INTERNATIONAL STANDARD

ISO 21549-7

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Health informatics — Patient healthcard data —

Part 7:
Medication data

Informatique de santé — Données relatives aux cartes de santé des patients —

Partie 7: Données de médication

Contents

Page

Foreword

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

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

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

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

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

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

This second edition cancels and replaces the first edition (ISO 21549-7:2007), which has been technically revised with the following changes:

— medication notes definition in Clause 1 is modified;

— the list of definitions in Clause 3 is shortened and several definitions are corrected and clarified;

— the list of abbreviation in Clause 4 is shortened;

— an explanation is added in 5.1 why MedicationData is modelled as a direct child of the PatientHealthcardData;

— "healthcare person" in 6.2.3 is replaced by "healthcare professional";

— "factor of the quantity" in 6.2.4 is replaced by "quantity units";

— "medication history" in 6.4 is changed to "medication notes" in the title and an explanation of a major use is modified;

— in Clause 7, all the names of attributes in the tables are harmonized with the class diagrams. The term "data object" is replaced by "class". Additional comments are included in the tables. For implementer's convenience, the fragments of ASN.1 definitions are gathered together in the new Annex A;

— explanation of MedicationNotes in 7.2.1 is modified;

— comments in Table 3 are modified;

— comments in Table 4 are modified;

— comments in Table 5 are modified;

— Example in 7.2.5 is moved to informative Annex B;

— Figures 7 and 8 are merged. Class "Prescriber" is defined as an attribute. The attribute "qualification" is replaced by the attribute "qualifier" having datatype "CodedData". The attribute "medicinalProduct" is renamed as "prescribedMedicinalProduct". The class "MedicinalProduct" is renamed as "PrescribedMedicinalProduct". The class "ManufacturedMedicinalProduct" is renamed as "PrescribedManufacturedMedicinalProduct". The class "MagistralMedicinalProduct" is renamed as "PrescribedMagistralMedicinalProduct". Datatype of the attribute "strength" is replaced by "Strength", the definition of this new datatype is added. Datatype of the attribute "quantityOfMedicinalProduct" is replaced by "Quantity". Datatype of the attribute "amountOfIngredient" is replaced by "Amount". The class "AmountOfIngredient" is replaced by the class "Amount";

— Figures 17 and 18 are merged. Class "Dispenser" is defined as an attribute. The attribute "dispensedMedicinalCode" is replaced by the attribute "dispensedMedicinalProduct" having new datatype "DispensedMedicinalProduct". This new datatype is a generalization of the classes "DispensedManufacturedMedicinalProduct" and "DispensedMagistralMedicinalProduct". The attributes "strength", "form", manufacturerOfMedicinalProduct" are moved from the class "ActualDispensedItem" to the class "DispensedManufacturedMedicinalProduct". The attributes "batchIdentifier", "genericSubstitution" are moved from the class "DispensingInformation" to the class "DispensedManufacturedMedicinalProduct". Datatype of the attribute "quantityDispensed" is replaced by "QuantityToDispense", so the class "QuantityDispensed" becomes unused and is deleted. The attributes "magistralMedicinalProductName" and "dispensedQuantity" are added to the class "DispensedMagistralMedicinalProduct". The attribute "nameOfIngredient" is deleted from the class "DispensedIngredient". Datatype of the attribute "quantityOfIngredient" is replaced by "Amount". The attribute "nameOfContainerOrApplicationAid" is deleted from the class "DispensedContainerOrApplicationAid";

— Figures 26 and 27 are merged;

— new ASN.1 definition is added in Annex A.

A list of all parts in the ISO 21549 series can be found on the ISO website.

Introduction

With a more mobile population, greater healthcare delivery in the community and at patients' homes, together with a growing demand for improved quality of ambulatory care, portable information systems and stores have increasingly been developed and used. Such devices are used for tasks ranging from identification, through portable medical record files, and on to patient-transportable monitoring systems.

The functions of such devices are to carry and to transmit person-identifiable information between themselves and other systems; therefore, during their operational lifetime, they may share information with many technologically different systems which differ greatly in their functions and capabilities.

Healthcare administration increasingly relies upon similar automated identification systems. For instance, prescriptions may be automated and data exchange carried out at a number of sites using patient transportable computer readable devices. Healthcare insurers and providers are increasingly involved in cross-region care, where reimbursement may require automated data exchange between dissimilar healthcare systems.

The advent of remotely accessible databases and support systems has led to the development and use of "Healthcare Professional" identification devices that are also able to perform security functions and transmit digital signatures to remote systems via networks.

With the growing use of data cards for practical everyday healthcare delivery, the need has arisen for a standardized data format for interchange.

The person-related data carried by a data card can be categorized in three broad types: identification (of the device itself and the individual to whom the data it carries relates), administrative and clinical. It is important to realize that a given healthcare data card "de facto" has to contain device data and identification data and may, in addition, contain administrative, clinical, medication and linkage data.

Device data is defined to include

— identification of the device itself, and

— identification of the functions and functioning capabilities of the device.

Identification data may include unique identification of the device holder or of all other persons to whom the data carried by the device are related.

Administrative data may include the following:

— complementary person(s) related data;

— identification of the funding of health care, whether public or private, and their relationships, i.e. insurer(s), contract(s) and policy(ies) or types of benefits;

— other data (distinguishable from clinical data) that are necessary for the purpose of healthcare delivery.

Clinical data may include

— items that provide information about health and health events,

— their appraisal and labelling by a healthcare provider (HCP), and

— related actions planned requested or performed.

Medication data may include

— a record of medications purchased by the patient for self administration,

— copies of prescriptions including the authority to dispense records of dispensed medications,

— records of medications dispensed by a pharmacist to the patient, and

— pointers to other systems that contain information that hold medication data, either medication history or prescribed medicines, (or both) and in the case of prescribed medicines, the authority to dispense.

Because a data card essentially provides specific answers to definite queries while having at the same time a need to optimize the use of memory by avoiding redundancies, "high level" Object Modelling Technique (OMT) has been applied with respect to the definition of healthcare data card data structures.

Patient Data Cards may offer facilities to

— communicate prescription information from one healthcare professional to another healthcare professional such as to a healthcare agent or healthcare organization, and

— provide indexes and/or authority to access prescription information held other than on the patient data card.

Health informatics — Patient healthcard data —

Part 7:
Medication data

1 Scope

This document applies to situations in which such data is recorded on or transported by patient healthcards compliant with the physical dimensions of ID-1 cards defined by ISO/IEC 7810.

This document specifies the basic structure of the data contained within the medication data object, but does not specify or mandate particular data sets for storage on devices.

The purpose of this document is for cards to provide information to other health professionals and to the patient or its non-professional caregiver.

It can also be used to carry a new prescription from the prescriber to the dispenser/pharmacy in the design of its sets.

Medication data include the following four components:

— **medication notes**: additional information related to medication and the safe use of medicines by the patient such as medication history, sensitivities and allergies;

— **medication prescriptions**: to carry a new prescription from the prescriber to the dispenser/pharmacy;

— **medication dispensed**: the records of medications dispensed for the patient;

— **medication references**: pointers to other systems that contain information that makes up medication prescription and the authority to dispense.

The following topics are beyond the scope of this document:

— physical or logical solutions for the practical functioning of particular types of data cards;

— how the message is processed further "downstream" of the interface between two systems;

— the form which the data takes for use outside the data card, or the way in which such data is visibly represented on the data card or elsewhere.

NOTE   Not only does the definition of "medicinal products" differ from country to country, but also the same name can relate to entirely different products in some countries. Therefore, it is important to consider the safety of the patient when the card is used across borders.

This document describes and defines the Medication data objects used within or referenced by patient-held health data cards using UML, plain text and Abstract Syntax Notation (ASN.1).

This document does not describe nor define the common objects defined within ISO 21549-2, even though they are referenced and utilized within this document.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 21549-2, *Health informatics — Patient healthcard data — Part 2: Common objects*

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at https://www.iso.org/obp/

NOTE   There are many different terms used to describe the basic concepts in healthcare for different purposes available from ISO, CEN, HL7 and various national organizations. The following definitions are not meant to be universal in ISO work in health informatics, only to facilitate the understanding of this document.

3.1
attribute
characteristic of an object or entity

3.2
batch
amount of material which is uniform in character and quantity as shown by compliance with production and quality assurance test requirements and produced during a defined validated process of manufacture

[SOURCE: EN 375:1992 E, EN 376:1992 E]

3.3
coding scheme
collection of rules that maps the elements of one set onto the elements of a second set

[SOURCE: ISO 21089:2004, 3.25]

3.4
data object
information object
instance of some *information object class* (3.11), being composed of a set of fields which conform to the field specifications of the class

[SOURCE: ISO/IEC 8824-2:2015, 3.4.9]

3.5
dispenser
healthcare professional (3.9) which is a representation of an individual, professionally responsible for filling/dispensing the *prescription* (3.22)

Note 1 to entry: This is usually the pharmacist, but may be other individuals according to local jurisdiction.

3.6
healthcare
activities, services or supplies related to the health of an individual

Note 1 to entry: This includes more than performing procedures for subjects of care. It includes, for example, the management of information about patients, health status and relations within healthcare framework.

Note 2 to entry: In this document, the term "care" is to be understood as a synonym for "healthcare".

[SOURCE: ISO 13940:2015, 3.1.1, modified]

3.7
healthcare data card
machine-readable card conformant to ISO/IEC 7810 intended for use within the healthcare domain

3.8
healthcare party
organization (3.16) or person involved in the direct or indirect provision of healthcare services to an individual or to a population

[SOURCE: ENV 13607]

3.9
healthcare professional
person entrusted with the direct or indirect provision of defined healthcare services to a *subject of care* (3.25) or a population of subjects of care

EXAMPLE   Qualified medical practitioner, pharmacist, nurse, social worker, radiographer, medical secretary or clerk.

[SOURCE: ENV 1613]

3.10
immediate container
container that is in direct contact with the *pharmaceutical product* (3.19)

[SOURCE: ENV 12610]

3.11
information object class
set of fields, forming a template for the definition of a potentially unbounded collection of information objects, the instances of the class

[SOURCE: ISO/IEC 8824-2:2015, 3.4.10]

3.12
ingredient
substance (3.26) included as a component in a product

Note 1 to entry: In this context, product refers to *pharmaceutical product* (3.19).

[SOURCE: ENV 13607]

3.13
magistral medicinal product
extemporaneous medicinal product
medicinal product (3.14) manufactured in a pharmacy or pharmacy department, which is based on a recipe and intended to be used for one and only one *subject of care* (3.25)

Note 1 to entry: A magistral/extemporaneous medicinal product is also a *pharmaceutical product* (3.19).

[SOURCE: ENV 12610, ENV 13607, modified]

3.14
medicinal product
substance (3.26) or combination of substances, which may be administered to human beings or animals for treating or preventing disease, with the view to making a medical diagnosis or to restore, correct or modify physiological functions

Note 1 to entry: A medicinal product may contain one or more manufactured items and one or more *pharmaceutical products* (3.19).

Note 2 to entry: In certain jurisdictions, a medicinal product may also be defined as any substance or combination of substances which may be used to make a medical diagnosis.

[SOURCE: ENV 13607, ENV 12610]

3.15
medicinal product package
delivery unit of a *medicinal product* (3.14) in an *outer container* (3.17)

[SOURCE: ENV 12610]

3.16
organization
unique framework of authority within which a person or persons act, or are designated to act towards some purpose

Note 1 to entry: Groupings or subdivisions of an organization may also be considered as organizations where there is a need to identify them for information interchange.

3.17
outer container
container that serves as an external layer of a package

[SOURCE: ENV 12610]

3.18
payment guarantor
organization (3.16) responsible for the total or partial reimbursement or payment of the price of the *medicinal product* (3.14)

[SOURCE: ENV 13607]

3.19
pharmaceutical product
qualitative and quantitative composition of a *medicinal product* (3.14) in the dose form approved for administration in line with the regulated product information

Note 1 to entry: A medicinal product may contain one or more pharmaceutical products.

Note 2 to entry: In many instances, the pharmaceutical product is equal to the manufactured item. However, there are instances where the manufactured item must undergo a transformation before being administered to the patient (as the pharmaceutical product) and the two are not equal.

[SOURCE: ISO 11616:2012, 3.1.20, modified]

3.20
prescriber
healthcare professional (3.9) authorized to issue *prescriptions* (3.22)

[SOURCE: ENV 13607]

3.21
prescribing
process of creating a *prescription* (3.22)

[SOURCE: ENV 13607]

3.22
prescription
direction created by an authorized *healthcare professional* (3.9), to instruct a dispensing agent regarding the preparation and use of a *medicinal product* (3.14) or medicinal appliance to be taken or used by a *subject of care* (3.25)

[SOURCE: ENV 13607]

3.23
prescription item
specification created by an authorized *healthcare professional* (3.9), to instruct a dispensing agent regarding the preparation and use of single *medicinal product* (3.14)/medicinal appliance or to inform other parties following dispensing regarding the preparation and use of a single dispensed medicinal product/medicinal appliance

Note 1 to entry: A prescription item may contain administrative details needed for dispensing or derived from dispensing, but does not contain information about the *prescriber* (3.20) or the *subject of care* (3.25) for whom the prescription item is prescribed or to whom it has been dispensed.

[SOURCE: ENV 13607]

3.24
prescription set
collection of one or more *prescription item(s)* (3.23) prescribed and/or dispensed as a unit

[SOURCE: ENV 13607]

3.25
subject of care
person or defined group of persons receiving or registered as eligible to receive healthcare services or having received healthcare services

[SOURCE: ENV 12443]

3.26
substance
matter of defined composition that has discrete existence, whose origin may be biological, mineral or chemical

Note 1 to entry: Substances can be either single substances mixture substances or one of a group of specified substances. Single substances shall be defined using a minimally sufficient set of data elements divided into five types: chemical, protein, nucleic acid, polymer and structurally diverse. Substances may be salts, solvates, free acids, free bases, mixtures of related compounds that are either isolated or synthesized together. Pharmacopoeial terminology and defining characteristics will be used when available and appropriate. Defining elements are dependent on the type of substance.

Note 2 to entry: Discrete existence refers to the ability of a substance to exist independently of any other substance. Substances can either be well-defined entities containing definite chemical structures, synthetic (i.e. isomeric mixtures) or naturally-occurring (i.e. conjugated oestrogens) mixtures of chemicals containing definite molecular structures or materials derived from plants, animals, microorganisms or inorganic matrices for which the chemical structure may be unknown or difficult to define. Substances may be salts, solvates, free acids, free bases, mixtures of related compounds that are either isolated or synthesised together.

[SOURCE: ISO 11238:2012, 2.1.58]

4   Abbreviated terms

ATC   Anatomical Therapeutic Chemical Classification System

DEA   Drug Enforcement Administration Registration Number

ENV   European Prestandard

NCDCP   National Council for Prescription Drug Programs

UML   Unified Modelling Language

5 Basic data object model for a healthcare data card

5.1 Patient healthcard data object structure

A set of basic data objects have been designed to facilitate the storage of clinical data in a flexible structure, allowing for future application specific enhancements. These tools should help the implementation of common accessory characteristics of stored data in a way that allows efficient use of memory, an important feature for many types of data cards.

The tools consist of a generic data structure based on an object-oriented model represented as an UML class diagram as shown in Figure 1.
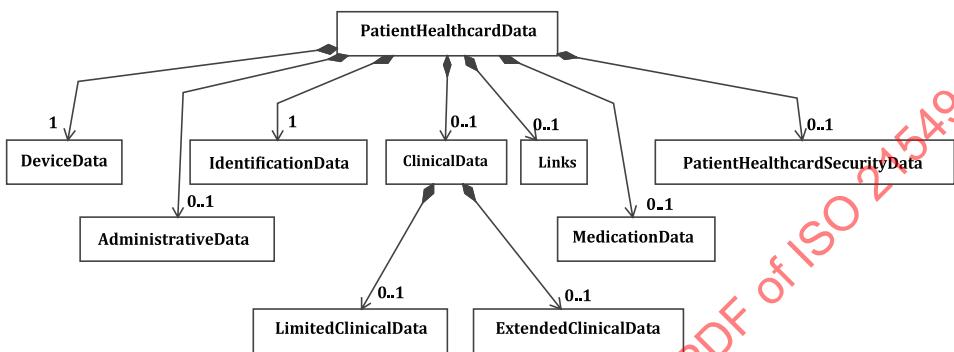
Figure 1 — Patient healthcard data — Overall structure

The content of this object-oriented structure is described both below and intrinsically will also require the use of data objects not defined within this document.

It is recognized that medication data is semantically a type of "clinical data". However, to enable more flexible implementation approaches, it is modelled as a direct child of the PatientHealthcardData object allowing a simpler and reduced model implementation where the full clinical data is not required.

NOTE   It is possible to take the data objects and recombine them while preserving their context specific tags, and to define new objects, while still preserving interoperability.

In addition to the capability of building complex aggregate data objects from simpler building blocks, this document allows for associations between certain objects, so that information can be shared. This feature is mainly used to allow, for example, a set of accessory attributes to be used as services to several stored information objects.

5.2 Basic data objects for referencing

5.2.1 Overview

A series of generally useful data type definitions have been made that have no underlying meaning in themselves, but which are used to define other objects within this document. Operations may be performed with these objects in association with other information objects to add usability or business purpose. These objects have formal definitions within ISO 21549-2.

5.2.2 Coded data

Coded values are understood by reference to the coding system to which they apply. The general principle in this document is that it is not mandatory to use a particular coding system, unless specified within this document, when such codes act as parameters. One example is the use of ISO 3166 for country codes.

When a coding scheme is exclusively specified within this document, no alternative coding scheme shall be allowed. Any references to coding schemes not so specified may however be modified in the future independent of the rest of this document.

The data object "CodedData" shall be constructed according to the definition contained in ISO 21549-2.

5.3 Device and data security attributes

Data stored in data cards used in health care may be personally sensitive. For this reason, this document utilizes a series of security attributes, defined in ISO 21549-2. The actual data content (value) is not within the scope of this document, nor are the mechanisms that make use of these data elements. It is emphasised that the security attributes cannot satisfy given security requirements without the implementation of the appropriate security functions and mechanisms within the data card.

Such rights of "access" are attributable to specific individuals with respect to discrete data items. These rights will be defined by local jurisdictions, organizational policies and local legal frameworks and implemented by application developers and can be controlled by automated systems such as health care professional cards. The rights may be defined at the application level, thereby providing application and potential country specificity.

The "SecurityServices" data object provides for the storage of data required to deliver these security functions and mechanisms. This data can be "attached" to individual data elements, thereby preserving the original author's security requirements when the data object is transferred between different forms of data card. This mechanism may therefore ensure that in the process of transferring data from active to passive media and then back to active media, the original security requirements are re-generated. This ability also allows exact replication of a data card such as on regeneration after failure.

5.4 Accessory attributes

The data object "AccessoryAttributes" shall consist of an ordered set of data that is essential to record of the resources which were accessed and/or used by whom regarding both the originator of the information and the means via which it arrives to the recipient as defined in ISO 21549-2.

6 Functional requirements on card information for prescriptions

6.1 Overview of supported uses

Healthcards may be considered useful in many different functions in relation to medicine prescriptions. Two functions are for the identification of the patient and of the prescribing health professional toward the prescribing system. These two uses are considered to be outside of this document.

The major consideration in this document is for cards to provide information to other health professionals and to the patient or its non-professional care giver. However, the use for carrying a new prescription from the prescriber to the dispenser/pharmacy are also considered in the design of its data sets.

6.2 Carry a prescription from prescriber to the dispenser

6.2.1 General

A healthcard designed to carry a prescription between a prescriber and dispenser has, within its data set, to incorporate several different objects such as identifiers relating to the prescriber, dispensing agent, subject of care and the actual information in relation to the prescribed item/items. Information relating to the subject of care is considered to be static and provided/defined by other parts of ISO 21549. Similarly are Prescriber and Dispensing agent, while there may be several different iterations of the same these are essentially static and as such are covered by other parts of ISO 21549.

6.2.2 Prescription set

A prescription issued for one patient by one prescriber at one occasion may contain several prescription items for individual medicinal products. The collection of items with some additional information relevant for all items is referred to as a prescription set.

6.2.3 Who

This is data relevant for the whole prescription set and has a series of specialisations of healthcare party.

Patient

This is the subject of care who is the intended recipient of a prescribed item.

NOTE   For healthcards, we are only considering one person, not animals, nor groups of patients.

Prescriber

This is a specialization of a more generic concept that may be called a healthcare professional (see Clause 3) and is the healthcare professional who takes legal responsibility for the creation of the prescription and for providing the authority to dispense.

Payment guarantor

This is a specialization of healthcare party. These may be one or more insurance companies or other entity that, in one way or another, is involved with financial aspects of the prescription.

NOTE   This can include the patient as guarantor.

Dispenser

This is a specialization of a healthcare professional which is a representation of an individual who has a pharmacist status who is filling/dispensing the prescription (see Clause 3).

6.2.4 What

These are the data relevant for a prescription item.

a)   Name of the medicinal product (see Clause 3):

— identified by brand name, generic name or code values for these (with reference to identification of code set, if used);

— this may include also medicinal appliance whereas magistral (extemporaneous) medicinal products are treated separately.

b)   Strength

c)   Drug form

d)   Quantity

e)   Quantity units

f)   Manufacturer

g)   Code in respect to all above except possibly quantity units

h)   Magistral medicinal product (synonym: "extemporaneous product")

6.2.5 Times

The followingh are the points of time and intervals relevant for prescription and dispense:

a) time/date when a prescription is authorized;

b) time/date when a prescription is dispensed;

c) validity time (length of validity of prescription may be defined by legal framework of medicine supply regulations);

d) specified interval between multiple supplies of the same medication (for example, "not less than 21 d between supplies").

6.2.6 How

The following information relates to a prescription item:

a) dosage instruction (plain text, CODED + numeric perhaps structure with time separate from amount);

b) comments of prescriber (to one item or the whole prescription);

c) special prescriptions (narcotics);

d) special license prescription;

e) substitution rules (if applicable in the local jurisdiction);

f) repeat prescription (no + possible time interval);

g) preferred language of the patient;

h) language of the prescription (these two refers to the prescription set).

6.3 Card information on dispensed prescriptions

Information on cards contains data on dispensed items. This information may be used at a future dispensing occasion by a health professional, in particular when considering new prescriptions. It is worth noting that this information remains as confidential as other clinical data in that patients do not always fill their prescriptions.

6.4 Medication notes

A major use of healthcards containing prescription information has been to create an accumulated list of all medication for a patient and information relating to the safe use of medicines by the patient such as sensitivities and allergies. This may result from the recording of dispensed prescription items, but it may also be of interest to record medication when medicines are directly purchased/acquired by the patient.

There are many issues to consider here when a system is designed such as a history of prescriptions as opposed to a list of current total medication from one or several prescribers and whether or not to remove from the list what is not currently taken.

The users of this data are health professionals involved with a patient's medication management or who have a requirement to understand the medical history of the patient.

Finally, this information could be accessed by patients or their non-health professional caregivers and thereby both be able to be used to inform but also aid them in decisions they may take.

7 Medication data

7.1 General

The MedicationData class is divided into four separate subclasses (see Figure 2):

— MedicationNotes;

— MedicationPrescriptions;

— MedicationsDispensed;

— MedicationReferences;

— MedicationDataStructureEdition.

Because of their groupings, each of these may have differing security settings including access rights as determined by the provisions contained within their attached attributes.
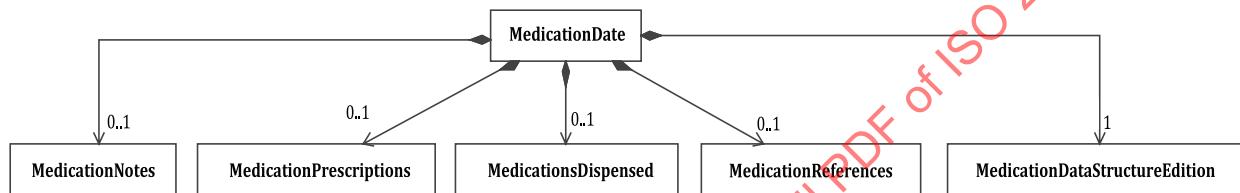

Figure 2 — Structure of MedicationData

Individual entities within MedicationData are specified in Table 1.

Table 1 — Specification of individual entities within MedicationData

Name	Data type	Multiplicity	Comments
MedicationNotes	Class	0..1	This class consists of the medication history record, the medication relevant characteristics record and the known medication risks record of the recorded person.
MedicationPrescriptions	Class	0..1	This class holds the data that forms the basis of a medication data record including the authority to dispense the medications. It consists of 1..* instances of MedicationPrescription.
MedicationsDispensed	Class	0..1	This class holds the data that forms the basis of a dispensing record. It consists of 0..* instances of MedicationDispensed. NOTE The data held in this object does not necessarily have to echo the data contained within the MedicationPrescribed object. They may reference that the object may however be different to it, but still reference it as is seen in the case of substitution. They may in addition be a record of a dispensing activity for which no relevant MedicationPrescription data object is present on the card.
MedicationReferences	Class	0..1	This class holds the globally unique identifiers and locations that relates to medication data sets held on other resources. It consists of 1..* instances of MedicationReference. NOTE The usage of the data contained therein allows the healthcard to function as a token for facilitating communication between overtly disconnected static information systems.
MedicationDataStructureEdition	Class	1	This class holds the number of the edition of the MedicationData structure. It is defined as ENUMERATED [edition 2016 (2)].

7.2 "MedicationNotes" class

7.2.1 General

The MedicationNotes contains personal documentation of pharmaceutical supply for patients. It includes the drugs dispensed for the patient and self-medication medicines. Medicines not utilized by the patient are not taken into account. In addition, the physician should also document drugs handed out as physician samples/discharge medication or used for treatment in an outpatient/inpatient setting. Apart from medication, patient characteristics causing drug intolerances should also be noted. The MedicationNotes may be logically linked with the data stored in a specialist information system in the pharmacy/doctor's surgery/hospital and can be automatically evaluated. This enables qualitatively better pharmaceutical treatments because of rapid recognition of multiple prescriptions of the same or similar agents, interactions and contra-indications between medications, atypical medications and dosages (e.g. school-child dose for an infant), special need for advice when prescribing a medication for the first time (e.g. antibiotics, aerosols, etc.) and allergies to medications.

The structure of MedicationNotes and associated classes is shown in Figure 3.

NOTE   The MedicationNotes does not necessarily give a complete overview of all medication-relevant data. Rather, it serves as a memo and does not absolve the physician or pharmacist of the obligation to verify warning notices or the data in the MedicationNotes on which these are based.
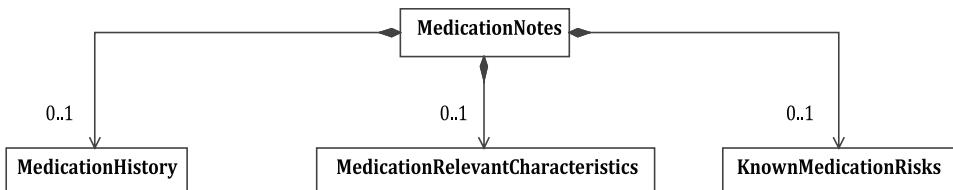
Figure 3 — Structure of MedicationNotes

Individual entities within MedicationNotes are specified in Table 2.

Table 2 — Specification of individual entities within MedicationNotes

Attribute name	Data type	Multiplicity	Comments
medicationHistory	MedicationHistory	0..1	This attribute holds the medication history record of the recorded person. It consists of 1..* instances of MedicationReceived and may contain the instance of AccessoryAttributes.
medicationRelevant Characteristics	MedicationRelevant Characteristics	0..1	This attribute holds the medication relevant characteristics record of the recorded person. It consists of 1..* instances of PatientCharacteristic and may contain the instance of AccessoryAttributes.
knownMedication Risks	KnownMedication Risks	0..1	This attribute holds the known medication risks record of the recorded person. It consists of 1..* instances of KnownInteractionOrContraindication and may contain the instance of AccessoryAttributes.

7.2.2 "MedicationHistory" class

The medication history record contains medication which has been supplied to the patient or administered to him. Here, provision is made for storing merely an unambiguous drug code that may be automatically linked to a medication database. For each new medication, the date and type of dispensation are stored. If the medication is dispensed repeatedly, medicationReceivedDate1 is transferred to medicationReceivedDate2 and the new date of dispensation is entered into the medicationReceivedDate1 field. If the medication is dispensed more than twice, the two most recent dispensation dates are saved in the two date fields and the iteration flag is entered. The archival code is entered if it emerges after consultation with the patient that the medication is no longer being taken. If the medication is dispensed once again, the archival code is deleted.

The structure of MedicationHistory and associated classes is shown in Figure 4.
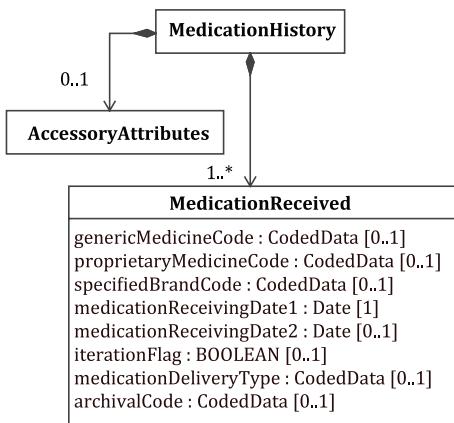
Figure 4 — Structure of MedicationHistory

Individual entities within MedicationReceived are specified in Table 3.

Table 3 — Specification of individual entities within MedicationReceived

Attribute name	Data type	Multiplicity	Comments
genericMedicineCode	CodedData	0..1	Contains the code of the medication received using international or national classification (e.g. ATC, NCDCP). The optional free text field of CodedData may be used to refine this code.
proprietaryMedicineCode	CodedData	0..1	Contains the code and optional code value from a proprietary nomenclature for the medication received.
specifiedBrandCode	CodedData	0..1	Coded data that shall represent the particular brand of a specified proprietary medicine. Code for "special" conditions e.g. re-imports; used to define the source of the drug. The manufacturer may be the same, but source may be different. The attributes genericMedicineCode, proprietaryMedicineCode and specifiedBrandCode are conditional i.e. one of these shall be present.
medicationReceivingDate1	Date	1	Contains the last date at which the patient received the medication.
medicationReceivingDate2	Date	0..1	Contains the date before last at which the patient received the medication.
iterationFlag	Boolean	0..1	If set to TRUE, it indicates that the patient received the medication more than twice.
medicationDeliveryType	CodedData	0..1	Contains coded data representation of the context in which the patient received the medication (e.g. prescription, administered by a doctor, self-administered).
archivalCode	CodedData	0..1	Records if a medication is not currently taken using the structure of coded data.

7.2.3 "MedicationRelevantCharacteristics" class

The medication relevant characteristics record contains patient characteristics that could result in ingestion of certain drugs being contra-indicated or requiring particular vigilance. These characteristics may relate to diagnoses, findings or risk situations such as allergies, diabetes, pregnancy or lactation. The medication relevant characteristics record may contain an instance of the class AccessoryAtributes.

The structure of MedicationRelevantCharacteristics and associated classes is shown in Figure 5.
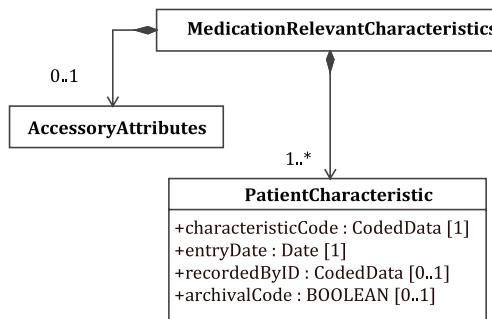
Figure 5 — Structure of MedicationRelevantCharacteristics

Individual entities within PatientCharacteristic are specified in Table 4.

Table 4 — Specification of individual entities within PatientCharacteristic

Attribute name	Data type	Multiplicity	Comments
characteristicCode	CodedData	1	Contains coded data representation of the medication relevant patient characteristic. NOTE If a coding system used does not contain a patient characteristic needed, then this characteristic may be communicated as follows: codingSchemeRef = 0 codeDataValue = "C" codeDataFreeText = text of characteristic
entryDate	Date	1	
recordedByID	CodedData	0..1	Contains the unique identifier of the doctor or pharmacist who recorded the characteristic.
archivalCode	Boolean	0..1	If set to TRUE, it indicates that a patient characteristic no longer exists (e.g. pregnancy).

7.2.4   "KnownMedicationRisks" class

The known medication risks record contains known interactions between medications and patient characteristics; after risk assessment, the physician has decided to prescribe such medication. For the data object, a partnership model has been selected comprising two partners which may be individually classified via a field type (e.g. medication, diagnosis, age, gender) and whose type of link (e.g. interaction, contraindication, drug allergy) has been specified.

The structure of KnownMedicationRisks and associated classes is shown in Figure 6.
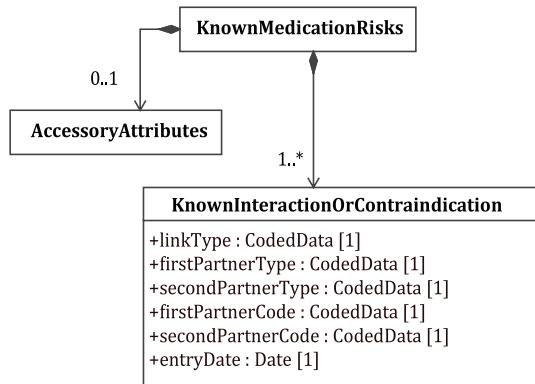
Figure 6 — Structure of KnownMedicationRisks

Individual entities within KnownInteractionOrContraindication are specified in Table 5.

Table 5 — Specification of individual entities within KnownInteractionOrContraindication

Attribute name	Data type	Multiplicity	Comments
linkType	CodedData	1	Contains coded data representation of the medication risk which is caused by the specified partners (e.g. interaction, contraindication).
firstPartnerType	CodedData	1	Contains coded data representation of the first partner type (e.g. drug).
secondPartnerType	CodedData	1	Contains coded data representation of the first partner value.
firstPartnerCode	CodedData	1	Contains coded data representation of the second partner type (e.g. drug, allergy, pregnancy).
secondPartnerCode	CodedData	1	Contains coded data representation of the second partner value.
entryDate	Date	1	

7.3 "MedicationPrescriptions" class

The MedicationPrescriptions class shall consist of a set of MedicationPrescription, which contains the classes "PrescriptionItem" and may contain the class "AccessoryAttributes" (see Figure 7).
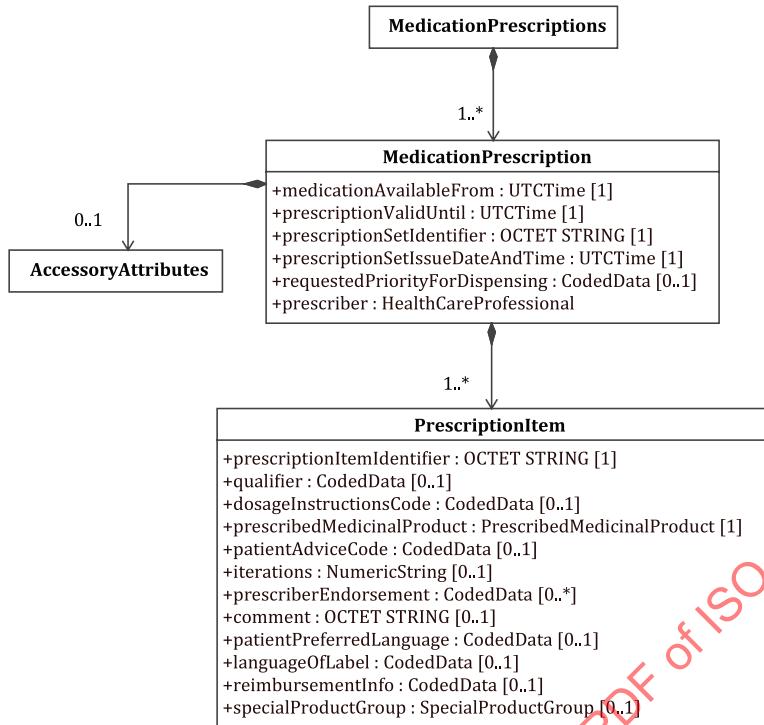
Figure 7 — Structure of MedicationPrescription

Tables 6 and 7 specify individual entities within MedicationPrescription and PrescriptionItem respectively.

Table 6 — Specification of individual entities within MedicationPrescription

Attribute name	Data type	Multiplicity	Comments
medicationAvailableFrom	UTCTime	1	This date is the representation of the legal date from which the medication should be dispensed.
prescriptionValidUntil	UTCTime	1	This date is the representation of the legal date from which the medication should no longer be dispensed. NOTE In some countries or organizations, this period is set by legislation. However, this date could also be set manually to a time frame less than this period as determined by the prescriber.
prescriptionSetIdentifier	String	1	The unique identification of the prescription set.
prescriptionSetIssueDateAndTime	UTCTime	1	
requestedPriorityForDispensing	CodedData	0..1	Request for a higher priority of dispensing than routine handling.
prescriber	HealtcareProfessional	1	The unique identifier of the prescribing person.
prescriptionItem	PrescriptionItem	1..*	This class holds the information about the prescribed medicinal product (see Table 7).

Table 7 — Specification of individual entities within PrescriptionItem

Attribute name	Data type	Multiplicity	Comments
prescriptionItemIdentifier	String	1	The unique identification of the prescription item.
qualifier	CodedData	0..1	Indicates if the prescribed item is acute medication, long-term medication, only administered when required, etc.
dosageInstructionsCode	CodedData	0..1	Contains the coded data representation of the instruction on how and when to take the medication. NOTE If a coding system used does not contain a dosage instruction needed, then this instruction may be communicated as follows: codingSchemeRef = 0 codeDataValue = "C" codeDataFreeText = text of instruction
prescribedMedicinalProduct	PrescribedMedicinalProduct	1	This class holds the information about the prescribed manufactured medicinal product (specialization "PrescribedManufacturedMedicinalProduct", see Table 8) or the information about the prescribed magistral medicinal product (specialization "PrescribedMagistralMedicinalProduct", see Table 12).
patientAdviceCode	CodedData	0..1	Contains the coded data representation of additional advice to be given to the recipient of the medication. NOTE If a coding system used does not contain a patient advice needed, then this advice may be communicated as follows: codingSchemeRef = 0 codeDataValue = "C" codeDataFreeText = text of advice
iterations	Numeric String	0..1	The number of times that the prescription may be dispensed. NOTE Will only be present and set to numeric value where it is intended by the prescriber that the dispenser may fill out the prescription on more than one occasion.
prescriberEndorsement	CodedData	0..*	May contain data that acts as trigger to case specific events or record case specific information added by the prescriber. For example, DEA Number may be communicated here.
comment	String	0..1	Contains additional information for the dispenser.

Table 7 *(continued)*

Attribute name	Data type	Multiplicity	Comments
patientPreferredLanguage	CodedData	0..1	Contains the coded data representation of the language the patient prefers to communicate in.
languageOfLabel	CodedData	0..1	Contains the coded data representation of the language used when labelling the medicine with the dosage instructions and patient advice.
reimbursementInfo	CodedData	0..1	Contains coded data representation of administrative financial reimbursement information.
specialProductGroup	SpecialProductGroup	0..1	This class holds additional information if the prescribed medicinal product belongs to a special product group (see Table 16).

The structure of PrescribedMedicinalProduct and its specializations is shown in Figure 8.
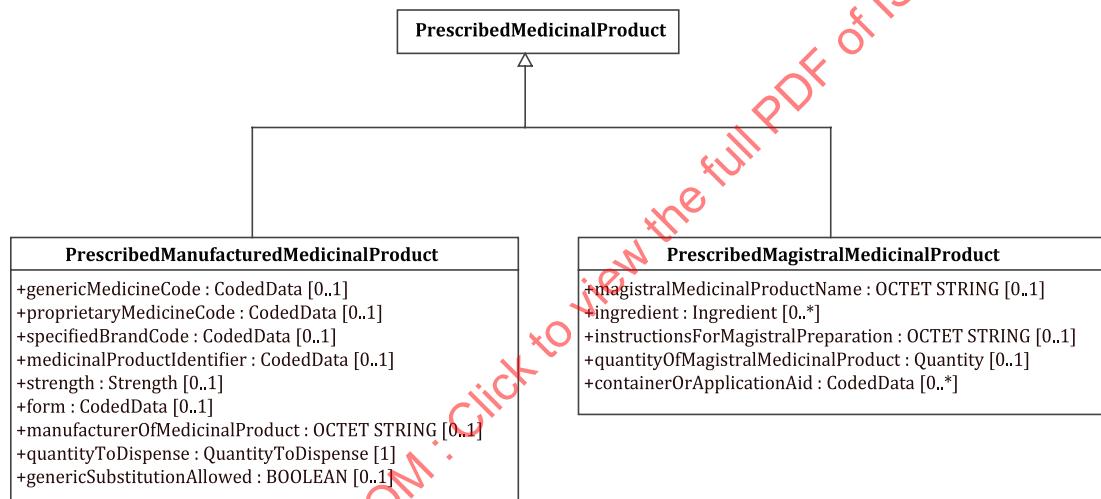
Figure 8 — Structure of PrescribedMedicinalProduct

Individual entities within PrescribedManufacturedMedicinalProduct are specified in Table 8.

Table 8 — Specification of individual entities within PrescribedManufacturedMedicinalProduct

Attribute name	Data type	Multiplicity	Comments
genericMedicineCode	CodedData	0..1	Coded data representation of the non-proprietary name for the medication using international or national classification (e.g. ATC, NCDCP). The optional free text field of CodedData may be used to refine this code.
proprietaryMedicineCode	CodedData	0..1	Contains the Coded data representation of the proprietary name for the medication.
specifiedBrandCode	CodedData	0..1	Coded data that shall represent the particular brand of a specified proprietary medicine. This is a code for "special" conditions, e.g. re-imports; used to define the source of the drug. The manufacturer may be the same, but source may be different. The genericMedicineCode, proprietaryMedicineCode and specifiedBrandCode are conditional, i.e. one of these shall be present.
medicinalProductIdentifier	CodedData	0..1	Contains the local code for the medication (explicit).
strength	Strength	0..1	The strength of the Medicinal Product (see Table 10).
form	CodedData	0..1	Contains the coded data representation of the form that the medicine is to be supplied in.
manufacturerOfMedicinalProduct	String	0..1	
quantityToDispense	QuantityToDispense	1	The total quantity of medication to be dispensed at each iteration (see Table 9).
genericSubstitutionAllowed	BOOLEAN	0..1	If set to TRUE, it indicates that the dispenser of the prescription may dispense the generic equivalent of the medication represented within proprietary medicine code

The structure of QuantityToDispense is shown in Figure 9.

```
QuantityToDispense
+daysOfSupply : NumericString [0..1]
+medicinalProductPackage : MedicinalProductPackage [0..1]
+quantityOfMedicinalProduct : Quantity [0..1]
```

Figure 9 — Structure of QuantityToDispense

Individual entities within QuantityToDispense are specified in Table 9.

Table 9 — Specification of individual entities within QuantityToDispense

Attribute name	Data type	Multiplicity	Comments
daysOfSupply	NumericString	0..1	The number of days of supply
medicinalProductPackage	MedicinalProductPackage	0..1	This class holds the information about the prescribed delivery unit of a medicinal product in an outer container (see Table 11).
quantityOfMedicinalProduct	Quantity	0..1	This attribute holds the information about the prescribed quantity of medicinal product (see Table 14).
The attributes daysOfSupply, quantityOfMedicinalProduct and medicinalProductPackage are conditional, i.e. one shall be present. They are also alternative, i.e. only one may be present.			

The structure of Strength is shown in Figure 10.

```
                    Strength
        +strengthNominator : Amount [1]
        +strengthDenominator : Amount [0..1]
```

Figure 10 — Structure of Strength

Individual entities within Strength are specified in Table 10.

Table 10 — Specification of individual entities within Strength

Attribute name	Data type	Multiplicity	Comments
strengthNominator	Amount	1	Strength nominator
strengthDenominator	Amount	0..1	Strength denominator

The structure of MedicinalProductPackage is shown in Figure 11.

```
              MedicinalProductPackage
        +numberOfPackages : NumericString [1]
        +packageContent : OCTET STRING [1]
```

Figure 11 — Structure of MedicinalProductPackage

Tables 11 and 12 specify individual entities within MedicinalProductPackage and PrescribedMagistralMedicinalProduct respectively.

Table 11 — Specification of individual entities within MedicinalProductPackage

Attribute name	Data type	Multiplicity	Comments
numberOfPackages	NumericString	1	Number of outer packages
packageContent	OCTET STRING	1	Amount of medicinal product in one outer package as supplied by the manufacturer or distributor

Table 12 — Specification of individual entities within PrescribedMagistralMedicinalProduct

Attribute name	Data type	Multiplicity	Comments
magistralMedicinalProductName	OCTET STRING	0..1	For example, an official name from a pharmacopoeia. NOTE For the case of using an official name, the designation of ingredients is not absolutely necessary.
ingredient	Ingredient	0..*	This class holds the information about a component of a magistral medicinal product (see Table 13). The magistralMedicinalProductName and ingredient are conditional, i.e. one of these shall be present.
instructionsForMagistralPreparation	OCTET STRING	0..1	Instruction to the dispenser in which way the magistered medicinal product should be prepared.
quantityOfMagistralMedicinalProduct	Quantity	0..1	The total quantity of the magistral medicinal product. It shall be present if the ingredients are not specified (e.g. when an official name from a pharmacopoeia is specified) (see Table 15).
containerOrApplicationAid	CodedData	0..*	Contains the coded data representation of the container (alternative: name) for the magistral medicinal product or the application aid for administering the magistral medicinal product.

The structure of Ingredient is shown in Figure 12.

```
┌─────────────────────────────────────────┐
│               Ingredient                 │
├─────────────────────────────────────────┤
│ +IngredientIdentifier : CodedData [0..1] │
│ +nameOfIngredient : OCTET STRING [1]     │
│ +amountOfIngredient : Amount [1]         │
└─────────────────────────────────────────┘
```
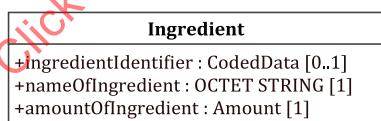
Figure 12 — Structure of Ingredient

Individual entities within Ingredient are specified in Table 13.

Table 13 — Specification of individual entities within Ingredient

Attribute name	Data type	Multiplicity	Comments
ingredientIdentifier	CodedData	0..1	The unique code of the ingredient. Examples of coding systems include Chemical Abstract Service (CAS) registry numbers, European Inventory of Existing Commercial Chemical Substances (EINECS), European drug codes (EVMPD) and Japanese drug codes.
nameOfIngredient[a]	OCTET STRING	0..1	The name of the ingredient. Required if ingredient identifier is omitted or if exact ingredient name is differ from the optional free text field of CodedData.
amountOfIngredient	Amount	1	See Table 14.
[a] This attribute may be integrated in "ingredientIdentifier" if it is possible to specify only free text. In that case, the multiplicity of "ingredientIdentifier" is 1.			

The structure of Amount is shown in Figure 13.

```
                    ┌─────────────────────────────────┐
                    │            Amount               │
                    ├─────────────────────────────────┤
                    │ +quantity : REAL [0..1]         │
                    │ +unitOfQuantity : CodedData [0..1] │
                    │ +nonNumericValue : OCTET STRING [0..1] │
                    └─────────────────────────────────┘
```

Figure 13 — Structure of Amount

Individual entities within Amount are specified in Table 14.

Table 14 — Specification of individual entities within Amount

Attribute name	Data type	Multiplicity	Comments
quantity	REAL	0..1	Numeric value.
unitOfQuantity	CodedData	0..1	Shall be present if "quantity" is not null.
nonNumericValue	OCTET STRING	0..1	Non-numeric value (e.g. "equal parts").
The attributes "quantity" and "nonNumericValue" are conditional, i.e. at least one shall be present. They are also alternative, i.e. only one shall be present.			

The structure of Quantity is shown in Figure 14.

```
                    ┌─────────────────────────────────┐
                    │            Quantity             │
                    ├─────────────────────────────────┤
                    │ +quantity : REAL [1]            │
                    │ +unitOfQuantity : CodedData [1] │
                    └─────────────────────────────────┘
```

Figure 14 — Structure of Quantity

Individual entities within Quantity are specified in Table 15.

Table 15 — Specification of individual entities within Quantity

Attribute name	Data type	Multiplicity	Comments
quantity	Real	1	Quantity value.
unitOfQuantity	CodedData	1	Coded data representation of unit of quantity.

The structure of SpecialProductGroup is shown in Figure 15.

```
                    ┌─────────────────────────────────────┐
                    │         SpecialProductGroup         │
                    ├─────────────────────────────────────┤
                    │ +specialProductType : CodedData [0..1] │
                    │ +specialProductInformation : CodedData [0..*] │
                    └─────────────────────────────────────┘
```

Figure 15 — Structure of SpecialProductGroup

Individual entities within SpecialProductGroup are specified in Table 16.

Table 16 — Specification of individual entities within SpecialProductGroup

Attribute name	Data type	Multiplicity	Comments
specialProductType	CodedData	0..1	Contains the coded data representation of the special product type e.g. narcotics, medicinal appliances, vaccines.
specialProductInformation	CodedData	0..*	Contains the coded data representation of the special product information, e.g. additional flag "N" to prescription for narcotics (Germany: N indicates a prescription for narcotics because of an emergency).

7.4 "MedicationsDispensed" data object

A "MedicationsDispensed" data object shall consist of a set of "MedicationDispensed", which includes one or more elements "DispensedItem" and it may include the element "AccessoryAttributes" (see Figure 16).
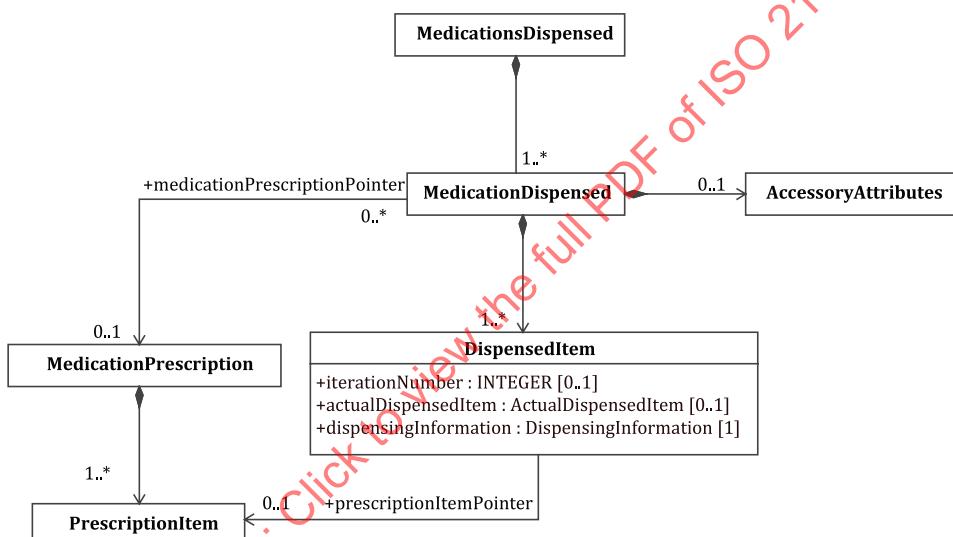
Figure 16 — Structure of MedicationDispensed

Tables 17 and 18 specify individual entities within MedicationDispensed and DispensedItem respectively.

Table 17 — Specification of individual entities within MedicationDispensed

Attribute name	Data type	Multiplicity	Comments
DispensedItem	Class	1..*	See Table 18.
AccessoryAttributes	Class	0..1	The AccessoryAttributes object.
medicationPrescriptionPointer	RefPointer	0..1	Points to the MedicationPrescription object.

Table 18 — Specification of individual entities within DispensedItem

Attribute name	Data type	Multiplicity	Comments
prescriptionItemPointer	RefPointer	0..1	Points to the PrescriptionItem object.
iterationNumber	Integer	0..1	Records the iteration number of this dispensing issue in relation to the medication referenced by the prescriptionItemPointer.
actualDispensedItem	ActualDispensedItem	0..1	Complete data set utilised where substitutions are made or the data set is altered in some way from that contained within the medication prescribed object and therefore, is not identical and should not be referenced (see Table 19).
			NOTE If no medicationPrescribedPointer exists in the DispensedItem object, then the data represents a record of a medication dispensed by the pharmacy for which no prescription existed, e.g. an over the counter sale.
			For manufactured medicinal products, a possibility must be provided to dispense two or more different packages (sizes) instead of the prescribed one (e.g. 2 × 20 tablets and 1 × 10 tablets instead of 1 × 50 tablets). For this reason, dispensing of more than one product for each prescription item is allowed.
dispensingInformation	DispensingInformation	1	Contains information particular to this dispense episode (see Table 23).

The structure of ActualDispensedItem is shown in Figure 17.

| ActualDispensedItem |
|---|
| +dispensedMedicinalProduct : DispensedMedicinalProduct [1]
+languageOfLabel : CodedData [0..1]
+dosageInstructionsCode : CodedData [0..1]
+patientAdviceCode : CodedData [0..1] |

Figure 17 — Structure of ActualDispensedItem

Individual entities within ActualDispensedItem are specified in Table 19.

Table 19 — Specification of individual entities within ActualDispensedItem

Attribute name	Data type	Multiplicity	Comments
dispensedMedicinalProduct	DispensedMedicinalProduct	1	Contains actually dispensed medicine identification.
languageOfLabel	CodedData	0..1	Contains the coded data representation of the language used when labelling the medicine with the dosage instructions and patient advice.
dosageInstructionsCode	CodedData	0..1	Contains the coded data representation of the instruction on how and when to take the medication. If a coding system used does not contain a dosage instruction needed, then this instruction may be communicated as follows: codingSchemeRef = 0 codeDataValue = "C" codeDataFreeText = text of instruction
patient Advice Code	CodedData	0..1	Contains the coded data representation of additional advice to be given to the recipient of the medication.

The structure of DispensedMedicinalProduct and its specializations is shown in Figure 18.
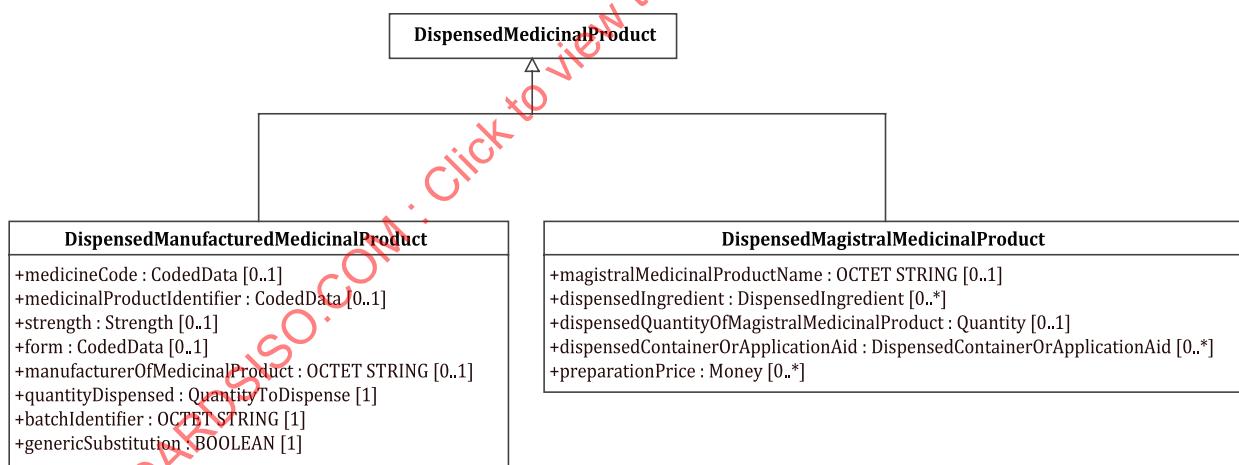
Figure 18 — Structure of DispensedMedicinalProduct

Tables 20 and 21 specify individual entities within DispensedManufacturedMedicinalProduct and DispensedMagistralMedicinalProduct respectively.

**Table 20 — Specification of individual entities within
DispensedManufacturedMedicinalProduct**

Attribute name	Data type	Multiplicity	Comments
medicineCode	CodedData	0..1	Coded data representation of the non-proprietary name for the medication using international or national classification (e.g. ATC, NCDCP). The optional free text field of CodedData may be used to refine this code.
medicinalProductIdentifier	CodedData	0..1	Contains the local code for the medication (explicit).
strength	Strength	0..1	The strength of the Medicinal Product (see Table 10).
form	CodedData	0..1	Contains the coded data representation of the form that the medicine is to be supplied in.
manufacturerOfMedicinalProduct	OCTET STRING	0..1	
quantityDispensed	QuantityToDispense	1	The total quantity of medication dispensed at each iteration (see Table 9).
batchIdentifier	OCTET STRING	1	The unique identifier of the batch of the dispensed medication. May be empty if not known.
genericSubstitution	BOOLEAN	1	If set to TRUE, it indicates that the pharmacist/dispenser has substituted a generic form of the medication for the one identified within the prescription item.

Table 21 — Specification of individual entities within DispensedMagistralMedicinalProduct

Attribute Name	Data Type	Multiplicity	Comments
magistralMedicinalProductName	OCTET STRING	0..1	For example, an official name from a pharmacopoeia. NOTE For the case of using an official name, the designation of ingredients is not absolutely necessary.
dispensedIngredient	DispensedIngredient	0..*	This class holds the information about a component of a dispensed magistral medicinal product. The magistralMedicinalProductName and dispensedIngredient are conditional, i.e. one of these shall be present.
dispensedQuantity	Quantity	0..1	The total quantity of the magistral medicinal product. It shall be present if the ingredients are not specified (e.g. when an official name from a pharmacopoeia is specified) (see Table 15)
dispensedContainerOrApplicationAid	DispensedContainerOrApplicationAid	0..*	Contains the coded data representation of the container (alternative: name) for the magistral medicinal product or the application aid for administering the magistral medicinal product.
preparationPrice	Money	0..*	

The structure of DispensedContainerOrApplicationAid is shown in Figure 19.

Figure 19 — Structure of DispensedContainerOrApplicationAid

Individual entities within DispensedContainerOrApplicationAid are specified in Table 22.

Table 22 — Specification of individual entities within DispensedContainerOrApplicationAid

Attribute name	Data type	Multiplicity	Comments
containerOrApplicationAidIdentifier	CodedData	1	Contains the coded data representation of the container (alternative: name) for the magistral medicinal product or the application aid for administering the magistral medicinal product. If a coding system used does not contain a container name needed, then this name may be communicated as follows: codingSchemeRef = 0 codeDataValue = "A" codeDataFreeText = text of container name
dispensedPriceOfContainerOr ApplicationAidIdentifier	Money	0..1	Total dispensed price of the containers or the application aids.
dispensedNumberOfUnits	INTEGER	0..1	Dispensed number of the containers or the application aids (1 by default).

The structure of DispensingInformation is shown in Figure 20.

DispensingInformation
+dispensedDate : UTCTime [1]
+dispensedPrice : Money [0..1]
+dispensedPaid : Money [0..1]
+exemptionStatus : CodedData [0..1]
+dispensingIdentifier : OCTET STRING [1]
+urgencyStatusOfDispensing Event : CodedData [0..1]
+specialProductGroup : SpecialProductGroup [0..1]
+commentOfDispenserToMedicinalProduct : CommentOfDispenserToMedicinalProduct [0..1]
+dispenser : HealthCareProfessional

Figure 20 — Structure of DispensingInformation

Individual entities within DispensingInformation are specified in Table 23.

Table 23 — Specification of individual entities within DispensingInformation

Attribute name	Data type	Multiplicity	Comments
dispensedDate	UTCTime	1	The date upon which the prescription was filled out.
dispensedPrice	Money	0..1	The real full cost of the prescription.
dispensedPaid	Money	0..1	The sum of money paid by the client upon dispensing.
exemptionStatus	CodedData	0..1	Use to give exemption or level of patient co-payment.
dispensingIdentifier	OCTET STRING	1	The unique identifier of dispensing.

Table 23 *(continued)*

Attribute name	Data type	Multiplicity	Comments
urgencyStatusOfDispensingEvent	CodedData	0..1	Contains the urgency of dispensing, e.g using code from HL7 User-Defined Table 0485.
specialProductGroup	SpecialProductGroup	0..1	This class holds additional information if the dispensed medicinal product belongs to a special product group (see Table 16).
commentOfDispenserToMedicinal Product	CommentOfDispenser ToMedicinalProduct	0..1	This class holds the information about the comment of a dispenser to a dispensed medicinal product (see Table 24).

The structure of CommentOfDispenserToMedicinalProduct is shown in Figure 21.
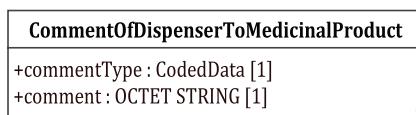
Figure 21 — Structure of CommentOfDispenserToMedicinalProduct

Individual entities within CommentOfDispenserToMedicinalProduct are specified in Table 24.

Table 24 — Specification of individual entities within CommentOfDispenserToMedicinalProduct

Attribute name	Data type	Multiplicity	Comments
commentType	CodedData	1	Specifies the intended use of the comment, e.g. if the comment is intended for the payment guarantor and additionally for the prescriber.
comment	OCTET STRING	1	Contains additional information to the dispensed medicinal product.

The structure of DispensedIngredient is shown in Figure 22.
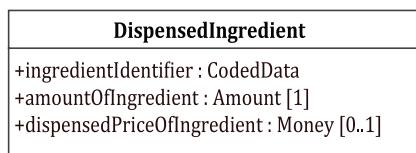
Figure 22 — Structure of DispensedIngredient

Individual entities within DispensedIngredient are specified in Table 25.

Table 25 — Specification of individual entities within DispensedIngredient

Attribute name	Data type	Multiplicity	Comments
ingredientIdentifier	CodedData	1	Contains the coded data representation of the ingredient.
			If a coding system used does not contain an ingredient name needed, then this name may be communicated as follows:
			codingSchemeRef = 0
			codeDataValue = "C"
			codeDataFreeText = text of ingredient name
amountOfIngredient	Amount	1	See Table 14.
dispensedPriceOfIngredient	Money	0..1	This attribute is only needed if attributes for prices should be provided.

The structure of HealthCareProfessional is shown in Figure 23.

```
            «dataType»
        HealthCareProfessional
─────────────────────────────────────────────
+healthcareProfessionalId : HealthCareProfessionalId [1]
+healthcareProfessionalName : OCTET STRING [0..1]
+assigningAuthority : CodedData [0..1]
```
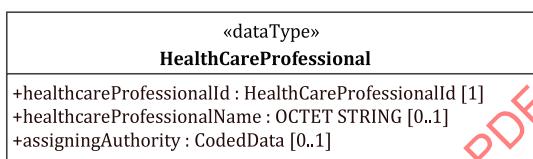
Figure 23 — Structure of HealthCareProfessional

Individual entities within HealthCareProfessional are specified in Table 26.

Table 26 — Specification of individual entities within HealthCareProfessional

Attribute name	Data type	Multiplicity	Comments
healthCareProfessionalId	HealthCareProfessionalId	1	The unique identification of the healthcare professional (choice of INTEGER, UTF8String, OCTET STRING, CodedData).
healthCareProfessionalName	OCTET STRING	0..1	The name of the healthcare professional.
healthCareProfessionalInstitution	CodedData	0..1	The unique identification of the healthcare employer.

7.5 MedicationReferences

A "MedicationReferences" data object shall consist of a set of "MedicationReference" (see Figure 24).

NOTE   The medication references provide the "addresses" of resources other than the card that contain medication data in relation to the patient.

```
┌─────────────────────────────┐
│    MedicationReferences     │
└─────────────────────────────┘
              ◆
              │
         1..* │
              ▼
┌───────────────────────────────────────────────┐
│              MedicationReference               │
├───────────────────────────────────────────────┤
│ +uniqueResourceLocator : OCTET STRING [1]      │
│ +prescriptionSetIdentifier : OCTET STRING [1]  │
│ +prescriptionItemIdentifier : OCTET STRING [0..*]│
│ +key : BIT STRING [0..1]                       │
└───────────────────────────────────────────────┘
```
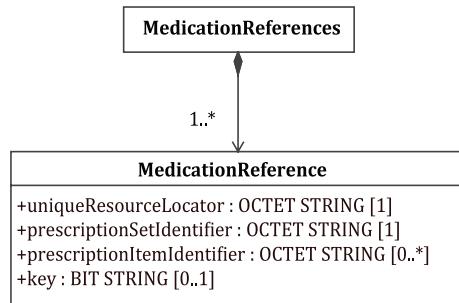
Figure 24 — Structure of MedicationReferences

Individual entities within MedicationReference are specified in Table 27.

Table 27 — Specification of individual within MedicationReference entities

Attribute name	Data type	Multiplicity	Comments
uniqueResourceLocator	OCTET STRING	1	Points to the external resource where the medication prescribed object is held.
prescriptionSetIdentifier	OCTET STRING	1	The unique identification of the prescription set.
prescriptionItemIdentifier	OCTET STRING	0..*	The unique identification of the prescription item.
key	OCTET STRING	0..1	This attribute provides the deciphering key if the referenced medication data is enciphered.

Annex A
(normative)

ASN.1 data definitions

The following definitions shall be used for all the new implementations of this document.

```
MedicationData {iso(1) standard(0) 21549 7 2} DEFINITIONS::= BEGIN
EXPORTS MedicationData;
IMPORTS AccessoryAttributes, CodingSchemesUsed, CodedData, RefPointer FROM
CommonDataTypes;
-- Classes AccessoryAttributes, CodingSchemesUsed, CodedData, RefPointer
-- are defined in ISO 21549-2

MedicationData ::= SEQUENCE
{
      medicationNotes              [0] MedicationNotes         OPTIONAL,
      medicationPrescriptions      [1] MedicationPrescriptions OPTIONAL,
      medicationsDispensed         [2] MedicationsDispensed    OPTIONAL,
      medicationReferences         [3] MedicationReferences    OPTIONAL,
      medicationDataStructureEdition [4] MedicationDataStructureEdition
}

MedicationNotes ::= SET
{
      medicationHistory     [0] MedicationHistory       OPTIONAL,
      medicationRelevantCharacteristics [1]
      MedicationRelevantCharacteristics OPTIONAL,
      knownMedicationRisks[2] KnownMedicationRisks      OPTIONAL
}

MedicationHistory ::= SET
{
      medicationReceived    [0] SET OF MedicationReceived,
      accessoryAttributes   [1] AccessoryAttributes  OPTIONAL
}

MedicationReceived ::= SET
{
      genericMedicineCode          [0] CodedData       OPTIONAL,
      proprietaryMedicineCode      [1] CodedData       OPTIONAL,
      specifiedBrandCode           [2] CodedData       OPTIONAL,
      medicationReceivingDate1     [3] Date,
      medicationReceivingDate2     [4] Date            OPTIONAL,
      iterationFlag                [5] BOOLEAN          OPTIONAL,
      medicationDeliveryType       [6] CodedData       OPTIONAL,
      archivalCode                 [7] CodedData       OPTIONAL
}
```

```
MedicationDataStructureEdition ::= ENUMERATED { edition2016(2) }

Date ::= NumericString (SIZE (8)) -- YYYYMMDD according to ISO 8601

MedicationRelevantCharacteristics ::= SET
{
     patientCharacteristic   [0] SET OF PatientCharacteristic,
     accessoryAttributes     [1] AccessoryAttributes  OPTIONAL
}

PatientCharacteristic ::= SET
{
     characteristicCode      [0] CodedData,
     entryDate               [1] Date,
     recordedByID            [2] CodedData          OPTIONAL,
     archivalCode            [3] BOOLEAN            OPTIONAL
}

KnownMedicationRisks ::= SET
{
     knownInteractionOrContraindication [0] SET OF
     KnownInteractionOrContraindication,
     accessoryAttributes                [1] AccessoryAttributes   OPTIONAL
}

KnownInteractionOrContraindication ::= SET
{
     linkType               [0] CodedData,
     firstPartnerType       [1] CodedData,
     secondPartnerType      [2] CodedData,
     firstPartnerCode       [3] CodedData,
     secondPartnerCode      [4] CodedData,
     entryDate              [5] Date
}

MedicationPrescriptions ::= SET OF MedicationPrescription

MedicationPrescription ::= SET
```

```
{
     medicationAvailableFrom         [0] UTCTime,
     prescriptionValidUntil          [1] UTCTime,
     prescriptionSetIdentifier       [2] OCTET STRING,
     prescriptionSetIssueDateAndTime [3] UTCTime,
     requestedPriorityForDispensing  [4] CodedData           OPTIONAL,
     prescriptionItem                [5] SET OF PrescriptionItem,
     prescriber                      [6] HealthCareProfessional,
     accessoryAttributes             [7] AccessoryAttributes  OPTIONAL
}

PrescriptionItem ::= SET
{
     prescriptionItemIdentifier  [0] OCTET STRING,
     qualifier                   [1] CodedData           OPTIONAL,
     dosageInstructionsCode      [2] CodedData           OPTIONAL,
     prescribedMedicinalProduct  [3] PrescribedMedicinalProduct,
     patientAdviceCode           [4] CodedData           OPTIONAL,
     iterations                  [5] NumericString       OPTIONAL,
     prescriberEndorsement       [6] SET OF CodedData     OPTIONAL,
     comment                     [7] OCTET STRING        OPTIONAL,
     patientPreferredLanguage    [8] CodedData           OPTIONAL,
     languageOfLabel             [9] CodedData           OPTIONAL,
     reimbursementInfo           [10] CodedData          OPTIONAL,
     specialProductGroup         [11] SpecialProductGroup OPTIONAL
}

PrescribedMedicinalProduct ::= CHOICE
{
     prescribedManufacturedMedicinalProduct [0]
     PrescribedManufacturedMedicinalProduct,
     prescribedMagistralMedicinalProduct    [1]
     PrescribedMagistralMedicinalProduct
          }
```

```
PrescribedManufacturedMedicinalProduct ::= SET
{
      proprietaryMedicineCode      [0] CodedData          OPTIONAL,
      genericMedicineCode          [1] CodedData          OPTIONAL,
      specifiedBrandCode           [2] CodedData          OPTIONAL,
      medicinalProductIdentifier   [3] CodedData          OPTIONAL,
      strength                     [4] Quantity           OPTIONAL,
      form                         [5] CodedData          OPTIONAL,
      manufacturerOfMedicinalProduct [6] OCTET STRING     OPTIONAL,
      quantityToDispense           [7] QuantityToDispense OPTIONAL,
      genericSubstitutionAllowed   [8] BOOLEAN            OPTIONAL
}

QuantityToDispense ::= CHOICE
{
      quantityOfMedicinalProduct   [0] Quantity,
      daysOfSupply                 [1] NumericString,
      medicinalProductPackage      [2] MedicinalProductPackage
}


Strength ::= SEQUENCE
{
      strengthNominator            [0] Amount,
      strengthDenominator          [1] Amount          OPTIONAL
}



MedicinalProductPackage ::= SEQUENCE
{
      numberOfPackages             [0] NumericString,
      packageContent               [1] OCTET STRING
}

PrescribedMagistralMedicinalProduct ::= SET
```

```
{
     magistralMedicinalProductName           [0] OCTET STRING      OPTIONAL,
     ingredient                               [1] SET OF Ingredient   OPTIONAL,
     instructionsForMagistralPreparation [2] OCTET STRING      OPTIONAL,
     quantityOfMagistralMedicinalProduct [3] Quantity          OPTIONAL,
     containerOrApplicationAid                [4] SET OF CodedData  OPTIONAL
}

Ingredient ::= SET
{
     ingredientIdentifier                  [0] CodedData        OPTIONAL,
     nameOfIngredient                      [1] OCTET STRING     OPTIONAL,
     amountOfIngredient                    [2] Amount
}

Amount ::= SEQUENCE
{
     quantity                              [0] REAL                  OPTIONAL,
     unitOfQuantity                        [1] CodedData        OPTIONAL,
     nonNumericValue                       [2] OCTET STRING     OPTIONAL
}

Quantity ::= SEQUENCE
{
     quantity                              [0] REAL,
     unitOfQuantity                        [1] CodedData
}

SpecialProductGroup ::= SET
{
     specialProductType                    [0] CodedData        OPTIONAL,
     specialProductInformation             [1] SET OF CodedData  OPTIONAL
          }
```

```
Prescriber ::= HealthCareProfessional -- The unique identifier of the
prescribing person.

MedicationsDispensed ::= SET OF MedicationDispensed

MedicationDispensed ::= SET
{
    medicationPrescriptionPointer      [0] RefPointer OPTIONAL,
    --Points to the Medication Prescription object
    dispensedItem                      [1] SET OF DispensedItem,
    accessoryAttributes                [2] AccessoryAttributes OPTIONAL
}

DispensedItem ::= SET
{
    prescriptionItemPointer [0] RefPointer       OPTIONAL,
    --Points to the Prescription Item object
    iterationNumber         [1] INTEGER          OPTIONAL,
    actualDispensedItem     [2] ActualDispensedItem  OPTIONAL,
    dispensingInformation   [3] DispensingInformation
}

ActualDispensedItem ::= SET
{
    dispensedMedicinalProduct  [0] DispensedMedicinalProduct,
    languageOfLabel            [1] CodedData      OPTIONAL,
    dosageInstructionsCode     [2] CodedData      OPTIONAL,
    patientAdviceCode          [3] CodedData      OPTIONAL
}

DispensedMedicinalProduct ::= CHOICE
{
    dispensedManufacturedMedicinalProduct    [0]
    PrescribedManufacturedMedicinalProduct,
    dispensedMagistralMedicinalProduct       [1]
    PrescribedMagistralMedicinalProduct
        }
```

```
DispensedManufacturedMedicinalProduct ::= SET
{
     medicineCode                 [0] CodedData       OPTIONAL,
     medicinalProductIdentifier   [1] CodedData        OPTIONAL,
     strength                     [2] Strength        OPTIONAL,
     form                         [3] CodedData       OPTIONAL,
     manufacturerOfMedicinalProduct [4] OCTET STRING OPTIONAL,
     quantityDispensed            [5] QuantityToDispense,
     batchIdentifier              [6] OCTET STRING,
     genericSubstitution          [7] BOOLEAN         OPTIONAL
}

DispensedMagistralMedicinalProduct ::= SET
{
     magistralMedicinalProductName [0] OCTET STRING          OPTIONAL,
     dispensedIngredient           [1] SET OF DispensedIngredient OPTIONAL,
     quantityOfMagistralMedicinalProduct [3] Quantity          OPTIONAL,
     dispensedContainerOrApplicationAid  [4] SET OF
DispensedContainerOrApplicationAid OPTIONAL,
     preparationPrice             [5] SET OF Money          OPTIONAL
}

DispensedIngredient ::= SET
{
     ingredientIdentifier         [0] CodedData      OPTIONAL,
     amountOfIngredient           [1] Amount,
     dispensedPriceOfIngredient   [2] Money          OPTIONAL
}

DispensedContainerOrApplicationAid ::= SET
{
     containerOrApplicationAidIdenifier  [0] CodedData,
     dispensedPriceOfContainerOrApplicationAidIdenifier [1] Money OPTIONAL,
     dispensedNumberOfUnits              [4] INTEGER          OPTIONAL
}

DispensingInformation ::= SET
```

```
{
     dispensedDate                [0] UTCTime,
     dispensedPrice               [1] Money          OPTIONAL,
     dispensedPaid                [2] Money          OPTIONAL,
     exemptionStatus              [3] CodedData       OPTIONAL,
     dispensingIdentifier          [4] OCTET STRING,
     urgencyStatusOfDispensingEvent [5] CodedData     OPTIONAL,
     specialProductGroup          [6] SpecialProductGroup  OPTIONAL,
     commentOfDispenserToMedicinalProduct [7]
     CommentOfDispenserToMedicinalProduct OPTIONAL,
     dispenser                    [8] Dispenser       OPTIONAL
}

CommentOfDispenserToMedicinalProduct ::= SET
{
     commentType                  [0] CodedData,
     comment                      [1] OCTET STRING
}

Dispenser ::= HealthCareProfessional -- The unique identifier of the
dispenser.

Money ::= Quantity -- monetary value and currency unit

MedicationReferences ::= SET OF MedicationReference

MedicationReference ::= SET
{
     uniqueRessourceLocator       [0] OCTET STRING,
     prescriptionSetIdentifier     [1] OCTET STRING,
     prescriptionItemIdentifier    [2] SET OF OCTET STRING    OPTIONAL,
     key                          [3] BIT STRING             OPTIONAL
          }



HealthCareProfessional ::= SET
{
     healthCareProfessionalId     [0] HealthCareProfessionalId,
     healthCareProfessionalName   [1] OCTET STRING        OPTIONAL,
     healthCareProfessionalInstitution [2] CodedData        OPTIONAL
}
HealthCareProfessionalId ::= CHOICE
{
healthCareProfessionalID1      INTEGER,
healthCareProfessionalID2      UTF8String,
healthCareProfessionalID3      OCTET STRING,
healthCareProfessionalID4      CodedData
}
END
```

The following definitions shall be used only for backward compatibility with the first edition of this document. These definitions may be obsoleted in future editions.

```
--
-- Part 7
--

MedicationData ::= SEQUENCE
{
    medicationNotes         [0] MedicationNotes          OPTIONAL,
    medicationPrescriptions [1] MedicationPrescriptions  OPTIONAL,
    medicationsDispensed    [2] MedicationsDispensed      OPTIONAL,
    medicationReferences    [3] MedicationReferences      OPTIONAL
}

MedicationNotes ::= SET
{
    medicationHistory       [0] MedicationHistory        OPTIONAL,
    medicationRelevantCharacteristics [1]
    MedicationRelevantCharacteristics OPTIONAL,
    knownMedicationRisks    [2] KnownMedicationRisks     OPTIONAL
}

MedicationHistory ::= SET
{
    medicationReceived   [0] SET OF MedicationReceived,
    accessoryAttributes  [1] AccessoryAttributes OPTIONAL
}

MedicationReceived ::= SET
{
    genericMedicineCode     [0] CodedData         OPTIONAL,
    proprietaryMedicineCode [1] CodedData         OPTIONAL,
    specifiedBrandCode       [2] CodedData          OPTIONAL,
    medicationReceivingDate1 [3] Date,
    medicationReceivingDate2 [4] Date              OPTIONAL,
    iterationFlag            [5] BOOLEAN           OPTIONAL,
    medicationDeliveryType   [6] CodedData         OPTIONAL,
    archivalCode             [7] CodedData OPTIONAL
        }
```