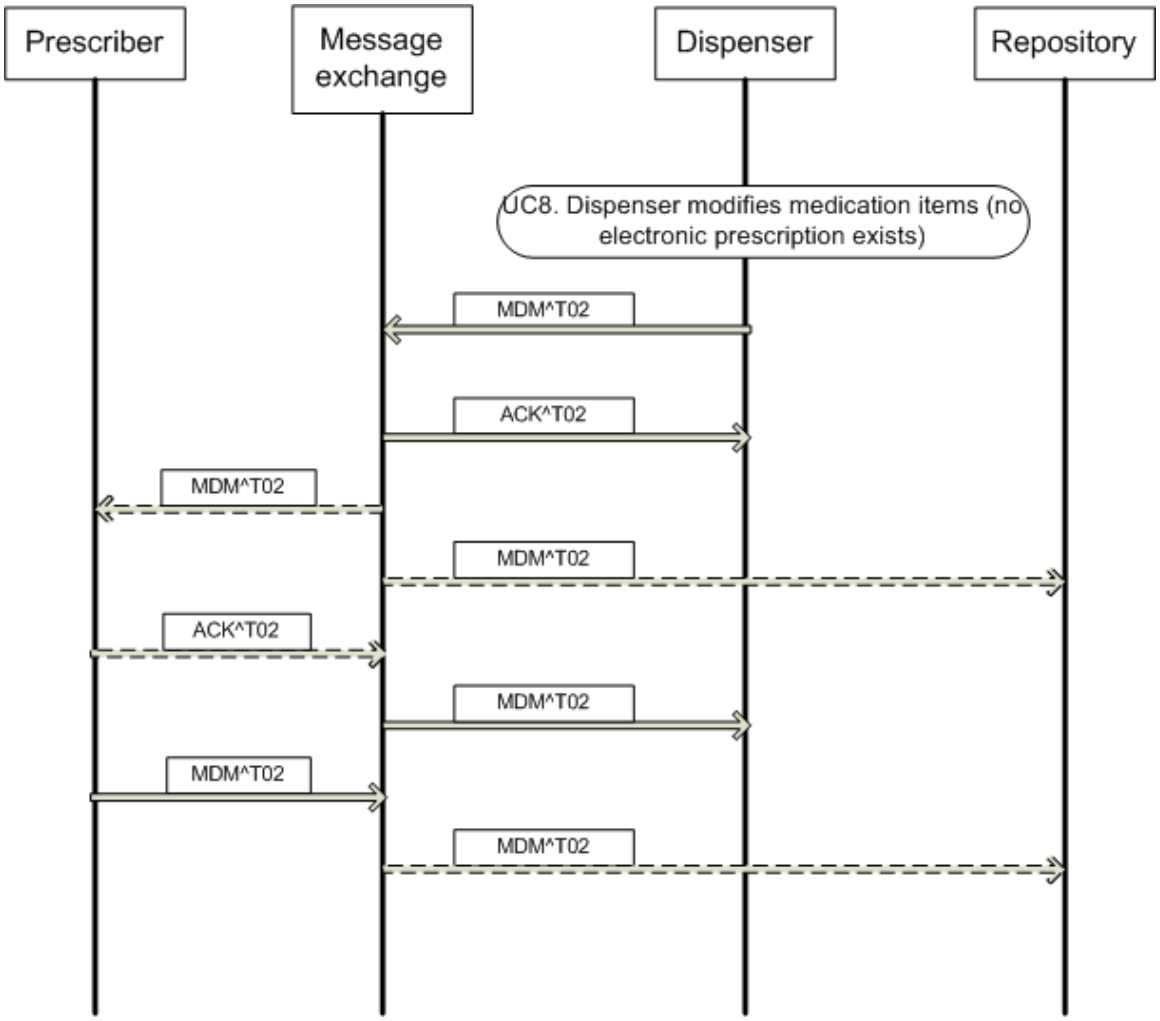


Figure 11 Pharmacist substitutes medication with required prescriber to authorise and issue a second prescription

UC8 – Dispenser modifies medication items (no electronic prescription exists)

The message type used for the dispenser to notify the message exchange that medication has been dispensed is MDM^T02. For the purpose of this standard, the response is ACK^T02. This message may also be forwarded to the electronic repository from the message exchange.

2.6 Scenario 6

A patient attends a prescriber who generates an electronic prescription which is sent and stored in the message exchange. After the patient has left, the prescriber decides the prescription should be cancelled.
The patient subsequently attends a dispenser and provides the dispenser with a bar coded paper prescription which allows the dispenser to identify and retrieve the prescription from the message exchange. The dispenser retrieves a cancelled prescription indicating that the prescriber has decided that the prescription is not required. The dispenser informs the patient of the cancellation.

A patient attends a prescriber who generates an electronic prescription which is sent and stored in the message exchange. The patient subsequently attends a dispenser and provides the dispenser with a bar coded paper prescription which allows the dispenser to identify and retrieve the prescription from the message exchange. The dispenser decides that the prescription should be cancelled. Authorisation is received from the prescriber and the dispenser cancels the prescription and informs the patient.

2.6.1 Clinical examples

- The prescriber or dispenser suspects medication misuse or abuse (Use case 9 and 10).
- The dispenser discovers the prescriber is not authorised to prescribe a certain type of medication (Use case 10).
- The dispenser may decide it is unsafe to dispense the medication prescribed (Use case 10).
- The dispenser may discover that the prescription is for an unlicensed medication and may cancel the prescription (Use case 10).

2.6.2 Message flows

Figure 12 below illustrates the message flows generated when either a prescriber or dispenser cancels a prescription.

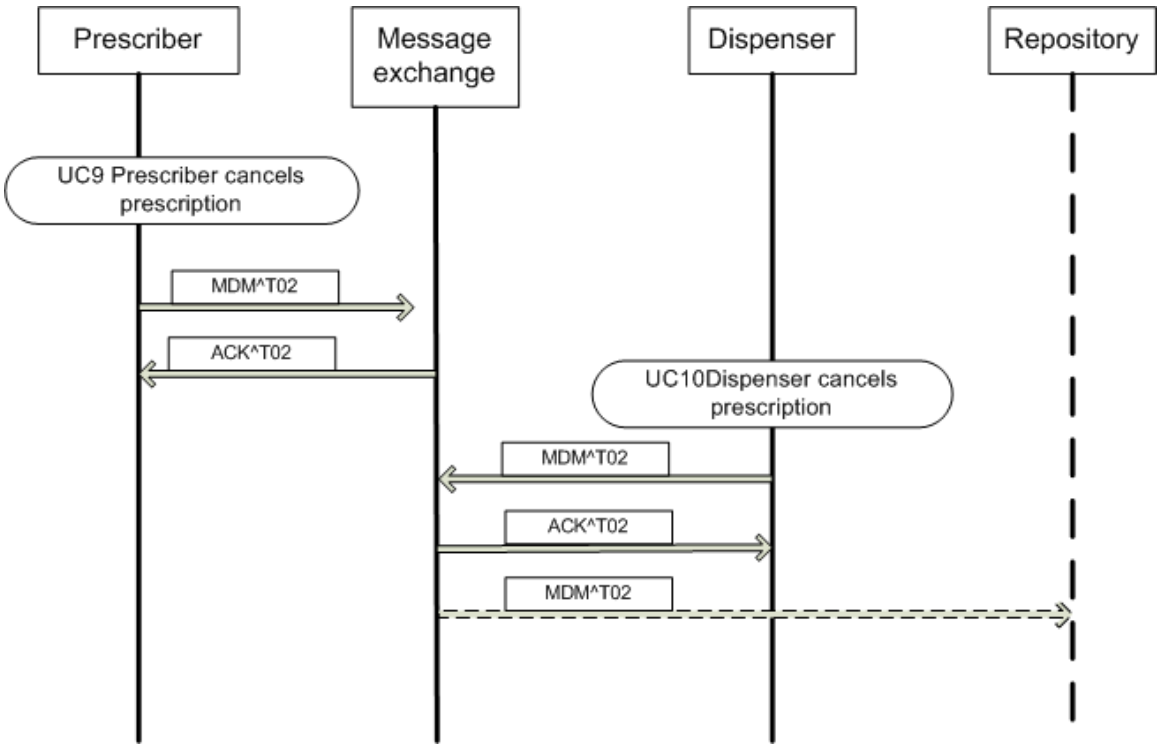


Figure 12 Prescriber or dispenser cancels prescription

Use case 9 – Prescriber cancels prescription

The message type used for the dispenser to notify the message exchange that medication has been dispensed is MDM^T02. For the purpose of this standard, the response is ACK^T02. This message may also be forwarded to the electronic repository from the message exchange.

Use case 10 – Dispenser cancels prescription

The message type used for the dispenser to notify the message exchange that medication has been dispensed is MDM^T02. For the purpose of this standard, the response is ACK^T02. This message may also be forwarded to the electronic repository from the message exchange.

Appendix 2 - Clinical Document Architecture (CDA) Standard

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

Several countries have adopted CDA 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 US. Implementers can refine the generic CDA specification by defining the structure and coding requirements to meet their local requirements.

CDA allows for three different levels of conformance to the standard. Level one enable implementers to develop documents that are displayed and presented to clinicians in a readable format. More complex documents can be created that are coded for machine processing using level two and three. This feature is referred to as the 'migration path' and provides a flexible approach to CDA implementation. 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 (entries) to the clinical document.

HL7 defines clinical documents as historical, human readable healthcare records that combine data and free text and are always (at least theoretically) attested. The following list describes the goals of an electronic clinical document expressed in CDA as:

- 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 human readable

In summary, some of the key benefits of CDA are:

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

Appendix 3 - Datasets

The following datasets are defined here and are needed for the eDispensing Standard :Subject of Care, Dispenser, Document, Author and Custodian

Subject of care (Patient)

The subject of care is the person who the medication is dispensed for.

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 per their birth certificate.	Mandatory	A patient's first name or given name (s) as per 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.
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 Gender	Gender identity is a person's sense of identification with either the male or female sex, as manifested in appearance, behaviour and other aspects of a person's life.	Mandatory	Gender identity is a person's sense of identification with either the male or female sex, as manifested in appearance, behaviour and other aspects of a person's life.
1.7 Health identifier	A number or code assigned to an individual to uniquely identify the	Optional	Both the code and the code type the code relates to should

	individual within an organisation.		be provided e.g. 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.

Table 3: Subject of Care

Healthcare Practitioner (Dispenser)

The Dispencer is the healthcare practitioner who dispenses the medication.

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 number	The telephone number of the healthcare practitioner.	Mandatory	The phone number to contact the 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.

Table 4: Healthcare Practitioner (Dispenser)

Document Identification

Name	Definition	Optionality	Usage
Clinical Document	The ClinicalDocument 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.
Type ID	This element represents the type of clinical document (e.g. ePrescription, eDispensation) and identifies the	Mandatory	This data element is fixed and must always be included in the document. The @root and

	constraints imposed by CDA R2 on the content, essentially acting as a version identifier.		@extension values of this element are specified as a long fixed identifier which is in two parts: root and extension.
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.	Madatory	This data element is fixed and must always be included in the document.
Document ID	This is the identifier of the Clinical Document which uniquely identifies the document instance.	Mandatory	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.
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.
Date of creation	The time and date that the document came into being.	Mandatory	The time and date that the document came into being.
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
Clinical document code	Determines the document type.	Mandatory	A coded value typically drawn from LOINC (HL7 LOINC Document Type Vocabulary Domain).
Confidentiality code	Codes that identifies how sensitive a piece of information is and/or that	Mandatory	A coded value, CDA defines a limited set which can be

	indicate how the information may be made available or disclosed.		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.
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.
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 CODE><languageCode code="en-GB"/>
Set ID	Identifier for a set of related documents. The original document and replacement documents versions thereof all share one and the same setId – they all have a different/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.
Version Number	Contains the version number of this instance/version of the document	Optional	For additional information see the description of *Other*

	within a set of related documents.		*Participants: relatedDocument:* it is used to link a later version of a document to a previous version of a document. Example: ClinicalDocument/versionNumber/@number="1"

Table 5: Document Information

Author

This section defines the author data items required by the CDA specification. The author is the preson responsible for the document. This information is required by the CDA standard.

Name	Definition	Optionality	Usage
Author 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.
Author title	Coded value that contains the title relevant to the author of the document	Optional	To be selected from a predefined list.
Author forename	The author's first or given name(s) as per their birth certificate	Mandatory	Where the Author is registered with a professional body, the forename should be the forename registered with the professional body.
Author 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.
Author profession	Coded element that specifies theauthor's particular profession.	Mandatory	This value can be selected from a predefined list.
Author telephone number	The author's telephone number	Mandatory	The phone number to contact the Author.
Author's email address	The author's email address	Mandatory	The secure email address to contact the Author.
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.

Table 6: Author Information

Custodian

The custodian represents the organisation that is in charge of maintaining the document. This information is required by the CDA standard.

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

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

Table 7: Custodian Information

Appendix 4 – CDA Specifications

Record Target (Patient Information)

In CDA documents the person the clinical information relates to is known as the record target. The recordTarget class represents the medical record that this document belongs to. A clinical document typically has exactly one recordTarget participant. The data attributes for patient information are outlined in table 4 below:

Num	Data Element	Description	CDA Xpath expression	HL7 v3 Data Type	Card/ Opt	Vocabulary
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)						
1.1	**Individual health identifier**	User ID of individual	/ClinicalDocument/recordTarget/patientRole/id	II	0[0...1]	
1.2	**Family Surname**	Patient's second name which denotes their family or marital name	/ClinicalDocument/recordTarget/patientRole/name/family	PN	R [1...*]	
1.3	**Given Name**	Patient's identifying name	/ClinicalDocument/recordTarget/patientRole/name/given	PN	R [1...*]	
1.4	**Prefix**	Coded value that contains the title relevant to a specific family name for this Patient .	/ClinicalDocument/recordTarget/patientRole/prefix	PN	O [0...*]	
1.5	**Date of Birth**	The date of birth of the subject of care	/ClinicalDocument/recordTarget/patientRole/patient/birthtime	TS	R [1..1]	
1.6	**Gender**	Sex is the biological distinction between male and female. Where there is inconsistency between anatomical and chromosomal	/ClinicalDocument/recordTarget/patientRole/patient/administrativeGenderCode	CE	R use nullFlavor = UNK	

		characteristics, sex is based on anatomical characteristics.			[1..1]	
1.7	**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]	

Table 8: Record Target

Dispenser

The electronic dispensing information consists of both the dispenser and the medication information. Table 5 outlines the data attributes for dispenser. Table 6 below outlines the data attributes for the medication information. Both tables are outlined below.

Num	Data Element	Description	CDA Xpath expression	HL7 v3 Data Type	Card/Opt	Vocabulary
The templateId for Dispenser (Author) is 1.3.6.1.4.1.19376.1.5.3.1.2.3 (without the PCC patient identifier extension) (epSOS) The template ID referenced here refers to HCP information in the ClinicalDocument/author/assignedAuthor/assignedPerson structure						
1.1	**Time of Dispensing**	The timestamp of dispensing the document. The date and time stamp when the edispensing document was created.	/ClinicalDocument/author/time	TS	R [1...*]	
1.2	**Dispenser ID number**	User ID of individual that is clinically responsible for the edispensing document.	/ClinicalDocument/author/assignedAuthor/id	II	R [1...1]	
1.3	**Dispenser Family**	Dispener's second name which denotes their family or marital	/ClinicalDocument/author/assignedAuthor/assign	PN	R [1...*]	

	Surname	name	edPerson/name/family			
1.4	**Given Name**	Dispenser's identifying name	/ClinicalDocument/author/assignedAuthor/assignedPerson/name/given	PN	R [1..*]	
1.5	**Dispenser 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...*]	
1.6	**Dispenser 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
1.7	**Dispenser telephone Number**	The Dispencer's telephone number	/ClinicalDocument/author/assignedAuthor /telecom/@value	TEL	R use nullFlavor [1..*]	
1.8	**Dispenser's email address**	The Dispenser's secure email address	/ClinicalDocument/assignedCustodian/representedCustodian /Organization/addr/ /telecom/@value	TEL	O [0..*]	
1.9	**Dispenser's fax number**	The prescribers 's fax number	/ClinicalDocument/author/assignedAuthor /telecom/@value	TEL	O [0...*]	

Table 9: Dispenser Information

Document Identification

This section defines the document identification and data items required by the CDA specification. This information is required by the CDA standard.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.

Num	Data Element	Description	CDA Xpath expression	HL7 v3 Data Type	Card /Opt	Vocabulary
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 ClinicalDocument 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 (e.g. ePrescription, eDispensation). The clinical document typeId 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.	/ClinicalDocument/typeId Example :<typeId extension="POCD_HD000040" root="2.16.840.1.113883.1.3"/> which is the unique id & extension for the CDA, Release Two Hierarchical Description.	II	Fixed	
1.3	**Template ID**	templateID is used to indicate any number of templates which might	/ClinicalDocument/templateId	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 CDA 2.0.

		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 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]	
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 elements 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 classifies the kind of clinical	/ClinicalDocument/code	CE	R [1..1]	

		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 1..1 and/or that indicate 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 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 Code**	Language Code as defined by RFC3066. <Language Code> <COUNTRY CODE><languageCode code="en-GB"/>	/ClinicalDocument/languageCode	CS	R [1..1]	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.
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 setId – they all have a different/unique document identifier.	ClinicalDocument/setID	II	O[0...1]	
1.13	**Version Number**	Contains the version number of this instance/version of the document within a set of related documents. Example: ClinicalDocument/versionNumber/@number="1"	ClinicalDocument/versionNumber	INT	O[0...1]	

Table 10: Document Identification

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." [From Implementation Guide for CDA Release 2: Imaging Integration – UV Realm, March 2009].

Num	Data Element	Description	CDA Xpath expression	HL7 v3 Data Type	Card/ Opt	Vocabulary
CDA header level template The templateId for Author is 1.3.6.1.4.1.19376.1.5.3.1.2.3 (without the PCC patient identifier extension) (epSOS)						
2.1	**Author ID number**	User ID of individual that is clinically responsible for the ePrescription	/ClinicalDocument/author/assignedAuthor/id	II	R [1...1]	

2.2	**Author 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 Given Name**	Author's identifying name	/ClinicalDocument/author/assignedAuthor/assignedPerson/name/given	PN	R [1..*]	
2.4	**Author 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 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...*]	

Table 11: Author Information

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 ClinicalDocument/custodian/assignedCustodian/representedCustodianOrganization element. The data attributes for custodian are outlined in table 10 below:

Num	Data Element	Description	CDA Xpath expression	HL7 v3 Data Type	Card/ Opt	Vocabulary
CDA header level template The template id for the epSOSCDAcustodian 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 steward organisation is an entity scoping the role of AssignedCustodian.	/Custodian/assignedCustodian		M[1..1]	
3.2	**CustodianID**	A unique identifier for the custodian	Custodian/assignedCustodia/representedCustodian/Organisation/id	II	M[1..1]	
3.3	**Name of Custodian**	Practice/Organisation Name) The name of the organisation that that is in charge of maintaining the document.	Custodian/Organisation/name	ON	R [1..1]	
3.4	**Custodian's 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/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/@value	TEL	R use nullFlavor [1..*]	
3.6	**Custodian's email address**	The custodians secure email address	/ClinicalDocument/assignedCustodian/representedCustodian /Organization/addr/telecom/@value	TEL	O [1..*]	

Table 12: Custodian Information

Appendix 5 - HL7 v3 Data Types

Each data element has a data type associated with it. A description of the HL7 datatypes used in the CDA ePrescribing are outlined below.

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.
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) etc. Instance Identifiers are defined based on ISO 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, 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 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 (e.g. 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 use 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 truncated.

The ClinicalDocument 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.

Appendix 6 - Value sets

Six standards, vocabularies or classification systems are used to define the allowable values for twelve of the thirteen data attributes that have coded element data types. Currently, no code-value set has yet been defined / 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[2]
- HL7 v3.0 Vocabulary Specification

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

ISO/TS 22220:2011: Health Informatics – Identification of Subject of Care

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
Herr	Herr	Sir	Sir
The Honourable	Hon	Sister	Sr
Madame	Mdm	The Venerable	The Ven

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

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.			

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	e-mail	E
6	URL	U
8	Other	O

Data attribute: sex

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

ISO 3166-1:2013

The full listing for this classification can be found HERE[3]. It is used to populate the Country Identifier data attribute.

The International Standard Classification of Occupations (ISCO)

Relevant professions and codes that have been extracted from the ISCO.

Data attribute: profession

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
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

[3]http://www.iso.org/iso/country_codes.htm

3254	Dispensing opticians
3255	Physiotherapy technicians and assistants
3256	Medical assistants
3257	Environmental and occupational health inspectors and associates
3258	Ambulance workers
3259	Health associate professionals not elsewhere classified

The Anatomical Therapeutic Chemical Classification System (WHO/ATC)

A searchable online database can be found at http://www.whocc.no/atc_ddd_index/, which contains the allowable values for the data attribute active ingredient code.

European Directorate for the Quality of Medicines (EDQM)

Data attribute: medicinal product package[4]

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
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

[4] 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

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
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

Pharmaceutical dose form[5]

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
10205000	Effervescent granules

[5] 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

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
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
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
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
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
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
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
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
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
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
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
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
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
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
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
50081000	Inhalation solution
50082000	Oral drops, powder for suspension

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) World Health Organization Essential Medicines and Health Products Information Portal. Introduction to Drug Utilization Research. 2003.

(3) 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

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

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

(6) 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

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