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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

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Foreword

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

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 21549-7 was prepared by Technical Committee ISO/TC 215, *Health informatics*.

ISO 21549 consists of the following parts, under the general title *Health informatics — Patient healthcard data*:

— *Part 1: General structure*

— *Part 2: Common objects*

— *Part 3: Limited clinical data*

— *Part 4: Extended clinical data*

— *Part 5: Identification data*

— *Part 6: Administrative data*

— *Part 7: Medication data*

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 data bases and support systems has led to the development and use of “Healthcare Person” 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, prescription and linkage data.

Device data is defined to include:

— identification of the device itself;

— 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:

— complementary person(s) related data;

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

— 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);
- related actions planned, requested or performed;

Prescription data may include:

- a record of medications received by the patient;
- copies of prescriptions including the authority to dispense records of dispensed medications;
- records of medications dispensed by the pharmacist to the patient;
- pointers to other systems that contain information that makes up an medication prescription and the authority to dispense.

Because a data card essentially provides specific answers to definite queries whilst 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

a) communicate prescription information from one healthcare person to another healthcare person such as to a healthcare agent or healthcare organization;

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

This part of ISO 21549 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 part of ISO 21549 does not describe and define the common objects defined within part 2 of ISO 21549 even though they are referenced and utilized within this document.

Health informatics — Patient healthcard data —

Part 7: Medication data

1 Scope

This part of ISO 21549 is applicable to situations in which such data are recorded on or transported by patient healthcards compliant with the physical dimensions of ID-1 cards defined by ISO 7810.

This part of ISO 21549 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 part of ISO 21549 is for cards to provide information to other health professionals and to the patient or to their non-professional care giver.

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

Medication data includes the following four components:

— **medication notes**: the list of all medication for a patient;

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

— **medication dispensed**: the records of medications bought by the patient;

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

In order to facilitate interoperability, whenever an application is built for use in the healthcare domain in compliance with this part of ISO 21549, data items required for that application shall be drawn from the list of objects (some of which are extensible) as provided in Clauses 6 to 8. These shall then be used in conjunction with other data defined in other parts of this part of ISO 21549. The detailed functions and mechanisms of the following services are not within the scope of this part of ISO 21549 (although its structures can accommodate suitable data objects elsewhere specified):

— the encoding of free text data;

— security functions and related services that are likely to be specified by users for data cards depending on their specific application, e.g.: confidentiality protection, data integrity protection and authentication of persons and devices related to these functions;

— access control services that may depend on active use of some data card classes such as microprocessor cards;

— the initialization and issuing process (which begins the operating lifetime of an individual data card, and by which the data card is prepared for the data to be subsequently communicated to it according to this part of ISO 21549).

The following topics are therefore beyond the scope of this part of ISO 21549:

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

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

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

It should be noted that not only the definition of “medicinal products” differs from country to country, but also the same name may relate to entirely different products in some countries. Therefore, special attention should be made for the safety of patient, when the card is used across borders

As a matter of course, exchange of prescription across borders must follow all laws, instructions, rules, terms and treaties between the said two countries.

2 Normative references

The following referenced documents are indispensable for the application 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 7810, *Identification cards — Physical characteristics*

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

ISO/IEC 7826-1, *Information technology — General structure for the interchange of code values — Part 1: Identification of coding schemes*

ISO/IEC 7826-2, *Information technology — General structure for the interchange of code values — Part 2: Registration of coding schemes*

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

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

ENV 13607:2000, *Health informatics — Messages for the exchange of information on medicine prescriptions*

3 Terms and definitions

Please note that there are many different terms used to describe the basic concepts in healthcare for different purposes available from ISO, CEN, HL-7 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 part of ISO 21549.

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

3.1
attribute
characteristic of an object or entity

3.2
audit trail
record of the resources that were accessed and/or used and by whom

NOTE This may involve a formal monitoring technique for comparison between the actual use of a medical information system and pre-established criteria.

3.3
authentication
process of reliably identifying security objects by securely associating an identifier and its authenticator

3.4
availability
property of being accessible and useable upon demand by an authorized entity

[ISO 7498-2, definition 3.3.11]

3.5
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

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

3.6
clinical information
information about a subject of care, relevant to the health or treatment of that subject of care, which is recorded by or on behalf of a healthcare person

NOTE Clinical information about a subject of care can include information about the subject of care's environment or about related people where this is relevant.

[ENV 1613]

3.7
code meaning
element within a coded set

EXAMPLE “Paris Charles-de-Gaulle” which is mapped on to the three-letter abbreviation "CDG" by the coding scheme for three-letter abbreviations of airport names.

3.8
code value
result of applying a coding scheme to a code meaning

EXAMPLE “CDG” as the representation of "Paris Charles-De-Gaulle" in the coding scheme for three-letter representations of airport names.

3.9
coding scheme
collection of rules that maps the elements of one set on to the elements of a second set

3.10
confidentiality
property that information is not made available or disclosed to unauthorized individuals, entities or processes

[ISO 7498-2:1989, definition 3.3.16]

3.11
data integrity
property that data has not been altered or destroyed in an unauthorized manner

[ISO 7498-2:1989, definition 3.3.21]

3.12
data object
collection of data that has a natural grouping and may be identified as a complete entity

3.13
data origin authentication
corroboration that the source of data received is as claimed

[ISO 7498-2:1989, definition 3.3.22]

3.14
dispenser
specialization of a more qualified healthcare person, which is a representation of an individual who has a pharmacist status and who is filling/dispensing the prescription

3.15
electronic healthcare record
healthcare record concerning the subject of care in computer-readable form

[ENV 13606-1]

3.16
healthcard holder
individual transporting a healthcare data card that contains a record with themselves identified as the major record person

3.17
healthcare
provision of health related services

NOTE This includes more than performing procedures on subjects of care. It includes also, e.g., the management of information about patients, their health status and their relationship with their healthcare framework.

[CEN TC/251 PT30]

3.18
healthcare agent
healthcare person, healthcare organization, healthcare device or healthcare software component that performs a role in a healthcare activity

[ENV 13607]

3.19
healthcare data card
machine-readable card conformant to ISO 7810 intended for use within the healthcare domain

3.20
healthcare organization
organization involved in the direct or indirect provision of healthcare services to an individual or to a population

NOTE 1 Groupings or subdivisions of an organization, such as departments or sub-departments, may also be considered as organizations where there is need to identify them.

NOTE 2 “Healthcare organizations” is a subset of “healthcare agents”.

[ENV 13607] [ENV 1613]

3.21
healthcare party
organization or person involved in the direct or indirect provision of healthcare services to an individual or to a population

NOTE "Healthcare parties" is a subset of "healthcare agents".

[ENV 13607]

3.22
healthcare person
person involved in the direct or indirect provision of healthcare services to an individual or to a population

NOTE "Healthcare persons" is a subset of "healthcare parties", which again is a subset of "healthcare agents".

EXAMPLE Primary care physician, dentist, nurse, social worker, pharmacist, medical secretary.

[ENV 13607]

3.23
healthcare professional
person entrusted with the direct or indirect provision of defined healthcare services to a subject of care or a population of subjects of care

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

[ENV 1613:1995]

3.24
immediate container
container that is in direct contact with the pharmaceutical product

[ENV 12610]

3.25
ingredient
substance included as a component in a product

NOTE In this context product refers to pharmaceutical product.

[ENV 13607]

3.26
international coding scheme identifier
unique permanent identifier of a coding scheme registered for use in information interchange under the terms of ISO/IEC 7826-1 and ISO/IEC 7826-2

[ENV 13607]

3.27
linkage
ability to join together two or more entities or parts

NOTE A linkage can be physical, electrical or relational.

3.28
magistral medicinal product
extemporaneous medicinal product
medicinal product manufactured in a pharmacy or a pharmacy department, which is based on a recipe and is intended to be used for one and only one subject of care

NOTE 1 A magistral/extemporaneous medicinal product is also a pharmaceutical product.

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

[ENV 13607] [ENV 12610]

3.29
medicinal appliance
device or piece of equipment which may be used by human beings or administered to animals for treating or preventing disease, with the view to making medical diagnosis, to restore, correct or modify physiological functions or to alleviate handicap

NOTE In order to be prescribable a medicinal appliance should fall within the purpose of prescribing as accepted by local rules/traditions in the area. The purpose of prescribing may be a requirement for formal reimbursement, restrictions on general sale of the appliance or need for labelling the appliance with individual instructions for use.

EXAMPLE Syringes, spacers for inhalation, diagnostic kits for pregnancy, bandages, catheters, nappies for incontinence, orthopaedic shoes, colostomy bags, wheel chairs, pneumatic mattresses.

[ENV 13607]

3.30
medicinal product
any substance 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 Some medicinal products are prescribed as a combination of a medicinal product and a medicinal appliance. Such combinations are regarded in this part of ISO 21549 as medicinal products.

[ENV 13607]

3.31
medicinal product package
package
delivery unit of a medicinal product in an outer container

[ENV 12610]

3.32
organization
unique framework of authority within which a person or persons act, or are designated to act towards some purpose

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

3.33
outer container
container that serves as an external layer of a package

[ENV 12610]

3.34
payment guarantor
organization responsible for the total or partial reimbursement or payment of the price of the medicinal product

[ENV 13607]

3.35
pharmaceutical product
product consisting of one or more ingredients

[ENV 13607]

3.36
prescriber
healthcare person authorized to issue prescriptions

[ENV 13607]

3.37
prescribing
process of creating a prescription

[ENV 13607]

3.38
prescription
direction created by an authorized healthcare person, to instruct a dispensing agent regarding the preparation and use of a medicinal product or medicinal appliance to be taken or used by a subject of care

NOTE The term “prescription” alone should be avoided as it is colloquially used at random for the following terms: new prescription message, prescription set and prescription item. Further, it is also used to describe a prescription form. The use of the terms prescription set, prescription item and new prescription message where appropriate is recommended.

[ENV 13607]

3.39
prescription item
specification created by an authorized healthcare person, to instruct a dispensing agent regarding the preparation and use of single medicinal product/medicinal appliance or to inform other parties following dispensing regarding the preparation and use of a single dispensed medicinal product/medicinal appliance

NOTE A prescription item may contain administrative details needed for dispensing or derived from dispensing, but not contain information about the prescriber or the subject of care for whom the prescription item is prescribed or to whom it has been dispensed.

[ENV 13607]

3.40
prescription set
collection of one or more prescription item(s) prescribed and/or dispensed as a unit

[ENV 13607]

3.41
record
collection of data

3.42
record person
individual about whom there is an identifiable record containing person-related data

3.43
security
combination of security properties (such as availability, confidentiality, integrity and accountability) which constitutes a guarantee that data items and, more generally, any kind of security object has not been altered, modified, disclosed or withheld by any kind of security subject in an unauthorized manner with respect to the security policy

[ITSEC]

3.44
standard
document established by consensus and approved by a recognised body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context

NOTE Standards are based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits.

[ISO/IEC Guide 2:2004, definition 3.2]

3.45
subject of care
person or defined groups of persons receiving or registered as eligible to receive healthcare services or having received healthcare services

EXAMPLE Patient.

[ENV 12443:1996]

3.46
syntax
structure of expressions in a language, and the rules governing the structure of the language; the relationships among characters or groups of characters, independent of their meanings or the manner of their interpretation and use

4 Symbols and abbreviated terms

DIM Domain Information Model

ENV European Prestandard

GMD General Message Description

GP General Practitioner

HGMD Hierarchical General Message Description

ICSI International Coding Scheme Identifier

IMS Implementable Message Specification

PrENV Draft European Prestandard

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 a UML class diagram as shown below in Figure 1.

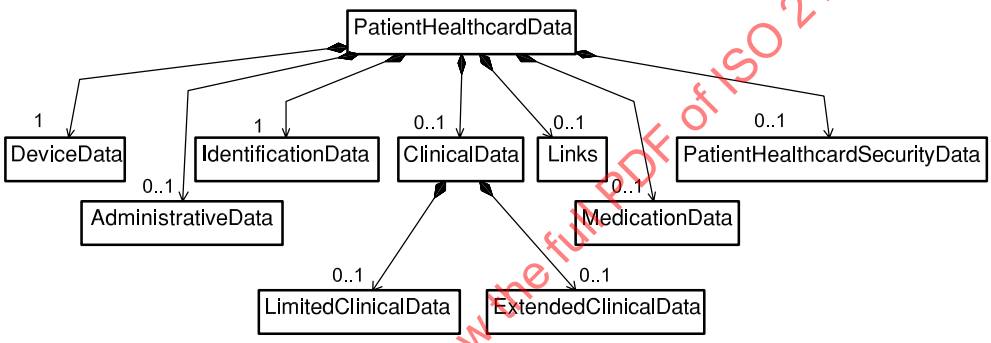

Figure 1 — Patient Healthcard data — Overall structure

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 part of ISO 21549.

NOTE It is possible to take the data objects and recombine them whilst 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 part of ISO 21549 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 intrinsic value in themselves, but which are used to define other objects within this part of ISO 21549. Operations may be performed with these objects in association with other information objects to “add value”. These objects have formal definitions within ISO 21549-2.

5.2.2 Coded data

Coded values are understood by reference to the coding scheme to which they apply. The general principle in this part of ISO 21549 is that it is not mandatory to use a particular coding scheme, unless specified within this part of ISO 21549, when such codes act as parameters. One example is the use of EN 23166 for country codes.

When a coding scheme is exclusively specified within this part of ISO 21549 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 part of ISO 21549.

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 part of ISO 21549 utilizes a series of security attributes, defined in ISO 21549-2. The actual data content (value) is not within the scope of this part of ISO 21549, 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 application developers and can be controlled by automated systems such as healthcare 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. These 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 an audit trail 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

Health cards 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 the scope of this part of ISO 21549.

The major consideration in this part of ISO 21549 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 dispensing agent 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. The case is similar for prescriber and dispensing agent; whilst 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 person (see Clause 3) and is the healthcare person 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 more qualified healthcare person 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 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 medicinal products* are treated separately.

b) Strength

c) Drug form

d) Quantity

e) Factor of the quantity

f) Manufacturer

g) Code in respect to all above except possibly factor of quantity

h) *Magistral medicinal product* (synonym – “extemporaneous product”)

6.2.5 Times

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 days between supplies”).

6.2.6 HOW

This information relates to a prescription item.

a) Dosage instruction (plain text, CODED + Numeric possible 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 *aut idem*.

f) Repeat prescription (No. + possible time interval).

g) Preferred language of the patient.

h) Language of the prescription (these two refer to the prescription set).

6.3 Card information on dispensed prescriptions

Information on cards may also contain data on the actual dispensed items. This information may be used at a future dispensing occasion by a dispenser or 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 history

A major use of healthcards containing prescription information has been to create an accumulated list of all medication for a patient. This may result from the recording of prescription items for dispensing, but it may also be of interest to record medication notes when there is no intention of using the information for dispensing.

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 information could be primarily prescribers, but also other health professionals trying to understand the medical history of the patient. It may also be used by a pharmacist not only when giving advice in relation to dispensing of a prescription item but also when considering the sale of non-prescription items.

Finally, this information could be accessed by patients or their non-health professional care givers thereby enabling them to not only use the information but also have it to aid them in decisions they may take.

7 Medication data

7.1 General

The medication data object is divided into four separate sub-objects:

— medication notes;

— medication prescriptions; medications dispensed;

— medication references.

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

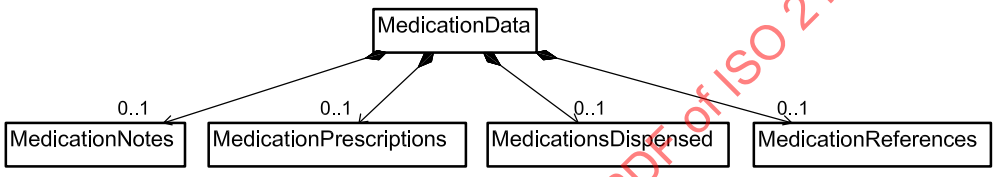

Figure 2 — Structure of Medication data

Table 1 — The specification of individual entities within Medication data

	Data type	Multiplicity	Comments
Medication Notes	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.
Medication Prescriptions	Class	0..1	This class holds the data that form the basis of a medication data record including the authority to dispense the medications. It consists of 1..M Medication Prescription.
Medications Dispensed	Class	0..1	This class holds the data that form the basis of a dispensing record. It consists of 1..M Medication Dispensed. NOTE The data held in this object do not necessarily have to echo the data contained within the medication prescribed object. They may reference that object, but may 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 medication prescription data object is present on the card.
Medication References	Class	0..1	This class holds the Globally Unique Identifiers and locations that relate to medication data sets held on other resources. It consists of 1..M Medication Reference. NOTE Use of the data contained therein allows the healthcard to function as a token for facilitating communication between overtly disconnected static information systems.

7.2 The “Medication Notes” data object

7.2.1 General

The medication notes contains voluntary, personal documentation of pharmaceutical supply for patients. It includes the drugs handed out in the pharmacy, including self-medication; prescriptions 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 Medication Notes can 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.

Use of the Medication Notes is voluntary for the patient, physician or pharmacist. Target groups are in particular patients who must be treated by more than one doctor as well as patients exposed to specific risks.

NOTE The Medical Notes do not necessarily give a complete overview of all medication-relevant data. Rather, because its use is voluntary, 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 Medical Notes on which these are based.

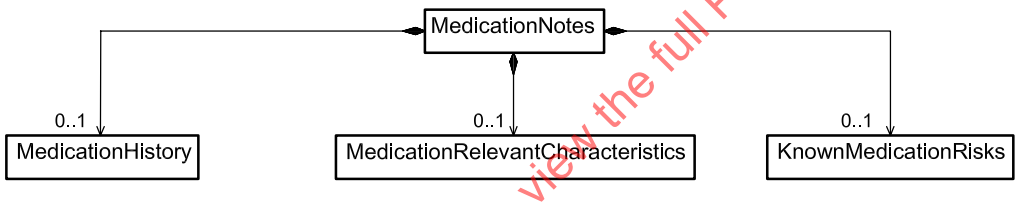

Figure 3 — Structure of Medication Notes

Table 2 — The specification of individual entities within Medication Notes

Attribute name	Data type	Multiplicity	Comments
Medication History	Class	0..1	This class holds the medication history record of the recorded person. It consists of 1..M Medication Received and may include the element “AccessoryAttributes”.
Medication Relevant Characteristics	Class	0..1	This class holds the medication relevant characteristics record of the recorded person. It consists of 1..M Patient Characteristic and may include the element “AccessoryAttributes”.
Known Medication Risks	Class	0..1	This class holds the known medication risks record of the recorded person. It consists of 1..M Known Interaction or Contra-indication and may include the element “AccessoryAttributes”.

ASN.1 data definitions:

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

7.2.2 The “Medication History” data object

The medication history record contains medication which has been supplied to the patient for ingestion or administered to him. Here provision is made for storing merely an unambiguous drug code that can 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, date 1 is transferred to date 2 and the new date of dispensation is entered into the date 1 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.

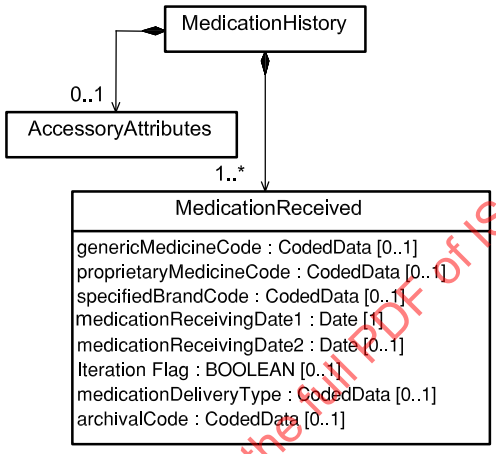

Figure 4 — Structure of Medication History

Table 3 — The specification of individual entities within Medication Received

Attribute name	Data type	Multiplicity	Comments
Generic Medicine Code	Coded data	0..1	Contains the generic description of the medication prescribed.
Proprietary Medicine Code	Coded data	0..1	Contains the proprietary nomenclature for the medication prescribed.
Specified Brand Code	Coded data	0..1	Coded data that shall represent the particular brand of a specified proprietary medicine. NOTE 1 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. NOTE 2 The Generic Med Code, Proprietary Med Code and Specified Brand Code are conditional i.e. one of these has to be present.
Medication Receiving Date1	Date	1	Contains the last date at which the patient received the medication.
Medication Receiving Date2	Date	0..1	Contains the date before last at which the patient received the medication.
Iteration Flag	Boolean	0..1	If set to TRUE indicates that the patient received the medication more than twice.
Medication Delivery Type	Coded data	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).
Archival Code	Coded data	0..1	Records if a medication is not currently taken using the structure of coded data.

ASN.1 data definitions:

```
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
}

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

NOTE Basic date format of ISO 8601: YYYYMMDD; also allowed: YYYYMM or YYYY.

7.2.3 The "Medication Relevant Characteristics" data object

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.

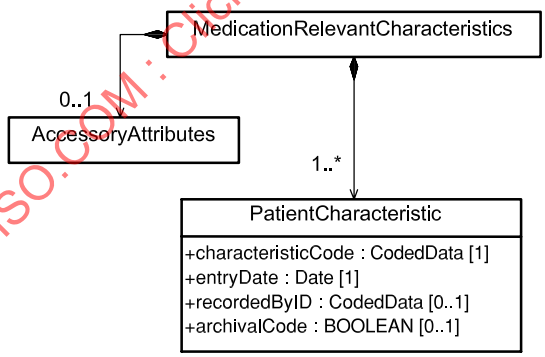

Figure 5 — Structure of Medication Relevant Characteristics

Table 4 — The specification of individual entities within Patient Characteristics

Attribute name	Data type	Multiplicity	Comments
Characteristic Code	Coded data	1	Contains coded data representation of the medication relevant patient characteristic.
Entry Date	Date	1	
Recorded By ID	Coded data	0..1	Contains the unique identifier of the doctor or pharmacist who recorded the characteristic.
Archival Code	Boolean	0..1	If set to TRUE indicates that a patient characteristic no longer exists (e.g. pregnancy).

ASN.1 data definitions:

```
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
}
```

7.2.4 The "Known Medication Risks" data object

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 can be individually classified via a field type (e.g. medication, diagnosis, age, gender) and whose type of link (e.g. interaction, contra-indication, drug allergy) has been specified.

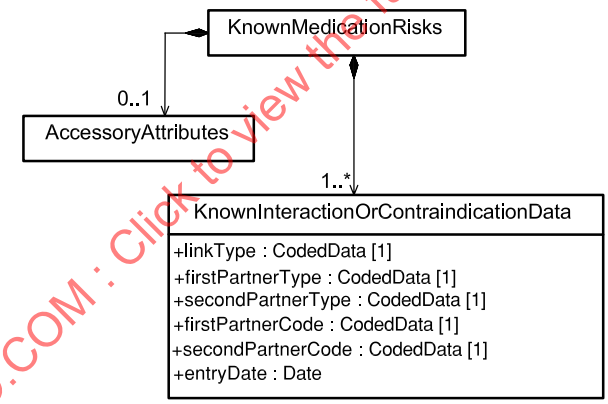

Figure 6 — Structure of Known Medication Risks

Table 5 — The specification of individual entities within Known Interaction or Contra-indication

Attribute name	Data type	Multiplicity	Comments
Link Type	Coded data	1	Contains coded data representation of the medication risk which is caused by the specified partners.
First Partner Type	Coded data	1	
Second Partner Type	Coded data	1	
First Partner Code	Coded data	1	
Second Partner Code	Coded data	1	
Entry Date	Date	1	

ASN.1 data definitions:

```
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
}
```

7.2.5 Example

Class/Attribute name	Data type	Multiplicity	Example data
Medication Notes	Class	0..1	
- Medication History	Class	0..1	
- - Medication Received	Class	1..M	
- - - Generic Medicine Code	Coded data	0..1	
- - - - codingSchemeRef	Integer	1	<RefPointer>
- - - - codeDataValue	String	1	C08CA05
- - - - codeDataFreeText	String	0..1	Nifedipine
- - - Medication Receiving Date1	Date	1	20030904
- - - Medication Receiving Date2	Date	0..1	20030618
- - - Medication Delivery Type	Coded data	0..1	
- - - - codingSchemeRef	Integer	1	<RefPointer>
- - - - codeDataValue	String	1	A
- - - - codeDataFreeText	String	0..1	Prescription
- Medication Relevant Characteristics	Class	0..1	
- - Patient Characteristic	Class	1..M	
- - - Characteristic Code	Coded data	1	
- - - - codingSchemeRef	Integer	1	<RefPointer>
- - - - codeDataValue	String	1	C
- - - - codeDataFreeText	String	0..1	allergic to milk
- - - Entry Date	Date	1	20021011
- - - Recorded By ID	Coded data		
- - - - codingSchemeRef	Integer	1..1	<RefPointer>
- - - - codeDataValue	String	1..1	<id of physician>
- Known Medication Risks	Class	0..1	
- - Known Interaction Or Contraindication	Class	1..M	
- - - Link Type	Coded data	1	
- - - - codingSchemeRef	Integer	1	<RefPointer>
- - - - codeDataValue	String	1	C
- - - - codeDataFreeText	String	0..1	Interaction
- - - First Partner Type	Coded data	1	
- - - - codingSchemeRef	Integer	1	<RefPointer>
- - - - codeDataValue	String	1	A
- - - - codeDataFreeText	String	0..1	Drug
- - - Second Partner Type	Coded data	1	
- - - - codingSchemeRef	Integer	1	<RefPointer>
- - - - codeDataValue	String	1	A
- - - - codeDataFreeText	String	0..1	Drug
- - - First Partner Code	Coded data	1	
- - - - codingSchemeRef	Integer	1	<RefPointer>
- - - - codeDataValue	String	1	C08CA05
- - - - codeDataFreeText	String	0..1	Nifedipine
- - - Second Partner Code	Coded data	1	
- - - - codingSchemeRef	Integer	1	<RefPointer>
- - - - codeDataValue	String	1	C07AB07
- - - - codeDataFreeText	String	0..1	Bisoprolol
- - - Entry Date	Date	1	20030317

7.3 The “Medication Prescriptions” data object

The medication prescriptions data object shall consist of a set of Medication Prescriptions, which includes the elements “Prescriber” and “PrescriptionItem” and it may include the element “AccessoryAttributes”. The element “Prescriber” contains data that identifies the healthcare party that is the legal authorizer for the prescription (can contain this data by reference or by containment).

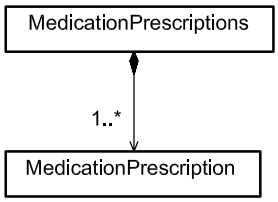

Figure 7 — Structure of Medication Prescriptions

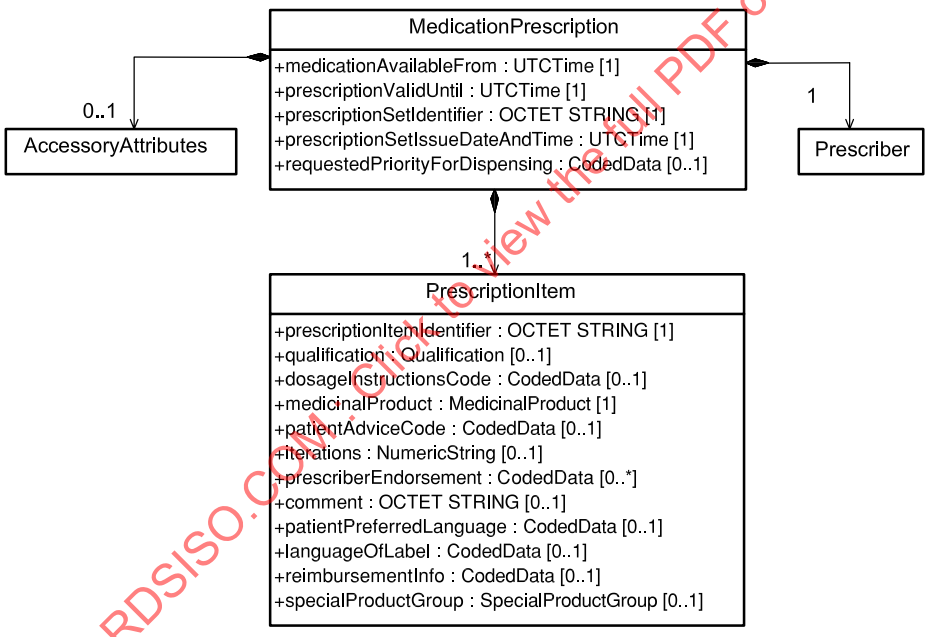

Figure 8 — Structure of Medication Prescription

Table 6 — The specification of individual entities within Medication Prescription

Attribute name	Data type	Multiplicity	Comments
Medication Available From	UTC Time	1	This date is the representation of the legal date from which the medication can be dispensed.
Prescription Valid Until	UTC Time	1	This date is the representation of the legal date from which the medication can no longer be dispensed. NOTE In some countries or organisations this period of time 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.
Prescription Set Identifier	String	1	The unique identification of the prescription set.
Prescription Set Issue Date And Time	UTC Time	1	
Requested Priority For Dispensing	Coded Data	0..1	Request for a higher priority of dispensing than routine handling.
Prescriber	Class	1	The unique identifier of the prescribing person.
Prescription Item	Class	1..M	This class holds the information about the prescribed medicinal product (see Table 7).

Table 7 — The specification of individual entities within Prescription Item

Attribute name	Data type	Multiplicity	Comments
Prescription Item Identifier	String	1	The unique identification of the prescription item.
Qualification	Enumerated	0..1	Indicates if the prescribed item is acute medication (0), long-term medication (1) or only administered when required (2).
Dosage Instructions Code	Coded data	0..1	Contains the coded data representation of the instruction on how and when to take the medication.
Medicinal Product	Class	1	This class holds the information about the prescribed manufactured medicinal product (specialization “Manufactured Medicinal Product”, see Table 8) or the information about the prescribed magistral medicinal product (specialization “Magistral Medicinal Product”, see Table 12).
Patient Advice Code	Coded data	0..1	Contains the coded data representation of additional advice to be given to the recipient of the medication.
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.
Prescriber Endorsement	Coded data	0..M	May contain data that act as trigger to case-specific events or record case-specific information added by the prescriber.
Comment	String	0..1	Contains additional information for the dispenser.
Patient Preferred Language	Coded data	0..1	Contains the coded data representation of the language the patient prefers to communicate in.
Language of Label	Coded data	0..1	Contains the coded data representation of the language used when labelling the medicine with the dosage instructions and patient advice.
Reimbursement Info	Coded data	0..1	Contains coded data representation of administrative financial reimbursement information.
Special Product Group	Class	0..1	This class holds additional information if the prescribed medicinal product belongs to a special product group (see Table 16).

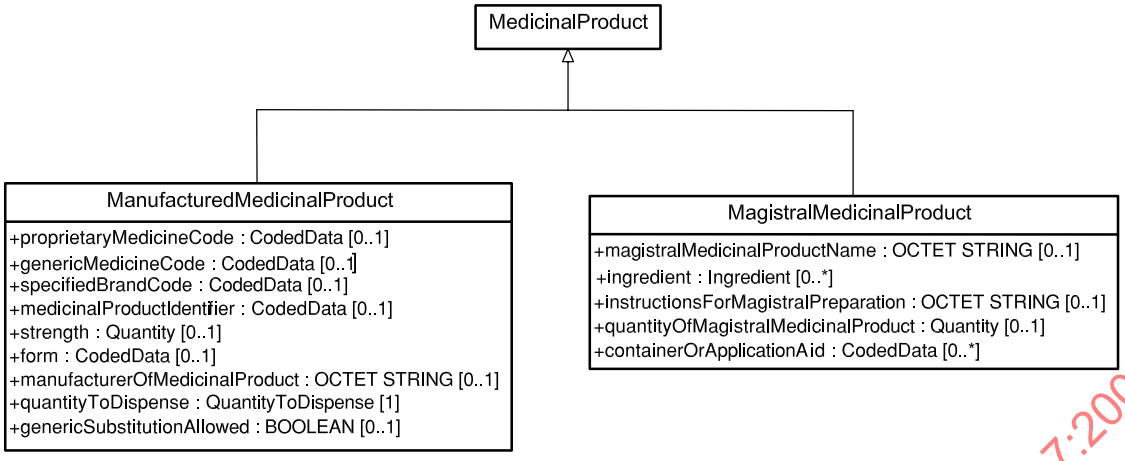

Figure 9 — Structure of Medicinal Product

Table 8 — The specification of individual entities within Manufactured Medicinal Product

Attribute name	Data type	Multiplicity	Comments
Proprietary Medicine Code	Coded data	0..1	Contains the Coded Data Representation of the proprietary name for the medication.
Generic Medicine Code	Coded data	0..1	Contains the Coded Data Representation of the Generic name for the medication (e.g. ATC code).
Specified Brand Code	Coded data	0..1	Coded data that shall represent the particular brand of a specified proprietary medicine. NOTE 1 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 NOTE 2 The Generic Med Code, Proprietary Med Code and Specified Brand Code are conditional i.e. one of these has to be present.
Medicinal Product Identifier	Coded data	0..1	Contains the local code for the medication (explicit).
Strength	Quantity	0..1	The pharmaceutical strength (see Table 15).
Form	Coded data	0..1	Contains the coded data representation of the form that the medicine is to be supplied in.
Manufacturer Of Medicinal Product	String	0..1	
Quantity To Dispense	Class	1	The total quantity of medication to be dispensed at each iteration (see Table 9).
Generic Substitution Allowed	BOOLEAN	0..1	If set to TRUE indicates that the dispenser of the prescription may dispense the generic equivalent of the medication represented within Proprietary Medicine Code.

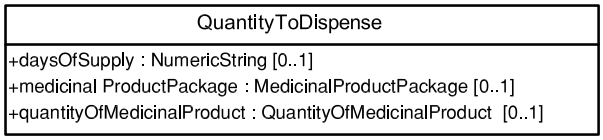

Figure 10 — Structure of Quantity to Dispense

Table 9 — The specification of individual entities within Quantity to Dispense

Attribute Name	Data Type	Multiplicity	Comments
Days Of Supply	Numeric string	0..1	The number of days of supply.
Medicinal Product Package	Class	0..1	This class holds the information about the prescribed delivery unit of a medicinal product in an outer container (see Table 11). NOTE The attributes Days of Supply Quantity Of Medicinal Product and Medicinal Product Package are conditional, i.e. one must be present. They are also alternative, i.e. only one may be present.
Quantity Of Medicinal Product	Class	0..1	This class holds the information about the prescribed quantity of medicinal product (see Table 10).

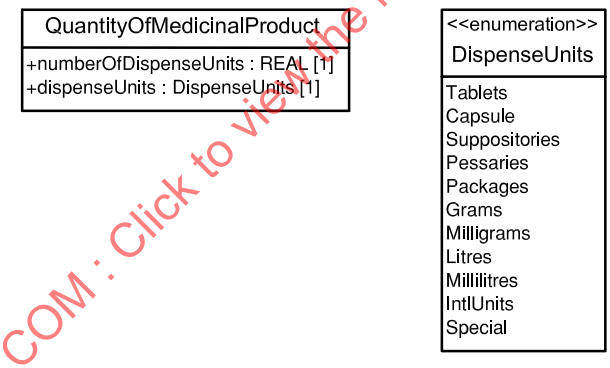

Figure 11 — Structure of Quantity of Medicinal Product

Table 10 — The specification of individual entities within Quantity Of Medicinal Product

Attribute Name	Data Type	Multiplicity	Comments
Number Of Dispense Units	Real	1..1	The number of units of supply
Dispense Units	Enumerated	1..1	

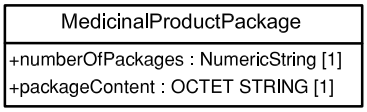

Figure 12 — Structure of Medicinal Product Package

Table 11 — The specification of individual entities within Medicinal Product Package

Attribute name	Data type	Multiplicity	Comments
Number Of Packages	Numeric string	1..1	
Package Content	String	1..1	Amount of medicinal product as supplied by the manufacturer or distributor.

Table 12 — The specification of individual entities within Magistral Medicinal Product

Attribute name	Data type	Multiplicity	Comments
Magistral Medicinal Product Name	String	0..1	E.g. an officinal name from a pharmacopoeia. NOTE For the case of using an officinal name the designation of ingredients is not absolutely necessary.
Ingredient	Class	0..M	This class holds the information about a component of a magistral medicinal product (see Table 13). NOTE The Magistral Medicinal Product Name and Ingredient are conditional i.e. one of these has to be present.
Instructions for Magistral Preparation	String	0..1	Instruction to the dispenser in which way the magistral medicinal product should be prepared.
Quantity of Magistral Medicinal Product	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 officinal name from a pharmacopoeia is specified). (See Table 15.)
Container or Application Aid	Coded data[a]	0..M	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.

[a] The data type “coded data” can only be used if it is possible to specify only the name. For example the attribute “codeDataValue” within “coded data” containing “0000” means that only free text is specified (in attribute “code DataFreeText”).

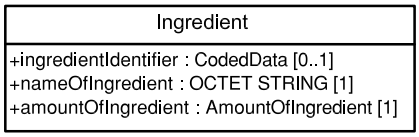

Figure 13 — Structure of Ingredient

Table 13 — The specification of individual entities within Ingredient

Attribute name	Data type	Multiplicity	Comments
Ingredient Identifier	Coded data	0..1	The unique identification of the ingredient.
Name Of Ingredient [a]	String	1..1	
Amount Of Ingredient	Class	1..1	(See Table 14.)

[a] This attribute can be integrated in “ingredient identifier” if it is possible to specify only free text. In that case the multiplicity of “ingredient identifier” is 1..1.

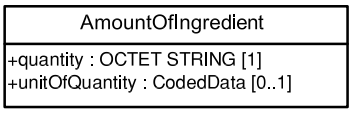

Figure 14 — Structure of Amount of Ingredient

Table 14 — The specification of individual entities within Amount of Ingredient

Attribute name	Data type	Multiplicity	Comments
Quantity	String	1..1	Numeric or non-numeric (e.g. equal parts) occurrence.
Unit Of Quantity	Coded data	0..1	Shall be present if the content of “Quantity” is of numeric type.

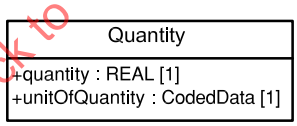

Figure 15 — Structure of Quantity

Table 15 — The specification of individual entities within Quantity

Attribute name	Data type	Multiplicity	Comments
Quantity	Real	1..1	
Unit Of Quantity	Coded data	1..1	

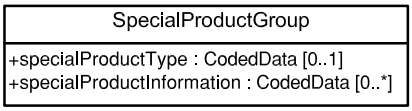

Figure 16 — Structure of Special Product Group

Table 16 — The specification of individual entities within Special Product Group

Attribute name	Data type	Multiplicity	Comments
Special Product Type	Coded data	0..1	Contains the coded data representation of the special product type e.g. narcotics, medicinal appliances, vaccines.
Special Product Information	Coded data	0..M	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.)

ASN.1 data definitions:

```
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] Prescriber,
accessoryAttributes              [7] AccessoryAttributes OPTIONAL
}

PrescriptionItem                 ::= SET
{
prescriptionItemIdentifier       [0] OCTET STRING,
qualification                    [1] ENUMERATED OPTIONAL {
                                 acute medication (0), long-term medication (1),
                                 only administered when required (2) }
dosageInstructionsCode           [2] CodedData OPTIONAL,
medicinalProduct                 [3] MedicinalProduct,
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
}

MedicinalProduct                 ::= CHOICE
{
manufacturedMedicinalProduct     [0] ManufacturedMedicinalProduct,
magistralMedicinalProduct        [1] MagistralMedicinalProduct
}

ManufacturedMedicinalProduct     ::= SET
{
proprietaryMedicineCode          [0] CodedData OPTIONAL,
genericMedicineCode              [1] CodedData OPTIONAL,
specifiedBrandCode               [2] CodedData OPTIONAL,
medicinalProductIdentifier       [3] Coded Data OPTIONAL,
strength                         [4] Quantity OPTIONAL,
form                             [5] Coded Data OPTIONAL,
```

```
manufacturerOfMedicinalProduct   [6] OCTET STRING OPTIONAL,
quantityToDispense               [7] QuantityToDispense,
genericSubstitutionAllowed       [8] BOOLEAN OPTIONAL
}

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

QuantityOfMedicinalProduct         ::= SEQUENCE
{
numberOfDispenseUnits            [0] REAL,
dispenseUnits                    [1] ENUMERATED
                                 {
                                 Tablets (0),
                                 -- This includes other forms of special “tablets” that may be sold as an
                                 arbitrary No. of individual entities
                                 Capsule (1),
                                 -- This includes other forms of special “capsules” that may be sold as an
                                 arbitrary No. of individual entities
                                 Suppositories (2),
                                 Pessaries (3),
                                 -- This includes other forms of special “pessaries” that may be sold as an
                                 arbitrary No. of individual entities
                                 Packages (4),
                                 Grams (5),
                                 Milligrams (6),
                                 Litres (7),
                                 Millilitres (8),
                                 IntlUnits (9),
                                 Special (10) }
}

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

MagistralMedicinalProduct          ::= 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,
amountOfIngredient                     [2] AmountOfIngredient
}
```

```
amountOfIngredient              ::= SEQUENCE
{
quantity                         [0] OCTET STRING,
unitOfQuantity                   [1] CodedData 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.
```

7.4 The “Medications Dispensed” data object

A "Medications Dispensed" data object shall consist of a set of "Medication Dispensed", which includes one or more elements “DispensedItem” and the element “Prescriber” and it may include the element “AccessoryAttributes”.

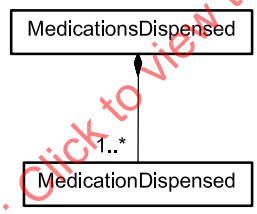

Figure 17 — Structure of Medications Dispensed

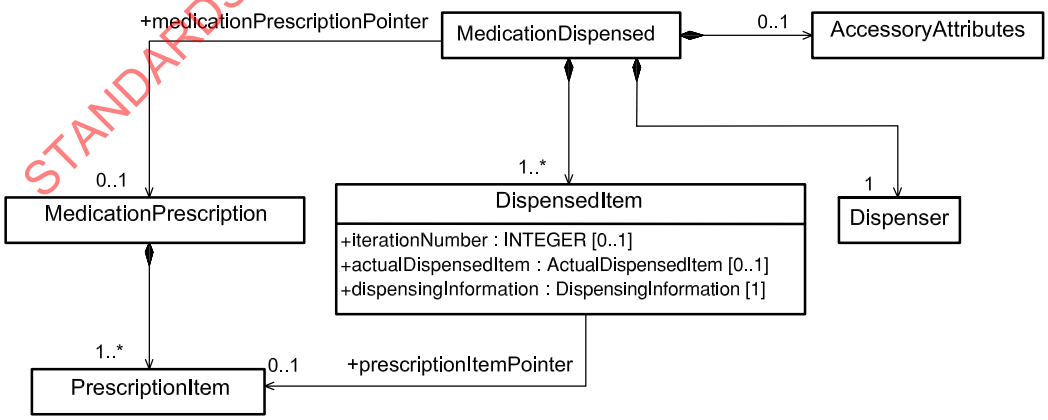

Figure 18 — Structure of Medication Dispensed

Table 17 — The specification of individual entities within Medication Dispensed

Attribute name	Data type	Multiplicity	Comments
Medication Prescription Pointer	Ref. pointer	0..1	Points to the Medication Prescription object.
Dispensed Item	Class	1..M	See Table 18.
AccessoryAttributes	Class	0..1	The Accessory Attributes
Dispenser	Class	1	The unique identifier of the dispenser

Table 18 — The specification of individual entities within Dispensed Item

Attribute name	Data type	Multiplicity	Comments
Prescription Item Pointer	Ref. pointer	0..1	Points to the Prescription Item object.
Iteration Number	Integer	0..1	Records the iteration number of this dispensing issue in relation to the medication referenced by the Prescription Item Pointer.
Actual Dispensed Item	Class	0..1	Complete data set utilized 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 cannot be referenced (see Table 19). NOTE If no Medication Prescribed Pointer exists in the Dispensed Item 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 and 1 × 10 tablets instead of 1 × 50 tablets). For this reason dispensing of more than one product for each prescription item is allowed.
Dispensing Information	Class	1	Contains information particular to this dispense episode (see Table 20).

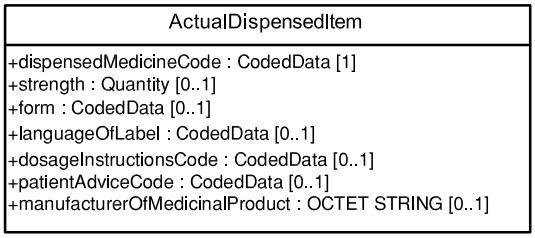

Figure 19 — Structure of Actual Dispensed Item