An Roinn Sláinte
DEPARTMENT OF HEALTH

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

ePrescription and eDispensation content Interoperability Specification

Document Information	
Title:	ePrescription and eDispensation content Interoperability Specification
Purpose:	The purpose of this document is to support several Core Interoperability Specifications and their associate use cases, in a specific area of interoperability and includes specific constraints for sharing prescription using the HL7 Clinical Document Architecture Release 2.0 (CDA) standard as the basis of the specifications and the Prescription specifications of the eHDSI project.
Owners:	HSE Enterprise Architecture and Department of Health
Publication Date:	14th December 2018
Version:	1.1
Target Audience:	All relevant stakeholders in the implementation of the Irish National Contact Point for eHealth Services.

Review Date:	20th May 2020

EHEALTH DIGITAL SERVICES INFRASTRUCTURE OPEN NATIONAL CONTACT POINT IMPLEMENTATION AND TEST PLATFORM SERVICES

ePrescription and eDispensation content Interoperability Specification

Author Karima Bourquard
Contract Reference Test Harness Support Service – HSE9100-LOT-2

Date 14/12/2018
Version 1.1
Status Final
Reference HSE9100-LOT2-IS-eP_eD_CONTENT-1.1.docx

IHE-Europe – Bluepoint Building – 80, boulevard A. Ryers, 1030 Brussels Belgium

Document Lifecycle

Version	Date	Author	Update
0.1	27/07/2018	A-G BERGE	Creation of the template
0.2	17/08/2018	K. BOURQUARD	Creation of the content of the document
0.3	27/08/2018	A-G BERGE	Apply new version of the template
0.4	24/09/2018	K. BOURQUARD	Update with HSE comments
0.5	8/10/2018	K. BOURQUARD	Update after the FTF meeting in Dublin (1-3 October 2018
1.0	13/12/2018	K. BOURQUARD	Final version following the comments of Brian
1.1	05/02/2019	H.RAMANANTSALAMA	Correction after Eamon's review

Approval

Name	Responsibility	Signature
Eamon Coyne		
Brian Markey		

Distribution list

Name	Date	Contact	Purpose*
Eamon Coyne		Eamon.Coyne@hse.ie	V
Caitriona Wray		Caitriona_Wray@health.gov.ie	V
Peter Connolly		PETER.CONNOLLY@hse.ie	V

* A: for action / V: for Approval / C: for comments/ I: for information

Reference documents

This section gathers the documents which are referenced in this document. In the body of this document, any reference to an external document is formatted using [KEYWORD] from the first column.

Keyword	Name and reference
[R1]	ePrescription and Patient Summary use cases analysis HSE9100-LOT-2-DELIVERABLE_1A
[R2]	Design of general interoperability architecture to support use cases HSE9100-LOT-2-DELIVERABLE_1B
[IS_GENERAL_TERM]	General Terminology Interoperability Specification HSE9100-LOT-2-IS-TERMINOLOGY
[R3]	PS functional requirements v2.2.2 https://ec.europa.eu/cefdigital/wiki/display/EHOPERATIONS/Specifications?preview=/35210463/65979541/PS%20functional%20requirements_v2.2.2.pdf
[R4]	epSOS Patient Summary template https://art-decor.ehdsi.eu/art-decor/decor-templates--epsos-
[R5]	Patient Identification Management HSE9100-LOT2-IS-PAT_ID_MGMT
[R6]	eHDSI document specifications in Art-Decor http://art-decor.org/art-decor/decor-templates--epsos-?id=1.3.6.1.4.1.12559.11.10.1.3.1.1.3
[R7]	ePrescription functional requirements v2.2.3 https://ec.europa.eu/cefdigital/wiki/display/EHOPERATIONS/Specifications?preview=/35210463/65979542/eP%20functional%20requirements_v2.2.3.pdf
[R8]	Patient Summary Content Interoperability Specification HSE9100-LOT2-IS-PATIENT_SUMMARY_CONTENT
[R9]	Health Level Seven (HL7) Clinical Document Architecture Release 2 (CDA R2) http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7

[R10]	IHE IT Infrastructure Technical Framework Volume 3 (ITI TF-3) Integration Profiles,– Final Text – Cross-Enterprise Sharing of Scanned Documents (Section 5.2 XDS-SD) https://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol3.pdf

Table of content

1 Preface

Ireland as a European country is becoming involved in the eHDSI (eHealth Digital Services Infrastructure) project led by the European Commission under the CEF (Connecting European Facilities) program and will participate to the deployment in the wave 3 (2020). To prepare the deployment of the NCPeH (National Contact Point for eHealth) in Ireland, the HSE (Health Service Executive) procured in 2018the support services that will facilitate the implementation of the NCPeH and its connection to central Irish services. The first step of the project is to define the needed use cases to support and to design the architecture for connecting the Irish NCPeH. These tasks will be followed by the design of the architecture within Ireland, the corresponding Interoperability Specifications, the testing strategy including test plans and the implementation of Gazelle test platform that includes test cases, test tools and test data.

1.1 Context

Directive 2011/24/EU provides rules for facilitating access to safe and high quality cross border healthcare and promotes cooperation on healthcare between member states. The aims of implementing the Irish NCPeH exchange of Patient Summaries and ePrescription are in line with the principles of cross-border care. The NCPeH and cross border exchange implementations are all key building blocks that will interact with the national data dictionary (single source of trust for clinical data definitions across the enterprise), the Patient Summary and ePrescribing documents and associated metadata will be stored there as minimum data sets.

The main goals are to design the platform based on the needs that will be developed in the first steps of the project that includes

- Use Cases for ePrescription and Patient Summary
- Corresponding Interoperability specifications and architecture orchestration
- Validated version of IHE Gazelle. The test harness will provide to the authority the ability to test prospective vendors and products against the above interoperability specifications.

1.2 Glossary

ePrescription: means a medicinal prescription issued and transmitted electronically, as elaborated in point 3 (f) of Commission Recommendation 2008/594/EC on cross-border interoperability of electronic health records. [PS/eP guidelines]

eDispensation: is defined as the act of electronically retrieving a prescription and giving the medicine to the patient. Once the medicine has been dispensed, a report on the items dispensed is sent to the prescribing Member State in a structured format. [PS/eP guidelines]

IHE profile: provides a common language for purchasers and vendors to discuss the integration needs of healthcare sites and the integration capabilities of healthcare IT products. A Profile is a guideline for implementation of a specific process, by providing precise definitions of how

standards can be implemented to meet specific clinical needs. [eHealth Interoperability Conformity Assessment Scheme for Europe (EURO-CAS)]

Patient Summary: is an identifiable "dataset of essential and understandable health information" that is made available "at the point of care to deliver safe patient care during unscheduled care [and planned care] with its maximal impact in the unscheduled care" [PS/eP guidelines]

Interoperability use case: description of a specific use of HIT(Health Information Technology) that includes depiction of both humans (business actors) and systems (technical actors), scope, workflows of tasks performed by healthcare professionals and associated data flows. It should be written in natural language and may include several scenarios. One or more use cases are derived from one business case [IHE taskforce]

Realisation scenario: description of human activities (business actors), systems (technical actors) roles (i.e., IHE actors) and transactions related to a set of technical use cases that support the interoperability infrastructure for use cases (implementable infrastructure). [IHE taskforce]

Interoperability Specification: description of the workflow, contents and terminology for the implementation of the exchange or share clinical documents and prescription using standards and IHE profiles in order to obtain interoperability when implemented by systems and solutions.

1.3 Document Purpose

The purpose of this document is to support several Core Interoperability Specifications and their associate use cases, in a specific area of interoperability and includes specific constraints for sharing prescription using the HL7 Clinical Document Architecture Release 2.0 (CDA) standard as the basis of the specifications and the Prescription specifications of the eHDSI project.

This Supporting Interoperability Specification is applicable to existing and new information systems that will connect to exchange Health Information. In particular this Interoperability Specification applies to the deployment of the ePrescription at the national level as the base for the "friendly" ePrescription to be exchanged Cross Border for an Irish patient moving in Europe.

At this stage of the project, the dispensation is out of the scope.

1.4 How to read this document

This document contains normative sections, as well as informative appendices for the reader convenience. The document is structured as follows:

This document contains six sections, as well as informative appendices for your convenience. The document is structured as follows:

Section 1: Contains an introduction to the Interoperability Specification (IS). This section contains a summary of the IS purpose and scope, as well as other content to help orient the first time reader to the topic of the IS and how it relates to other specifications;

Section 2: provides an overview of the use cases that were selected during the workshops held during the first period of the Irish project (Feb-July 2018);

Section 3: This section establishes the Content and Conformance Requirements for the Interoperability Specification;

Section 4: This section describes attributes and constraints on the header of the document based on HL7 CDA V2 standard used for the specifications of the clinical documents shared Cross border;

Sections 5, 6: Provides additional constraints on the standard for Prescription such as ePrescription that are shared within the Irish country;

Appendix A: Provides examples that conform to the requirements of this specification.

1.5 References

A (Core) Interoperability Specification (IS) is targeted to be the sole entry point for the technology developers, the compliance assessment testing and possibly certification, and the purchaser of IT systems in term of technical requirements that will ensure interoperability.

From this Interoperability Specification the following Interoperability Specifications is referenced:

- General Terminology Interoperability Specification [ITERM]

The above Interoperability Specifications include precise references to internationally adopted profiles and standards as well as Irish specific constraints.

Implementations are required to conform to the requirements within this Interoperability Specification; all referenced Interoperability Specifications, and the standards and profiles they specify.

This document is a Supporting Interoperability Specification that may be referenced by a number of Core Interoperability Specifications.

A Supporting Interoperability Specification (IS) may be referenced by multiple Core Interoperability Specifications and may also be referenced by other Supporting Interoperability Specifications.

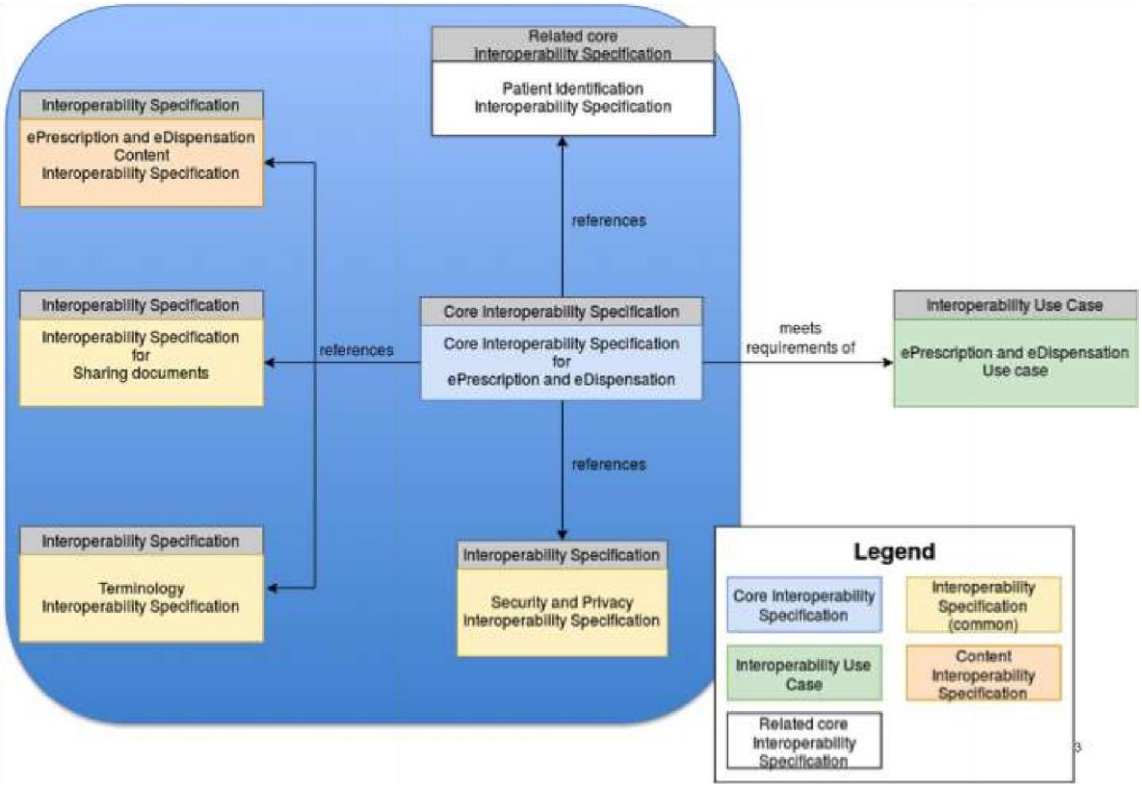

FIGURE 1: EPRESCRIPTION AND DISPENSATION CORE IS

1.6 Description

This Supporting Interoperability Specification describes how elements for date, time, personal names, and common metadata about persons and organizations are to be provided in documents using the HL7 Clinical Document Architecture R2 (CDA) Standard [R9] for the ePrescription/Dispensation content.

1.7 Document convention

1.7.1 Requirements numbering conventions

Interoperability Specifications contain numbered requirements that follow this format:

[ABCD-###] where ABCD is a three or four letter acronym unique to that Interoperability Specification for convenient purposes, and ### is the unique number for that requirement within the Interoperability Specification.

These numbered requirements are the elements of the Interoperability Specification that the system conforms to. In other words, in order to implement a system that fully supports the Use Case and Interoperability Specification, the system shall be able to demonstrate that it conforms to every numbered requirement for the system actors to which it is claiming conformance.

Please note that all numbered requirements are numbered uniquely, however numbered requirements are not always sequential.

1.7.2 Requirements language

Throughout this document the following conventions[1] are used to specify requirement levels:

- **SHALL:** the definition is an absolute requirement of the specification.
- **SHALL NOT:** the definition is an absolute prohibition of the specification.
- **SHOULD:** there may exist valid reasons in particular circumstances to ignore a particular item, but the full implications must be understood and carefully weighed before choosing a different course.
- **SHOULD NOT:** there may exist valid reasons in particular circumstances when the particular behaviour is acceptable or even useful, but the full implications should be understood and the case carefully weighed before implementing any behaviour described with this label.
- **MAY or OPTIONAL:** means that an item is truly optional. One vendor may choose to include the item because a particular marketplace requires it or because the vendor feels that it enhances the product while another vendor may omit the same item.

1.8 Methodology

This Interoperability Specification has been developed with input from various Irish stakeholders collected during several months through workshops and teleconferences. Stakeholders included Physicians from many different disciplines and Irish IT specialists.

The development of a Core Interoperability Specification relies on the high-level requirements set by the associated Use Case. These high-level requirements are not restated in this specification and readers may consider reviewing the related Use Case document.

1.8.1 Introduction of the use case driven approach

This methodology[1] has the objective to

- Define Use cases and their priorities to answer the eHealth strategy objectives of nation/region;
- From use cases to design the interoperability specifications and infrastructure based on IHE profiles;
- To define the testing strategy and identify test plan and test methods (test cases, test tools and test data);
- To support Project teams to procure products or solutions for their eHealth Project (Telemedicine, national/regional EHR, replacement of product in

hospitals, …); The methodology is based on experiences and good practices in other countries or regions.

It is further described in the report “ePrescription and Patient Summary use case analysis”, HSE9100-LOT-2-1A and the report “Design of general interoperability architecture to support use cases” , HSE9100-LOT-2-1B.

2 Use case overview

The use case is described in [R1]. During the workshops, two use cases were selected:

- Irish Prescription abroad (Irish citizen)
- Dispensation received from EU country for an Irish patient (Irish citizen) ePrescription of a foreign EU Patient (Foreigner)

The dispensation use case is out of the scope at this stage of the project. Therefore, no specification on dispensation is included in the present document.

2.1 Scope

The scope of this document is the specification of the header, sections, entries and data types that appear within CDA documents exchanged Cross Border that need to be refined for “ePrescription,” and “eDispensation” used in Irish care processes.

The following topics are in scope for this Interoperability Specification:

- Constraints on data types used within CDA documents;
- Constraints on the cardinality of common data elements appearing within CDA documents;
- Constraints on sections and entries which are used in one or more Interoperability Specifications and which are common in all cases.

As a reminder, the following schema describes what are the documents that are exchanged through the NCPeH:

1 Definitions based upon IETF RFC 2119 2 Bourquard, Karima and Berler, Alexander: Use case driven approach for a pragmatic implementation of interoperability in eHealth. IGI Global Journal

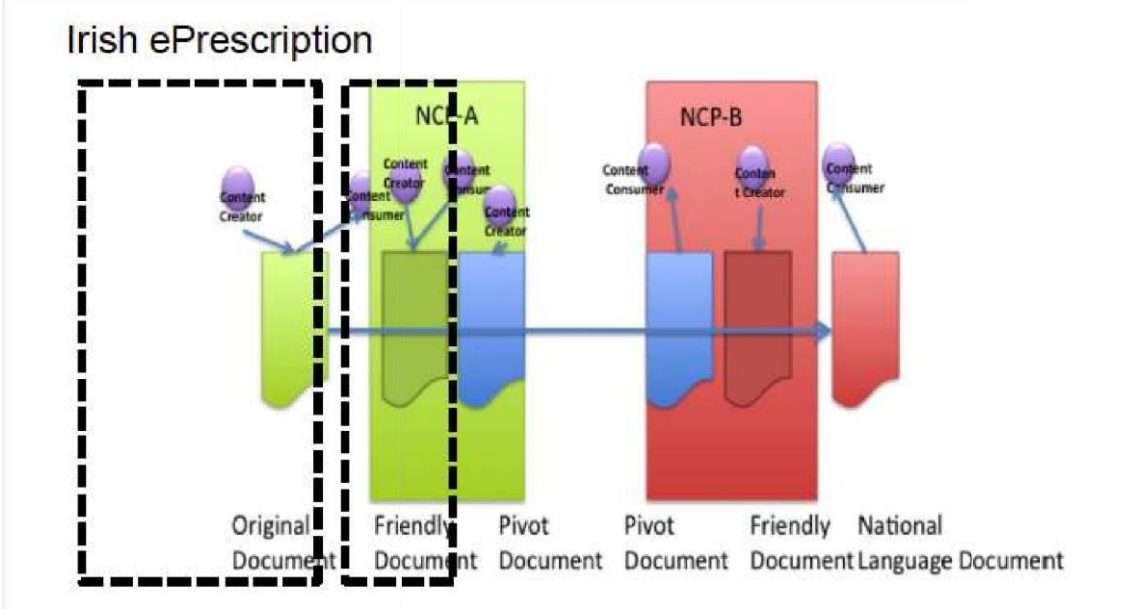

FIGURE 2: EPRESCRIPTION CROSS BORDER EXCHANGE

The Friendly Document is the Irish ePrescription built and created by an actor called content creator from the existing ePrescription stored in the national ePrescription server (see [R2]).

The Friendly document is transformed and translated by the Irish NCPeH in order to obtain the PS Pivot Document before sending to the requested European country.

A PDF document representing the Patient Summary is also sent as it was created in Ireland (in native language).

Note that functional requirements of ePrescription are described in the [R7] and the ePrescription template is now described in Art Décor [R4].

3 Conformance requirements

This Section provides Irish constraints to be implemented for Prescription documents as defined in this Supporting Interoperability Specification.

The HL7 CDA standard has been identified as the standard for use in Cross Border exchanges. Therefore this interoperability specification establishes the conformance requirements for the ePrescription document using the HL7 Clinical Document Architecture R2 (CDA) standard. To further detail on the interoperability architecture, see [R2].

[IPD-001] Constraints in eHDSI ePrescription SHALL apply to all Prescription documents.

[IPD-002] Constraints in Patient Summary Interoperability specification, section 2 on conformance requirements SHALL apply to all Prescription documents.

[IPD-003]The language SHALL be present

4 CDA Header attributes and Constraints

This Section provides Irish constraints to be implemented for Prescription documents as defined in this Supporting Interoperability Specification.

[IPD-004] Constraints in Patient Summary content Interoperability specification, section on CDA Header attributes and constraints SHALL apply to all Prescription documents.

[IPD-005]The Author SHALL contain one [1..1] assigned Author that SHALL NOT be null flavour.

Note: the doctors and nurses identifiers are available (GS1 identifier)

[IPD-006] If assigned Author has an associated represented Organization with no assigned Person or assigned Authoring Device, then the value for “Clinical Document/author/assigned Author/id/@Null Flavour” SHALL be “NA” “Not applicable” 2.16.840.1.113883.5.1008 Null Flavour. [IPD-007] The Patient gender SHALL be present.

5 Content Modules and constraint for Prescription Documents

This section describes the specific constraints Cross Border and Irish shared Prescription documents and more specifically the medication item.

TABLE 1: SUBSTANCEADMINISTRATION ENTRY (FROM EHDSI SPECIFICATION [R6])

ENTRY	CONTENT ENTRY DEFINITION	CDA LOCATION
Prescription Id	Prescription Id. The prescription Id provides the link from the dispensed medicine to the prescription	HL7:Id
Code	The <code> element is used to supply a code that describes the <substance Administration> act, not the medication being administered. This may be a procedure code, such as those found in ICD-10, or may describe the method of medication administration, such as by intravenous injection. The type of medication is coded in the consumable;. This element is optional.	HL7:Code
Status Code	The status of all <substance Administration> elements must be either “active” or “completed” and track the progress of the Act in its specified mood. For example, status Code=”completed” when mood Code is “RQO” doesn’t mean that the substance has been administrated, but that the request (e.g. the prescription) has been completed.	HL7:statusCode
Effective Time	The first <effective Time> element encodes the start and stop time of the medication regimen. This an interval of time (xsi:type=’IVL_TS’), and must be specified as shown. This is an additional constraint placed upon CDA Release 2.0 by this profile, and simplifies the exchange of start/stop and frequency information between EMR systems. The <low> and <high> values of the first <effective Time> element represent the start and stop times for the medication. The <low> value represents the start time, and the <high> value represents the stop time. If either the <low> or the <high> value is unknown, this shall be recorded by setting the null flavour attribute to UNK.	HL7:effectiveTime

	The <high> value records the end of the medication regime according to the information provided in the prescription or order. For example, if the prescription is for enough medication to last 30 days, then the high value should contain a date that is 30 days later then the <low> value. The rationale is that a provider, seeing an un-refilled prescription would normally assume that the medication is no longer being taken, even if the intent of the treatment plan is to continue the medication indefinitely.	
Effective Time	The second <effective Time> element records the frequency of administration. This <effective Time> element must be intersected with the previous time specification (operator='A'), producing the bounded set containing only those time specifications that fall within the start and stop time of the medication regimen. Several common frequency expressions appear in the table below, along with their XML representations. This effective Time has a xsi:type of either TS, PIVL_TS, EIVL_TS, or SXPR_TS. Frequency Description	HL7:effectiveTime

ENTRY	CONTENT ENTRY DEFINITION		CDA LOCATION
	b.i.d.	Twice a day	
	q12h	Every 12 hours	
	Once	Once, on 2005-09-01 at 1:18am.	
	t.i.d.	Three times a day, at times determined by the person administering the medication .	
	q8h	Every 8 hours	
	qam	In the morning	
		Every day at 8 in	

	the morning for 10 minutes q4-6h Every 4 to 6 hours. The mean (average) of the low and high values is specified for the period. The mean of 4 and 6 is 5. The standard deviation is recorded as one half the differences between the high and low values, with an unspecified distribution. The type attribute of the <effective Time> element describes the kind of frequency specification it contains.	
Route Code	The element specifies the route of administration using the EDQM route of administration vocabulary. A code must be specified if the route is known, and the display Name attribute should be specified. If the route is unknown, this element shall not be sent.	HL7:routeCode
Dose Quantity	The dose is specified in the <dose Quantity> element. If a dose range is given (e.g., 1-2 tablets, or 325-750mg), then the <low> and <high> bounds are specified in their respective elements... If the dose is in countable items (tablets, caplets, "eaches"), then the unit should be valorized = '1'. In this case it is allowed to used the UCUM annotations for describing the type of countable items (e.g. .{tablet}, {puff},..). The unit attribute – when expresses unit of measures- shall be derived from the Value Sets epSOSUnits, 1.3.6.1.4.1.12559.11.10.1.3.1.42.16 based on the UCUM code system. The countable units attribute is derived from the value set epSOSDoseForm, OID 1.3.6.1.4.1.12559.11.10.1.3.1.42.2	HL7:doseQuantity

Rate Quantity	The rate is specified in the <rate Quantity> element. The rate is given in units that have measure over time. In this case, the units should be specified as a string made up of a unit of measure (see dose Quantity above), followed by a slash (/), followed by a time unit (s, min, h or d). Again, if a range is given, then the <low> and <high> elements contain the lower and upper bound of the range, otherwise, they contain the same value. Any <low> and <high> elements used for <rate Quantity> should contain a <translation> element that provides a <reference> to the <original Text> found in the narrative body of the document.	
Consumable	Contain Manufactured Product	HL7:consumable
ENTRY	**CONTENT ENTRY DEFINITION**	**CDA LOCATION**
Author Prescriber	In the unlikely case where the prescriber of a prescription item is different from the author of the prescription, the prescription item prescriber shall be represented by prescriber of the item if known, otherwise the prescriber of the prescription.. When the Prescription Item Entry is part of a Dispensed Medicine Entry as a Related Prescription the author element shall be present, and shall contain the prescription item author (or author of the prescription if the prescription item has no separate author)..	HL7:author Prescriber
Organization	The organization which provided the credentialing for the prescriber needs to be expressed via a <participant> structure, which is in addition to the <author> element specified earlier. The type code of the <participant> element shall be “AUT”, and the class code of the <participant Role> element shall be “LIC”. The ID of the participation role is optional, and when present it shall be the prescriber ID as specified in the <author> structure at the section or entry level. The credentialing organization (College) is represented by the <scoping Entity> element with a class code of “ORG”. The name is	HL7:Organization

	represented by the <desc> element, and the credentialing organization (College) ID is represented by the <id> element of the scoping entity	
Entry Relationship	Number of Packages	HL7:entryRelationship
Entry Relationship	An entry relationship may be present to provide the substitution instructions. When present, this entry relationship SHALL contain one and only one observation. This observation SHALL have : the code element valorized with @code="SUBST' and @codeSystem='2.16.840.1.113883.5.6' the value element valorized with one of the value of the epSOSSubstitutionCode Value Set (Vaue Set OID 1.3.6.1.4.1.12559.11.10.1.3.1.42.7). Nullflavor is not allowed. NOTE : Within the epSOS-I scope the "N" code shall be interpreted as No substitution allowed excepting for the Package Size. The presence of any other code that is not "N", or the absence of the substitution instructions, means that also the brand name (as well as the Package Size) can be changed.	HL7:ntryRelationship
Entry Relationship	An entry relationship may be present to provide the patient medication instructions. When present, this entry relationship shall contain a Patient Medications Instructions entry content module. Again, a related statement is made about the medication or immunization. In CDA, this observation is recorded inside an <entry Relationship> element occurring at the end of the substance administration or supply entry.	HL7:entryRelationship

	The containing <act> is the subject (type Code='SUBJ') of this new observation, which is the inverse of the normal containment structure, thus inversionInd='true'.	

[IPD-008] Constraints in eHDSI ePrescription substance Administration entry SHALL apply to all Prescription documents.

[IPD-009] Prescription section SHALL contain one [1..1]medication item

Note 1: the prescription in Ireland contains several items. Partial information on dispensation is included in the prescription. The system should split the prescription on several prescriptions (one per items linked with the dispensation when the item is dispensed partially before sending to country B).

Note 2: the expired date can be calculated but it would be better to have the information in the prescription before transformation to CDA document.

Example

```
<substanceAdministrationclassCode=”SBADM”moodCode=”INT”>
 <templateIdroot=”2.16.840.1.113883.10.20.1.24”/>
 <templateIdroot=”1.3.6.1.4.1.12559.11.10.1.3.1.3.2”/>
 <templateIdroot=””/> <!—Prescription Item ID
 <idroot=””extension=””/>
 <codecode=””codeSystem=””displayName=””codeSystemName=””/>
 <!—Reference to narrative text of prescription, e.g. Pyrimon, Chloramphenicol/
Dexamethasone 1% w/v/ 0.1% w/v 5 ml Eye
Drops – three drops
 <text>
  <referencevalue=”#med-1”/>
 </text>
 <statusCodecode=”active”/>
 <effectiveTimexsi:type=”IVL_TS”>
  <lowvalue=””/>
  <highvalue=””/>
 </effectiveTime>
 <effectiveTimeoperator=”A”xsi:type=”TS|PIVL_TS|EIVL_TS|SXPR_TS”>
  <!-- …
 </effectiveTime>
 <routeCodecode=”20051000”codeSystem=”1.3.6.1.4.1.12559.11.10.1.3.1
.44.1”displayName=”Ocular use”codeSystemName=”EDQM”/>
 <doseQuantityvalue=”3”/>
 <!—Optional
 <approachSiteCodecode=””codeSystem=””displayName=””codeSystemName= ””/>
 <rateQuantityvalue=””unit=””/> <consumable>
  <!-- …
 </consumable> <participanttypeCode=”AUT”>
  <participantRoleclassCode=”LIC”> <idroot=”“extension=”“/>
   <scopingEntityclassCode=”ORG”>
    <idroot=”“extension=”“/>
    <desc>…</desc>
   </scopingEntity>
  </participantRole>
 </participant>
```

```
<author>
  <time/>
  <assignedAuthor>
    <id/>
    <assignedPerson>
      <name/>
    </assignedPerson>
  </assignedAuthor>
</author>  <!—0..* entries describing the components
<entryRelationshiptypeCode=”COMP”>
  <sequenceNumbervalue=””/>
</entryRelationship>
<!—Optional instructions for Pharmacist
<entryRelationshiptypeCode=”SUBJ”>
<!--  …
</entryRelationship>
<!—Optional Substitution information
<entryRelationshiptypeCode=”SUBJ”>
<!--  …
</entryRelationship>
</substanceAdministration>
```

TABLE 2: MANUFACTUREDPRODUCT ENTRY (FROM EHDSI SPECIFICATION R6)

ENTRY	CONTENT ENTRY DEFINITION	CDA LOCATION
Code	The <code> element of the <manufacturedMaterial> describes the medication. For the scope of epSOS this is used to convey the “Country A Cross-border/regional/national medicinal product code.	HL7:code
name	In an epSOS ePrescription or eDispensation document, the element should contain the brand name of the medication.	HL7:name
desc	Free-text representation of the strength.	HL7:desc
Form Code	This code represents the form of the medication (e.g. tablet, capsule, liquid). The value of this code affects the units used in the substance administration quantity element – if the form is a tablet, for example, the unit is 1; if the form is a liquid, the unit will be part of UCUM. The	HL7:formCode

	value set is epSOSDoseForm, OID: 1.3.6.1.4.1.12559.11.10.1.3.1.42.2.	
As Content	This structure describes the packaging of the medication. The element provides the code for the particular package. If the package has a brand name, it can be described in the element. The element described the capacity of the packaging. For example, to represent 30 tablets, the element at the level must indicate tablets as the form, value attribute of the element must have the value of 30, and the unit attribute must be 1. In the cases where the unit attribute is not 1, UCUM units shall be used. The value set is epSOSUnits, OID 1.3.6.1.4.1.12559.11.10.1.3.1.42.16 and epSOSDoseForm, OID 1.3.6.1.4.1.12559.11.10.1.3.1.42.2.	HL7:asContent
As Specialized Kind	This module is used for representing the classification of the Substance according to the WHO Anatomical Therapeutic Chemical (ATC) Classification System.	HL7:asSpecialized Kind
ENTRY	**CONTENT ENTRY DEFINITION**	**CDA LOCATION**
	The classCode of « GEN » identifies this structure as the representation of a generic equivalent of the medication described in the current Medicine entry. The <epsos :code> element contains the ATC code, and the <epsos :name> element may be used for the plain text representation.	
ingredient	One or more active ingredients may be represented with this structure. The classCode of “ACTI” indicates that this is an active ingredient. The element contains the coded representation of the ingredient and the element may be used for the plain text representation.	HL7:ingredient

[IPD-010] Constraints in eHDSI ePrescription Manufactured Product entry SHALL apply to all Prescription documents.

6 Scanned ePrescription

The IHE profile is used for exchanging pdf embedded or plain text document. There are no additional constraints for the HL7 CDA header as already described in the present document.

[IPD-011]Constraints in the IHE IT Infrastructure (ITI) Volume 3 (ITI TF-3) Section5.2 Scanned Document Content Profile XDS-SD using the PDF or plaintext Option □R10] SHALL apply to all clinical scanned ePrescription documents.

[IPD-012] Constraints on CDA Header attributes described in □R8□SHALL apply to all clinical scanned ePrescription documents.

7 Appendices

The following list of URL provides samples of ePrescriptions produced in the context of the eHDSI project along with their validation report using the Gazelle platform.

- https://gazelle.ehdsi.eu/EVSClient/detailedResult.seam?type=CDA&oid=1.3.6.1.4.1.1 2559.11.30.2.1.17126
- https://gazelle.ehdsi.eu/EVSClient/detailedResult.seam?type=CDA&oid=1.3.6.1.4.1.1 2559.11.30.2.1.14954
- https://gazelle.ehdsi.eu/EVSClient/detailedResult.seam?type=CDA&oid=1.3.6.1.4.1.1 2559.11.30.2.1.16206
- https://gazelle.ehdsi.eu/EVSClient/detailedResult.seam?type=CDA&oid=1.3.6.1.4.1.1 2559.11.30.2.1.15804
- https://gazelle.ehdsi.eu/EVSClient/detailedResult.seam?type=CDA&oid=1.3.6.1.4.1.1 2559.11.30.2.1.16970