Data model for an electronic medicinal product reference catalogue – a National Standard.

January 2015

Safer Better Care

About the Health Information and Quality Authority

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

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

- **Setting Standards for Health and Social Services** – Developing person-centred standards, based on evidence and best international practice, for those health and social care services in Ireland that by law are required to be regulated by the Authority.

- **Supporting Improvement –** Supporting health and social care services to implement standards by providing education in quality improvement tools and methodologies.

- **Social Services Inspectorate** – Registering and inspecting residential centres for dependent people and inspecting children detention schools, foster care services and child protection services.

- **Monitoring Healthcare Quality and Safety** – Monitoring the quality and safety of health and personal social care services and investigating as necessary serious concerns about the health and welfare of people who use these services.

- **Health Technology Assessment** – Ensuring the best outcome for people who use our health services and best use of resources by evaluating the clinical and cost effectiveness of drugs, equipment, diagnostic techniques and health promotion activities.

- **Health Information** – Advising on the efficient and secure collection and sharing of health information, evaluating information resources and publishing information about the delivery and performance of Ireland's health and social care services.

Overview of Health Information function

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

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

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

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

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

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

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

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

One of the areas currently being addressed is the area of electronic prescribing and the electronic transfer of prescriptions. In order to electronically exchange information on medicinal products between prescribers and dispensers, medicinal products need to be uniquely identified. This is achieved through maintaining an electronic catalogue of medicinal products which can be used in both prescribing and dispensing systems. This project aims to identify the required concepts and their attributes to support the implementation of an electronic medical product reference catalogue.

Table of Contents

Executive Summary

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

In recent years, the Authority has undertaken multiple projects in the area of ePrescribing and ETP. An international review of ePrescribing and the electronic transfer of prescriptions[2] showed that in the countries reviewed, ETP was successfully implemented at a national level between primary care and community pharmacies. Based on this international review, it was apparent that there are a number of fundamental building blocks that must be in place prior to developing an ETP solution. These include:

- the introduction of an individual health identifier (IHI) and an identifier for health and social care professionals and organisations.
- the development of an interoperability framework and supporting infrastructure to facilitate the safe and secure electronic transfer of prescriptions between prescribers and dispensers.
- the development of a data model to support the implementation of a national medicinal product reference catalogue.
- the development of messaging standards to support ETP.

This project defines the data model required to support the implementation of an electronic medicinal product reference catalogue. An electronic medicinal product reference catalogue is an electronic dictionary of medications available for prescribing and dispensing. The key aim of the catalogue is to provide a consistent approach to the identification and naming of medicines prescribed and dispensed.

A data model is a formal description of how data may be structured and accessed for a given business process. Data models provide a structure for data used within information systems and provide formal definitions for the structure of the data. If a data model is used consistently across systems, then compatibility of data can be achieved.

The data model catalogue was developed by the Authority in collaboration with our eHealth Standards Advisory Group (eSAG) and a technical subgroup supporting the work of the eSAG. Implementations of data models in other jurisdictions including Australia and the United Kingdom and a collection of five standards known as the Identification of Medicinal Product[3-7] developed by the Internal Standards Organisation informed the development of the draft data model for an electronic medicinal product reference catalogue.

In order to consult with important interested and informed parties, a targeted consultation was conducted by the Authority. The Authority distributed a consultation document in late 2014. Emails were sent to interested and informed parties (see Appendix A) inviting them to participate in the consultation. Overall, the data model for a medicinal product reference catalogue standard was welcomed by respondents and the benefits that it can bring were recognised. Each submission was read in its entirety and informed the development of the final standard. The standard was approved by the Authority's Executive Management Team (EMT) and the Authority's Board. It has been submitted to the Minister for Health for approval as a national standard.

The model consists of three 'virtual' concepts and three 'actual' concepts, as illustrated in Figure 1 below. The first horizontal axis represents the active ingredients or chemical compounds that are in the medicinal products. The second horizontal axis, the product level, represents creams, tablets, vials. They are the active ingredients with form, strength, route of administration and manufacturer information added. The third horizontal axis, the package level contains information on medication packs available on the market. At this level we are representing how the creams and tablets and vials of medication are packaged together.

Figure 1. High level data model
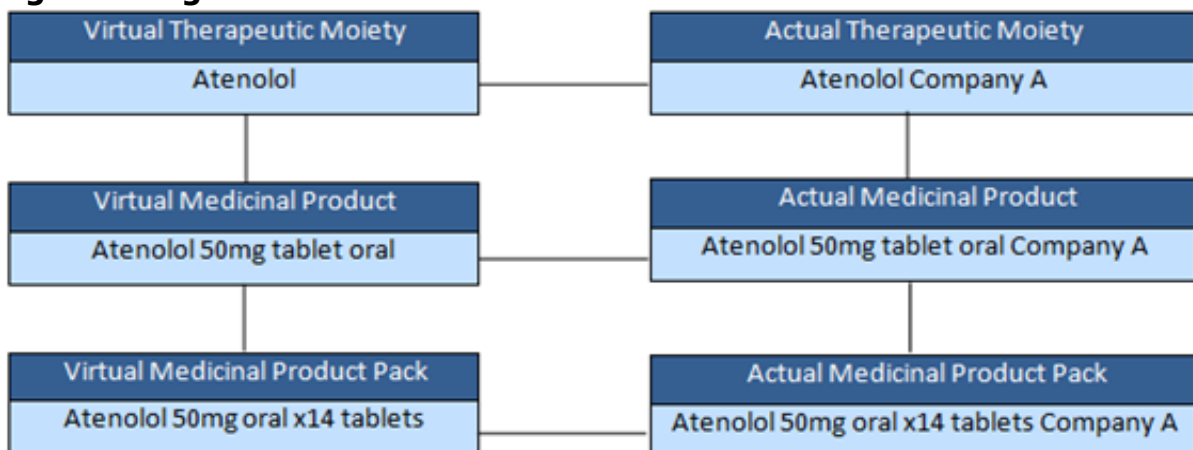
1. Introduction

ePrescribing was identified in the National eHealth Strategy (2013)[1] as a key priority for Ireland. In recent years, the Authority has undertaken multiple projects in the area of ePrescribing and the electronic transfer of Prescriptions (ETP). An international review of ePrescribing and the electronic transfer of prescriptions [2] undertaken by the Authority showed that in the six jurisdictions reviewed, each has commenced implementation or has already implemented ePrescribing solutions, with similarities and differences between them.

Each focused mainly on the prescribing and dispensing of medication in the community, rather than from a hospital setting to the community pharmacies. This can be explained by both GPs and pharmacists having similar processes with their peers and hence being able to support computerisation of the process. By contrast, hospital medication management processes are typically more complex, making standardisation and computerisation more complicated.

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

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

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

- the introduction of an individual health identifier (IHI) and an identifier for health and social care professionals and organisations
- the development of an interoperability framework and supporting infrastructure to facilitate the safe and secure electronic transfer of prescriptions between prescribers and dispensers
- the development of a data model to support the implementation of a national drugs reference catalogue
- the development of messaging standards to support ETP.

Based on the international review, a work plan for the Authority's eHealth Standards Advisory Group was developed. One of the items on the work plan was the development of a data model to support the implementation of an electronic medicinal product catalogue.

An electronic medicinal product catalogue is an electronic dictionary of medications available for prescribing and dispensing within a jurisdiction. The key aim of the electronic medicinal product reference catalogue is to provide a consistent approach to the identification and naming of medicines, which can support medicines management, prescribing and dispensing activity across health domains.

A data model is a formal description of how data may be structured and accessed for a given business process. It identifies the information classes and attributes associated with each class. Data models provide a structure for data used within information systems and provide formal definitions for the structure of the data. If a data model is used consistently across systems, then compatibility of data can be achieved.

The scope of a data model should include those classes and the attributes required to identify individual medicinal products that are available within the Irish healthcare sector, for the treatment or alleviation of discomfort in patients in both primary and secondary care.

Informed by a review of implementations of data models in other jurisdictions, including Australia and the United Kingdom, it was agreed that the scope of an electronic medicinal product reference catalogue should be limited to:

- product identification
- medicinal product names
- strength
- route of administration
- pack information
- price
- ingredient substances
- legal status
- form
- units of weight, volume and strength
- supplier identity
- certain specified additive substances (excipients)
- reimbursement information.

'Use cases' which will be supported include:

- dose based prescribing
- recording of partial medication information
- product based prescribing
- product identification and selection for dispensing
- recording of information within patient records
- identification/selection of pack size for dispensing
- provision of information for electronic reimbursement
- identification of pack size and availability
- pricing information.

There is a wide range of knowledge about medicines that could be recorded against individual medicinal products. Some of this information is best provided by knowledge bases and decision support application, rather than a reference catalogue. Examples of knowledge-based information that is not considered to be within the scope of the reference catalogue include, but are not limited to:

- adverse effects
- cautionary and advisory label recommendations
- contraindications
- counselling instructions
- dose checking
- drug/allergy interactions
- drug/drug interactions
- drug/food interactions
- indications
- normal dose ranges
- physiological equivalence
- precautions for use
- storage or supply chain related information.

2. Benefits of the electronic transfer of prescriptions

The implementation of a national electronic medicinal product reference catalogue based on an agreed data model is one of the initial steps required to support the implementation of electronic prescribing and the electronic transfer of prescriptions (ETP).

ETP and ePrescribing will benefit patients by ensuring safer care through:

- the reduction of manual data entry and therefore transcription errors, resulting in reduced risk of a prescribed medicine not being correctly dispensed
- greater accuracy in prescribed medicines descriptions and improved legibility of prescription details
- fewer hospital admissions or unwanted adverse effects because prescribers and dispensers can monitor patient compliance with prescribed medicines
- more efficient processes with prescriptions dispensed more quickly.

Healthcare practitioners who prescribe medicines will benefit from ETP through:

- notification when a patient collects prescribed medicines, which enables patient compliance and patient follow-up
- reduced interruptions from pharmacies querying prescriptions and fewer prescriptions returned to the prescriber for not complying with legal or subsidy requirements

▪ timely access to selected health information about an individual, if the ETP solution is linked to an electronic patient record, leading to better clinical decision making, safer and higher quality care.

Pharmacists who dispense medicines will benefit from ETP through:

▪ the use of a common list of medicines in both prescriber and pharmacy systems, meaning the pharmacy can more quickly and accurately select the intended medicine for the patient
▪ improved quality of prescription information and therefore a reduction in time spent contacting prescribers to clarify or correct prescriptions
▪ the ability to download prescription details can make the process more efficient with less room for error
▪ reduced reliance on the individual's recollection of their medication history
▪ efficiency gains, enabling pharmacists to provide other patient orientated services.

Organisations that fund the health and disability sector will benefit from ETP through:

▪ improved efficiency to health information flows and a reduction in duplicate prescribing
▪ potential cost reductions from improved patient compliance and reduced hospitalisation, due to monitoring the collection of prescriptions by individuals

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

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

3. Methodology

A draft data model for an electronic medicinal product reference catalogue was developed by the Authority in collaboration with our eHealth Standards Advisory Group and a technical subgroup supporting the work of the eSAG.

In order to develop an initial draft data model for a medicinal products reference catalogue, implementations of similar data models in other jurisdictions including Australia and the United Kingdom were reviewed. The collection of five standards known as the Identification of Medicinal Products, developed by the Internal Standards Organisation (ISO), were also reviewed and contributed to the process. The standards are:

- ISO 11615 - Identification of medicinal products – Data elements and structures for the unique identification and exchange of regulated medicinal product information[3].
- ISO 11616 - Identification of medicinal products – Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information[4].
- ISO 11238 - Identification of medicinal products – Data elements and structures for the unique identification and exchange of regulated information on substances[5].
- ISO 11239 - Identification of medicinal products – Data elements and structures for the unique identification and exchange on pharmaceutical dose form, units of presentation and routes of administration[6].
- ISO 11240 - Identification of medicinal products – Data elements and structures for the unique identification and exchange of units of measurement[7].

Subject matter experts in the Irish Pharmacy Union (IPU) and the Heath Products Regulatory Authority (HPRA) extensively reviewed the initial draft. Both organisations currently implement medicinal products reference catalogues. Their experience in maintaining their own products brought valuable expertise to the project and allowed for local requirement to be added to the data model. This was additional to the requirements identified from the review of the implementations internationally and the ISO standards.

In order to consult with key stakeholders, the Authority distributed a consultation document, the *Draft data model for an electronic medicinal product reference catalogue – a National Standard.* It was distributed in November 2014. A consultation feedback form was included which contained five questions. Targeted emails were sent to 25 organisations inviting them to participate in the consultation (see Appendix A). In total seven detailed responses were received to the targeted consultation. The responses were reviewed and 11 alterations to the data model were made in order to produce the final document – *Data model for an electronic medicinal product reference catalogue – a National Standard.* The standard was approved by the Authority's Executive Management Team (EMT) and the Authority's

Board. It has been submitted to the Minister for Health for approval as a national standard.

4. Data model classes

The data model consists of three 'virtual' concepts and three 'actual' concepts.

'Virtual' concepts refer to pharmacological information and are displayed on the left side of Figure 2. They are independent of supplier and jurisdiction and identify pharmaceutical concepts which may be used in actual medicinal products.

'Actual' concepts are displayed on the right side of the diagram and are used to identify actual medicinal products produced by suppliers and available for prescribing and dispensing. These concepts identify the packages dispensed by pharmacists and subsequently taken by patients.

The first horizontal axis represents information about the therapeutic moiety with the generic name on the left side and the commercial name on the right. The second horizontal axis represents the medicinal products with a specific strength and a route of administration included. The third horizontal axis contains information about the medicinal product packages as they are available on the market (including pack size and inner package).

Figure 2. High level data model
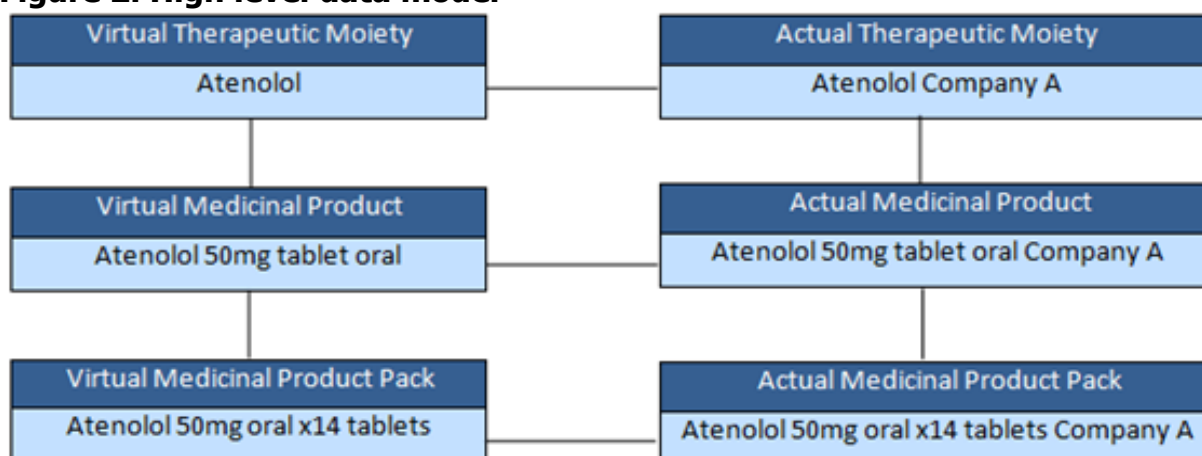
4.1 Virtual therapeutic moiety

A virtual therapeutic moiety (VTM) is an abstract representation of an active medicinal ingredient or substance devoid of strength and form, which when formulated as a medicinal product, is intended for use in preventing or treating diseases in patients.

It provides the highest level description of pharmaceutical agents and does not contain information on indication, strength, dose or route of administration. It is an abstract representation of substances intended for use by an authorised healthcare practitioner for use in the treatment of a patient. Figure 3 provides some examples of VTMs.

Figure 3. VTM examples

VTM – atenolol
VTM – atenolol + chlortalidone
VTM – paracetamol + codeine
VTM - sulfamethoxazole + trimethoprim (synonym Co-trimoxazole)
VTM - calcium carbonate
VTM - doxorubicin
VTM - hyoscine hydrobromide.

VTMs exist in order to support generic prescribing in primary or secondary care settings. A VTM may exist for a single active ingredient or may be a multi-ingredient VTM.

Extemporaneous preparation or manufacture refers to the process by which a pharmacist, using traditional compounding techniques, produces a medicinal product to meet the special needs of a patient, or group of patients, when no suitable authorised medicinal product is available. VTM's may not exist for extemporaneous preparations.

New VTMs arise when a patent is granted, or two existing VTMs are combined for use for the first time in a fixed combination. They may also arise through the regulatory authority on one jurisdiction becoming aware of the registration of a VTM in another jurisdiction.

VTMs are the highest level of the hierarchy and all other concepts are directly (virtual medicinal product, actual therapeutic moiety) or indirectly (virtual medicinal product pack, actual medicinal product, actual medicinal product pack) related to a VTM.

4.2 Actual therapeutic moiety

An actual therapeutic moiety (ATM) is a representation of a virtual therapeutic moiety associated with the brand name or principal marketing company. It is a trade level version of a VTM with a recognisable brand name. For generic products it will be the generic product and name of the registration holder. It contains no indication of strength or pack size.

Actual therapeutic moieties arise when a product is introduced onto the market. It may be removed after a product is discontinued or withdrawn from the market. An ATM is always linked to only one VTM, but a VTM may have multiple ATMs. Figure 4 provides examples of ATMs.

Figure 4. ATM examples

VTM – atenolol	
	ATM – Tenormin COMPANY A
	ATM – Ternomin COMPANY B
	ATM – Atenolol COMPANY C
VTM – atenolol + chlortalidone	
	ATM – Tenoretic COMPANY A
	ATM – Tenoretic COMPANY B
	ATM – Atenolol/Chlortalidone COMPANY C

4.3 Virtual medicinal product

A virtual medicinal product (VMP) is a representation of a VTM associated with strength information and a route of administration. It represents a collection of clinically equivalent pharmaceutical products with the same strength, dose form and the same routes of administration.

VMPs generally will equate to prescribable products but there will be some VMPs which will not be directly prescribable and an ability to flag this is required. A VMP may only be encountered as part of a combination pack and may not be prescribable in any pack size in its own right.

This level of concept supports decision making in clinical applications. It also represents products a healthcare practitioner may prescribe. In most cases, the name and strength will uniquely define a VMP, however, as in some cases therapeutic effect is determined by route and this is required when defining and naming a VMP.

The form of the VMP identifies if the VMP has a unit dose form such as a tablet or ampoule, if it is a continuous substance such as a cream or fluids, or if it belongs to a category of product for which unit dose form is not appropriate (catheters, colostomy bags). Strength is defined using three attributes - a numeric value relating to the dose, for example, 1, 5, 10, a unit of measure relating to the dose, for

example, tablet, ml, vial, application, and a description of the dose e.g. tablet, spoonful, vial, dose. Figure 5 provides examples of VTMs.

Figure 5. VTM examples

VTM – atenolol	
	VMP – atenolol 50mg tablet oral
	VMP – atenolol 100mg tablet oral
VTM – atenolol + chlortalidone	
	VMP – atenolol 50mg tablet + chlortalidone 12.5mg tablet oral
	VMP – atenolol 100mg tablet + chlortalidone 25mg tablet oral
	VMP – atenolol 100mg tablet + chlortalidone 12.5mg tablet oral
	VMP – atenolol 100mg tablet + chlortalidone 25mg tablet oral

A new VMP is created when a product is registered with a new therapeutic moiety or when an existing product is registered with a new strength or route of administration. A new VMP is also created when a new combination product is registered, or the constituents of an existing combination product are altered. VMPs allow daily dose and duration of treatments to be defined.

A VMP is always linked to a VTM and may be linked to one or more ATMs. A VMP will also be linked to one or more virtual medicinal product pack. A combination VMP will be linked to multiple VMPs.

4.4 Actual medicinal product

An actual medicinal product (AMP) is a medicinal product that has been made available by a supplier. It is the medicinal product that is taken by a patient. Each AMP is associated with an identifiable supplier. It is possible that certain AMPs may not be available for direct dispensing as they may only be part of a combination pack. An AMP may contain ingredients, known as excipients, which may be of clinical significance.

An AMP may comprise of a VMP with an associated brand name or principal marketing company, administration form and route of administration. Alternatively an AMP may be viewed as an ATM with strength, route of administration and administration form information.

AMPs corresponding to a certain VMP will contain the same therapeutic moiety but may vary in excipients used and the form (salt or ester) of the active product, hence differences in indications for use between AMPs may exist. Figure 6 provides examples of AMP's.

Figure 6. AMP examples

VTM – atenolol	
	AMP – atenolol 50mg oral COMPANY A
	AMP – atenolol 50mg oral COMPANY B
VTM – atenolol + chlortalidone	
	AMP – atenolol 50mg + chlortalidone 12.5mg oral COMPANY A
	AMP – atenolol 100mg + chlortalidone 25mg oral COMPANY A
	AMP – atenolol 100mg + chlortalidone 12.5mg oral COMPANY A
	AMP – atenolol 100mg + chlortalidone 25mg oral COMPANY A
	AMP – atenolol 50mg + chlortalidone 12.5mg oral COMPANY B
	AMP – atenolol 100mg + chlortalidone 25mg oral COMPANY B
	AMP – atenolol 100mg + chlortalidone 12.5mg oral COMPANY B
	AMP – atenolol 100mg + chlortalidone 25mg oral COMPANY B

An AMP is created when a pharmaceutical company registers a new product with a therapeutic moiety, or an existing product with a different strength, pharmaceutical form and route than previously registered.

Each AMP may be associated with one VMP group and is linked to exactly one ATM. An AMP may be supplied in various pack sizes and hence can be linked to multiple actual medicinal product packs.

4.5 Virtual medicinal product pack

A virtual medicinal product pack (VMPP) is an abstract concept representing one or more quantitatively equivalent actual medicinal product packs (AMPP). It is the unit of delivery or dispensing for a VMP. Each VMPP will have one or more AMPPs linked to it.

At this level, the therapeutic moiety, strength, route of administration and unit doses are known for each of the VMPs and this concept defines how a collection of VMPs are packaged together. The concept also includes the single dose distribution often used in hospitals where distribution is recorded as the unit of administration, and also the larger pack sizes of hospital packages. Figure 7 provides examples of VMPP.

Figure 7. VMPP examples

VTM – atenolol	
	VMPP – atenolol 50mg oral (14 tablets)
	VMPP – atenolol 50mg oral (28 tablets)
VTM – atenolol + chlortalidone	
	VMPP – atenolol 50mg + chlortalidone 12.5mg oral (14 tablets)
	VMPP – atenolol 100mg + chlortalidone 25mg oral (14 tablets)
	VMPP – atenolol 50mg + chlortalidone 12.5mg oral (28 tablets)
	VMPP – atenolol 100mg + chlortalidone 25mg oral (28 tablets)

VMPPs are created as new AMPPs are created and placed on the market. The concept allows comparison of prices between different suppliers for similar

packages, which may determine the choice. Each VMPP is always associated with at least one instance of a VMP and may have many AMPPs associated with it.

4.6 Actual medicinal product pack

An actual medicinal product pack (AMPP) is the commercially produced packaged product which is supplied for direct patient use. The concept contains information on the pack size, the inner packaging, price and reimbursement information, and other administrative information linked to the concept.

An AMPP contains components which may or may not be available for supply as independent prescribable products. Within an AMPP there may be specific containers, for example, bottle, tube, blister pack. These sub-packs can be supported by a recursive relationship between components and packs.

It is at this level that medicinal products are distributed by manufacturers to wholesalers and on to pharmacies for dispensing to the patient. It is also the level where refunding conditions are determined. Figure 8 provides examples of AMPPs.

Figure 8. AMPP examples

VTM – atenolol			
	VMP – atenolol 50mg oral tablet		
		VMPP atentol 50mg oral, 90 tablets	
			AMPP – Atenolol (COMPANY A) 90 tablets
			AMPP – Atenolol (COMPANY B) 90 tablets
			AMPP – Atenolol (COMPANY C) 90 tablets
VTM – atenolol + chlortalidone			
	VMP – atenolol 50mg + chlortalidone 12.5mg oral tablet		
		VMPP – atenolol 50mg + chlortalidone 12.5mg oral (90 tablets)	
			AMPP – Atenolol / Chlortalidone (COMPANY A) 90 tablets
			AMPP – Atenolol / Chlortalidone (COMPANY B) 90 tablets
			AMPP – Atenolol / Chlortalidone (COMPANY C) 90 tablets

Each AMPP will be associated with exactly one instance of a VMPP and each AMPP will be associated with one instance of an AMP.

4.7 Reference classes

The concepts above are considered the core concepts of the data model. Other concepts are required to complete the model along with reference data organised around these six concepts. The other concepts required include: classes to record information on ingredients, administration form, route of administration and active substances. These additional concepts are illustrated in Figure 9.

Figure 9. Core and additional concepts
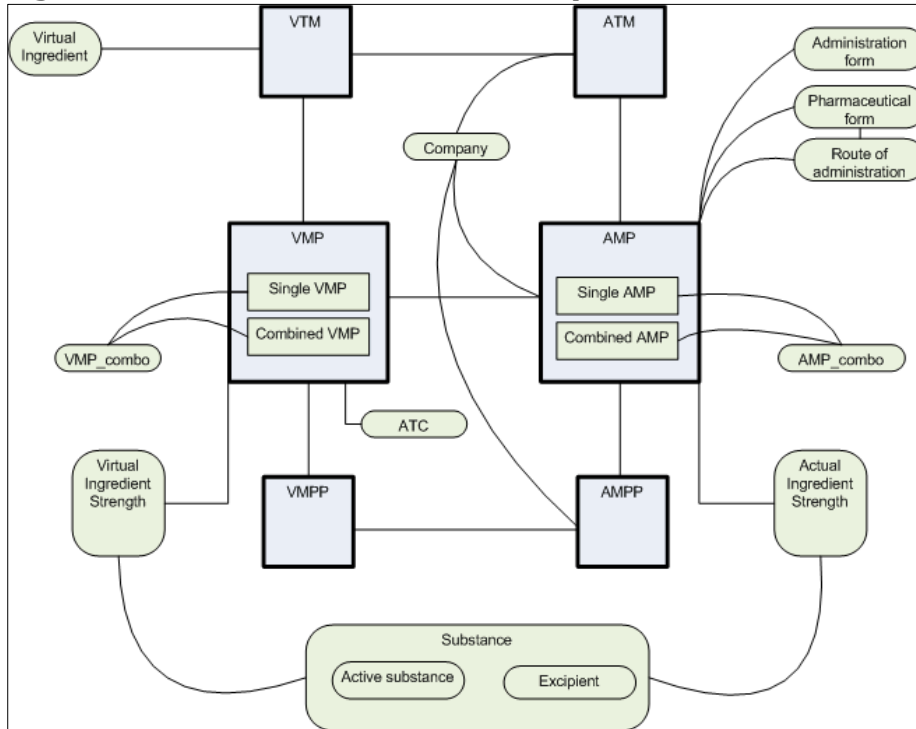
5. Core classes

This section describes in detail the attributes of the virtual and actual classes described in Section 4.

5.1 Virtual therapeutic moiety

A virtual therapeutic moiety (VTM) is an abstract representation of an active medicinal ingredient or substance without strength and form, which when formulated as a medicinal product, is intended for use in preventing or treating diseases in patients. VTMs exist in order to support generic recording of prescribing in primary or secondary care settings. A VTM may exist for a single active ingredient or may be a multi-ingredient VTM.

Table 1. VTM attributes

Name	Definition/Usage		Data type	Reference
Identifier.	A unique number used to identify a VTM concept. The identifier is a unique identifier allocated to a concept. It is never allocated to another concept.	1..1	Numeric.	
Name – fully specified.	A text string describing the concept. Multiple descriptions may be required – name, preferred term, abbreviated term.	1..*	Text (255).	
Substances.	A list of the active substances in the VTM. This should link to entries in the substance table. See 5.1 above. This item may repeat.			
	Identifier from a substance instance.	1..*	Identifier of substance instance in the substance reference table.	See 6.1 below.
ATC code.	A link to the relevant Anatomical Therapeutic Chemical (ATC) Classification System.	1..*	Text	
Invalidity flag.	A flag to identify that the concept is no longer active and should not be used. If the invalidity flag is populated it indicates the concept is invalid. If the invalidity flag is populated then invalidity flag end date should be populated.	0..1	Value from reference table.	See Appendix B – table 10 for exemplar values.
Invalidity flag date.	The date the VTM instance was made inactive.	0..1	Format dd/mm/yyyy.	

5.2 Actual therapeutic moiety

An actual therapeutic moiety (ATM) is a representation of a virtual therapeutic moiety associated with the brand name or principal marketing company. Its attributes include:

Table 2. ATM attributes

Name	Definition/Usage		Data type	Reference
Identifier.	A unique number used to identify an ATM concept. The identifier is a unique identifier allocated to a concept. It is never allocated to another concept. It may not be deleted but may be marked as invalid.	1..1	Numeric.	
Start date.	The date the concept was created.	1..1	Format dd/mm/yyyy.	
Name – fully specified.	A text string describing the concept. Multiple descriptions may be required – name, preferred term, abbreviated term. The name will also include the supplier who manufactures the product.	1..*	Text. (255)	
Manufacturer.	The identifier of the manufacturer from a reference table.	0..1	Identifier.	See 6.2 below.
Substances.	A list of the active ingredients in the ATM. This should link to entries in the substance table. This item may repeat.			
	Identifier from a substance instance.	1..*	Identifier of substance instance in the substance reference table.	See 6.1 below.
ATC code.	A link to the relevant Anatomical Therapeutic Chemical (ATC) Classification System.	1..*	Text	
Authorisation Status.	Indicates the authorisation status of the concept. If the concept is unauthorised the concept will be retained in the catalogue in case it was used in clinical information systems prior to its invalidation.	0..1	Value from reference table.	See Appendix B – table 11 for exemplar values.
Authorisation Status Date.	The date the authorisation status was set.	0..1	Format dd/mm/yyyy.	

5.3 Virtual medicinal product

A virtual medicinal product (VMP) is a representation of a VTM associated with strength information and a route of administration. VMPs generally will equate to prescribable products but there will be some VMPs which will not be directly prescribable and an ability to flag this is required. A VMP may only be encountered as part of a combination pack and not prescribable in any pack size in its own right. VMPs exist in order to facilitate generic prescribing in practice. Its attributes consist of:

Table 3. VMP attributes

Name	Definition/Usage		Data type	Reference
Identifier.	A unique number used to identify a VMP concept. The identifier is a unique identifier which is allocated to a concept. It is never allocated to another concept.	1..1	Identifier.	
Start date.	The date the concept was created.	1..1	Format dd/mm/yyyy.	
Name – fully specified.	A text string describing the concept. Multiple descriptions may be required – name, preferred term, abbreviated term.	1..*	Text.	
Substances.	A list of the active substances in the VMP. Any component that is intended to furnish a direct effect, pharmacological or other, in the diagnosis, cure, mitigation, treatment or prevention of a disease, or to affect the structure or any function of the body. This item may repeat.			
	Identifier from a substance instance.	1..*	Identifier of substance instance in the substance reference table.	See 6.1 below.
Dose form – category.	Identifies if the VMP has a unit dose form (a discrete unit is applicable such as a tablet or ampoule), if it is a continuous substance such as a cream or fluids, or if it belongs to a category of product for which unit dose form is not appropriate (catheters, colostomy bags).	1..1	Value from reference table.	See Appendix B – table 13 for exemplar values.
Dose form – type.	A description of the dose type, for example, tablet, spoonful, vial, dose.	1..1	Value from a reference table.	See Appendix B – table 21 for exemplar values.
Strength.	The amount of active ingredient present in each dosage. It is a combination of a value and unit.			
	Strength (value). A numeric value relating to the dose, for example, 1, 50, 250, 1000.	1..1	Numeric.	

	Strength (unit). A unit of measure relating to the dose, for example, ml, mg, gram.	1..1	Value from a reference table.	See Appendix B – table 12 for exemplar values.
Route information	Route of Administration identifier.	1..*	Identifier of route information instance in the route information reference table.	See Appendix B – table 20 for exemplar values.
Consultant level restriction.	A flag to indicate if a consultant level restriction to prescribing this VMP exists.	1..1	Value set to either Yes or No.	
Reimbursement level restriction.	A flag to indicate if a reimbursement level restriction to prescribing this VMP exists.	1..1	Value set to either Yes or No.	
Marketing status.	A flag to indicate whether there are currently no available VMP on the market.	1..1	Value from reference table.	See Appendix B – table 14 for exemplar values.
Controlled drug.	Indicates the VMP is considered a controlled drug. Indicator to identify that the VMP is controlled by the Misuse of Drug Act.	1..1	Value from reference table.	See Appendix B – table 15 for exemplar values.
ATC code.	A link to the relevant Anatomical Therapeutic Chemical (ATC) Classification System.	1..*	Text	ATC code.
Prescribable	Flag to indicate whether the VMP may be prescribed in its own right.	1..1	Value set to either Yes or No.	
Invalidity flag.	A flag to identify the concept is no longer active and should not be used. If the invalidity flag is populated it indicates that the concept is invalid. If invalidity flag is populated then invalidity flag end date should be populated.	0..1	Value from reference table.	See Appendix B – table 10 for exemplar values.
Invalidity flag date.	The date the VMP instance was made inactive.	0..1	Format dd/mm/yyyy.	

5.4 Actual medicinal product

An actual medicinal product (AMP) is a medicinal product that has been made available by a supplier. It is the medicinal product that is taken by a patient. It derives a lot of its information from the VMP it is associated with. Its attributes include:

Table 4. AMP attributes

Name	Definition/Usage		Data type	Reference
Identifier.	A unique number used to identify an AMP concept. The identifier is a unique identifier which is allocated to a concept. It is never allocated to another concept	1..1	Numeric.	
Name.	A text string describing the concept. Multiple descriptions may be required – name, preferred term, abbreviated term.	1..*	Text.	
Market Authorisation holder.	Field used to identify the organisation responsible for placing the AMP onto the market.	1..1	Identifier of organisation instance.	See 6.2 below.
Supplier.	Field used to identify the organisation responsible for supplying the AMP into the market.	1..1	Identifier of organisation instance.	See 6.2 below.
Licensing authority.	A field to indicate the organisation, if any, which is responsible for licensing the product.	1..1	Value from reference table.	See Appendix B – table 17 for exemplar values.
Marketing Status.	The marketing status of the AMP.	1.1	Value from a reference table.	See Appendix B – table 14 for exemplar values.
Marketing status date.	The date the marketing status came into effect.	1..1	Format dd/mm/yyyy.	
Legal status.	Status of the medicinal products' legal prescribing category.	1.1	Value from a reference table.	See Appendix B - table 22 for exemplar values.
Substances.	A list of the active substances in the AMP. Any component that is intended to furnish a direct effect, pharmacological or other, in the diagnosis, cure, mitigation, treatment or prevention of a disease or to affect the structure or any function of the body. This item may repeat.			
	Identifier from a substance instance.	1..*	Identifier of substance	See 6.1 below.

			instance in the substance reference table.	
Dose form – category.	Identifies if the AMP has a unit dose form (a discrete unit is applicable such as a tablet or ampoule), if it is a continuous substance such as a cream or fluids, or if it belongs to a category of product for which unit dose form is not appropriate (catheters, colostomy bags).	1..1	Value from reference table.	See Appendix B – table 13.
Dose form – type.	A description of the dose type, for example, tablet, spoonful, vial, dose.	1..1	Value from reference table.	See Appendix B – table 21 for exemplar values.
Strength.	The amount of active ingredient present in each dosage. It is a combination of a value and unit.			
	Strength (value). A numeric value relating to the strength, for example, 1, 50, 250, 1000.	1..1	A numeric value relating to the dose.	
	Strength (unit of measure). A unit of measure relating to the strength, for example, ml, mg, gram.	1..1	Value from reference table.	See Appendix B – table 12 for exemplar values.
Route information.	Route information - identifier. A unique number used to identify the route of administration.	1..*	Identifier of route information instance in the route information reference table.	See Appendix B – table 20 for exemplar values.
Consultant level restriction.	A flag to indicate if a consultant level restriction to prescribing this AMP exists.	1..1	Value set to either Yes or No.	
Reimbursement level restriction.	A flag to indicate if a reimbursement level restriction to prescribing this AMP exists.	1..1	Value set to either Yes or No.	
Interchangeability code.	Code which is used to indicate which other AMP this AMP may be safely interchanged with.	0..1	Alphanumeric.	
ATC code.	A link to the relevant Anatomical Therapeutic Chemical (ATC) Classification System.	1..*	Text	
Product Authorisation Number.	This is a unique number associated with the AMP which is assigned by the licensing authority.	1..1	Alphanumeric.	
SmPC.	When a product is granted an authorisation by the licensing authorities (for example, Health Products Regulatory Authority)	0..1	Text (URL).	

	allowing it to be sold or supplied in Ireland, that authorisation contains a document known as the summary of product characteristics (known as SPC or SmPC). The wording of the SmPC is agreed with the licensing authority as part of the regulatory approval process. The SmPC is designed to assist doctors and pharmacists in prescribing and supplying the product and describes what is in the product, what it is used for, the dose, side effects, when not to use it and so on. This field provides a URL link to the SmPC for the AMP as hosted on the HPRA website.			
Authorisation Status.	Indicates the authorisation status of the concept. If the concept is unauthorised the concept will be retained in the catalogue in case it was used in clinical information systems prior to its invalidation.	1.1	Value from a reference table.	See Appendix B – table 11 for exemplar values.
Authorisation status date.	The date the authorisation status was set.	1..1	Format dd/mm/yyyy.	

5.5 Virtual medicinal product pack

A virtual medicinal product pack (VMPP) is an abstract concept representing one or more quantitatively equivalent actual medicinal product packs (AMPP). Its attribute include:

Table 5. VMPP attributes

Name	Definition/Usage		Data type	Reference
Identifier.	A unique number used to identify a VMPP concept. The identifier is a unique identifier which is allocated to a concept. It is never allocated to another concept.	1..1	Numeric.	
Name – fully specified.	A text string describing the VMPP concept. Multiple descriptions may be required – name, preferred term, abbreviated term.	1..*	Text.	
Combination pack identifier.	Flag to indicate the VMPP is a combination product pack, or only available as a component of a combination product i.e. it is not available in its own right.	1..1	Value from reference table.	See Appendix B – table 18 for exemplar values.
Pack quantity.	For packs which have multiple sub-packs, the pack will indicate the number of sub-packs i.e. 4 blister packs, and the individual sub-packs will indicate the units of use, or units of size contained in each of the sub-packs i.e. 28 tablets. Usage will depend on whether the content is a pack or sub-pack. For oral contraceptive pills, the top level VMPP will be a box containing 4 blister packs each of which will be modeled as a sub-pack containing 28 tablets. This item may repeat.			
	Pack quantity (Quantity). A numeric value relating to the pack quantity.	1..*	Numeric.	
	Pack quantity (Unit of measure). A unit of measure relating to the pack quantity.	1..*	Value from a reference table.	See Appendix B – table 19 for exemplar values.
Pack quantity. VMP(s).	This will contain a link to the VMPs contained in the pack and will provide strength, administrative form and unit of presentation for each VMP included in the pack. This item may repeat.			
	Ids of the VMP contained in the pack.	1.*	Id(s) of a VMP.	See 5.3 above.
	Number of VMPs.	1.*	Numeric.	
Sub-pack quantity.	For packs which have multiple sub-packs, the pack will indicate the number of sub-packs i.e. 4 blister packs, and the individual sub-packs will indicate the units of use ,or units of size contained in each of the sub packs i.e. 28 tablets. Usage will depend on whether the content is a pack or sub-pack. For oral contraceptive pills, the top level VMPP will be a box			

	containing 4 blister packs each of which will be modeled as a sub-pack containing 28 tablets.			
	Sub-pack quantity (Quantity). A numeric value relating to the sub-pack quantity.	1..*	Numeric.	
	Sub-pack quantity (Unit of measure). A unit of measure relating to the sub-pack quantity.	1..*	Value from a reference table.	See Appendix B – table 19 for exemplar values.
Sub-pack quantity. VMPs	This will contain a link to the VMPs contained in the pack and will provide strength, administrative form and unit of presentation for each VMP included in the pack. This item may repeat.	1..*	Id(s) of a VMP.	See 5.3 above.
	Ids of the VMP contained in the pack.	1.*	Id(s) of a VMP.	See 5.3 above.
	Number of VMPs.	1.*	Numeric.	
Invalidity flag.	A flag to identify the concept is no longer active and should not be used. If the invalidity flag is populated it indicates that the concept is invalid. If invalidity flag is populated then invalidity flag end date should be populated.	0..1	Value from reference table.	See Appendix B – table 10 for exemplar values.
ATC code.	A link to the relevant Anatomical Therapeutic Chemical (ATC) Classification System.	1..*	Text	
Invalidity flag date	The date the VMPP concept was made inactive.	0..1	Format dd/mm/yyyy.	

5.6 Actual medicinal product pack

An actual medicinal product pack (AMPP) is the commercially produced packaged product which is supplied for direct patient use. It derives a lot of its information from the VMPP it is associated with. Its attributes include:

Table 6. AMPP attributes

Name	Definition/Usage		Data type	Reference
Identifier.	A unique number used to identify the concept. The identifier is a unique identifier which is allocated to a concept. It is never allocated to another concept. It may not be deleted but may be marked as invalid.	1..1	Numeric.	
Authorisation Status.	The authorisation status of the AMP.	1.1	Value from a reference table.	See Appendix B – table 11 for exemplar values.
Authorisation status date.	The date the authorisation status came into effect.	1..1	Format dd/mm/yyyy.	
Name – fully specified.	A text string describing the concept. Multiple descriptions may be required – name, preferred term, abbreviated term.	1..*	Text.	
Sub-pack information.	Information about the composition of medicinal products composed of products packs and sub-packs. An example would be a number of separate strips of tablets: 2 x 14 tablets.	0..1	Text.	
Market Authorisation holder.	Field used to identify the organisation responsible for placing the AMPP onto the market.	1..1	Identifier of organisation instance.	See 6.2 below.
Supplier.	Field used to identify the organisation responsible for placing the AMPP onto the market.	1..1	Identifier of organisation instance.	See 6.2 below.
Legal status.	Status of the medicinal product's legal prescribing category.	1.1	Value from a reference table.	See Appendix B - table 22 for exemplar values.
Appliance pack information.	Information relating to AMPPs where these contain appliances. Information relating to the size of an appliance where this information is not captured within the VMP name. Examples of this type of appliance include incontinence and ostomy	1..1	Text.	

	equipment where size may be expressed in SI units, for example, mm, by a description, for example, small, or a mixture of both.			
Reimbursement information.	Information relating to the financial reimbursement to financial contractors.			
	GMS reimbursable item number.	0..1	Numeric.	
	Reference price – the price set for a group of medications which have the same effect.	0..1	Numeric.	
	Reimbursement price – the price that will be reimbursed to the pharmacy by the primary care reimbursement service.	0..1	Numeric.	
Combination pack indicator and content.	Used to identify the component packs within an actual combination pack. A combination product is a product containing two or more components each of which is an AMP in its own right. It may consist of different forms, for example, cream + pessaries or the same form, for example, tablets + tablets.	1..1	Value from reference table.	See Appendix B – table 18 for exemplar values.
Trade produce and suffix.	Description of the product as provided by the supplier.	1..1	Text.	
Medicinal product pack price.	Information relating to the price (indicative only) for the AMPP.	1..1	Text.	
ATC code.	A link to the relevant Anatomical Therapeutic Chemical (ATC) Classification System.	1..*	Text	
Authorisation Status	Indicates the authorisation status of the concept. If the concept is unauthorised the concept will be retained in the catalogue in case it was used in clinical information systems prior to its invalidation.	1.1	Value from a reference table	See Appendix B – table 11 for exemplar values.
Authorisation status date.	The date the authorisation status was set.	1..1	Format dd/mm/yyyy.	

6. Reference classes and attributes

Two reference classes are required to support the data model, a Substance class and an Organisation class. This section details these two classes.

6.1 Substance

A substance is any matter that has a discrete existence, whose origin may be biological, mineral or chemical. Substances may be either single substances or mixed substances.

Table 7. Substance Class

Name	Definition/Usage		Data type	Reference
Identifier.	A unique number used to identify the substance. The identifier is a unique identifier allocated to a concept. It is never allocated to another concept.	1..1	Numeric.	
Name – fully specified.	A text string describing the substance.	1..1	Text (255).	
Substance type.	Coded field used to indicate whether the substance is an active ingredient or an excipient.	1.1	Value from reference table.	See Appendix B – table 9 for exemplar values.
Start date.	The date the substance was created.	1..1	Format dd/mm/yyyy.	
Invalidity flag.	A flag to identify the concept is no longer active and should not be used. If the invalidity flag is populated it indicates the concept is invalid. If invalidity flag is populated then invalidity flag end date should be populated.	0..1	Value from reference table.	See Appendix B – table 10 for exemplar values.
Invalidity flag end date.	The date the substance instance was made inactive.	0..1	Format dd/mm/yyyy.	

6.2 Organisation

This class identifies the organisations which have a role in placing medicinal products on the Irish market.

Table 8. Organisation class

Name	Definition/Usage		Data type	Reference
Identifier.	A unique number used to identify a supplier concept. The identifier is a unique identifier allocated to a concept. It is never allocated to another concept.	1..1	Numeric.	
Name.	A textual description of the organisation.	1..1	Text.	
Invalidity flag.	A flag to identify the concept is no longer active and should not be used. If the invalidity flag is populated it indicates the concept is invalid. If invalidity flag is populated then invalidity flag end date should be populated.	0..1	Value from reference table.	See Appendix B – table 10 for exemplar values.
Invalidity flag date.	The date the organisation instance was made inactive.	0..1	Format dd/mm/yyyy.	

Reference List

(1) Department of Health. *eHealth Strategy for Ireland*. 2013. Available online from: http://www.dohc.ie/publications/eHealth_Strategy_2013.html. Accessed on: 24 April 2014.

(2) Health Information and Quality Authority. *Eprescribing and Electronic Transfer of Prescriptions: An International Review*. 2012. Available online from: http://www.hiqa.ie/publications/eprescribing-and-electronic-transfer-prescriptions-international-review. Accessed on: 2 April 2014.

(3) International Standards Organisation. *ISO 11615:2012 Health informatics -- Identification of medicinal products -- Data elements and structures for the unique identification and exchange of regulated medicinal product information*. 2012. Available online from: http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=55034.

(4) International Standards Organisation. *ISO 11616:2012 Health informatics -- Identification of medicinal products -- Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information*. 2012. Available online from: http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=55035.

(5) International Standards Organisation. *ISO 11238:2012 Health informatics -- Identification of medicinal products -- Data elements and structures for the unique identification and exchange of regulated information on substances*. 2012. Available online from: http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=55031.

(6) International Standards Organisation. *ISO 11239:2012 Health informatics -- Identification of medicinal products -- Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging*. 2012. Available online from: http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=55032.

(7) International Standards Organisation. *ISO 11240:2012 Health informatics -- Identification of medicinal products -- Data elements and structures for the unique identification and exchange of units of measurement*. 2012. Available online from: http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=55033.

Appendix A - Targeted consultation

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

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

Appendix B – Reference tables

Reference tables are required to support the implementation of the data model.The following tables provide exemplar values for these reference tables.

Table 9. Substance type

Code	Description
AS	ACTIVE INGREDIENT
EX	EXCIPIENT

Table 10. Invalidity status

Code	Description
V	VALID
IV	INVALID

Table 11. Authorisation status

Code	Description
AP	APPROVED
WD	WITHDRAWN

Table 12. Strength (unit of measure)

Code	Description	UcMC equivalent
1	ALLERGY UNITS	[AU]
2	Amb a 1 units	[Amb'a'1'U]
3	BIOEQUIVALENT ALLERGY UNITS	[BAU]
4	ARBITRARY UNITS	[arb'U]
5	CELL CULTURE INFECTIOUS DOSE 50%	[CCID_50]
6	COLONY FORMING UNITS	[CFU]
7	CURIE	Ci
8	DAY	d
9	D-ANTIGEN UNITS	[D'ag'U]
10	DECILITER	dL
11	FOCUS-FORMING UNITS	[FFU]
12	GRAM	g
13	HOMEOPATHIC POTENCY OF CENTESIMAL SERIES	[hp_C]
14	HOMEOPATHIC POTENCY OF CENTESIMAL KORSAKOVIAN SERIES	{kp_C}
15	HOMEOPATHIC POTENCY OF MILLESIMAL SERIES	[hp_M]
16	HOMEOPATHIC POTENCY OF QUINTAMILLESIMAL SERIES	[hp_Q]
17	HOMEOPATHIC POTENCY OF DECIMAL SERIES	[hp_X]
18	HOUR	h
19	INTERNATIONAL UNITS	[iU]
20	KILOGRAM	kg
21	LIMIT OF FLOCCULATION	[Lf]
22	LITER	L
23	MICROCURIE	uCi
24	MICROGRAM	ug
25	MICROLITER	uL
26	MICROMOLE	umol
27	MICRON	um
28	MILLICURIE	mCi
29	MILLIEQUIVALENT	meq
30	MILLIGRAM	mg

31	MILLILITER	mL
32	MILLIMETER	mm
33	MILLIMOLE	mmol
34	MINUTE	min
35	MOLE	mol
36	MONTH	mo
37	NANOGRAM	ng
38	NANOMOLE	nmol
39	PLAQUE-FORMING UNITS	[PFU]
40	PROTEIN NITROGEN UNITS	[PNU]
41	SECOND	s
42	SQUARE CENTIMETER	cm2
43	TISSUE CULTURE INFECTIOUS DOSE 50%	[TCID_50]
44	UNIT - CATALYTIC ACTIVITY	U
45	UNITED STATES PHARMACOPEIA UNIT	[USP'U]
46	WEEK	wk
47	YEAR	a

Table 13. Dose form (category)

Code	Description
0	UNIT DOSE FORM
1	CONTINUOUS SUBSTANCE
2	DOSE FORM IS NOT APPROPRIATE

Table 14. Non availability

Code	Description
0	AVAILABLE
1	NOT AVAILABLE

Table 15. Controlled drug information

Code	Description
0	UNCONTROLLED
1	CONTROLLED

Table 16. Combination product

Code	Description
1	COMBINATION PACK
2	COMPONENT PACK ONLY

Table 17. Licensing authority

Code	Description
1	HEALTH PRODUCT REGULATORY AUTHORITY

Table 18. Combination pack

Code	Description
0	COMBINATION
1	COMPONENT

Table 19. Pack quantity (unit of measure)

Code	Description
1	AMPULE
2	APPLICATOR
3	BAG

4	BLISTER PACK
5	BOTTLE
6	BOTTLE, DISPENSING
7	BOTTLE, DROPPER
8	BOTTLE, GLASS
9	BOTTLE, PLASTIC
10	BOTTLE, PUMP
11	BOTTLE, SPRAY
12	BOTTLE, UNIT-DOSE
13	BOTTLE, WITH APPLICATOR
14	BOX
15	BOX, UNIT-DOSE
16	CAN
17	CANISTER
18	CAPSULE
19	CARTON
20	CARTRIDGE
21	CASE
22	CELLO PACK
23	CONTAINER
24	CONTAINER, FLEXIBLE INTERMEDIATE BULK
25	CUP
26	CUP, UNIT-DOSE
27	CYLINDER
28	DEWAR
29	DIALPACK
30	DOSE PACK
31	DRUM
32	INHALER
33	INHALER, REFILL
34	JAR
35	JUG
36	KIT
37	PACKAGE
38	PACKAGE, COMBINATION
39	PACKET
40	PAIL
41	PATCH
42	POUCH
43	SUPERSACK
44	SYRINGE
45	SYRINGE, GLASS
46	SYRINGE, PLASTIC
47	TABMINDER
48	TANK
49	TRAY
50	TUBE
51	TUBE, WITH APPLICATOR
52	VIAL
53	VIAL, DISPENSING
54	VIAL, GLASS
55	VIAL, MULTI-DOSE
56	VIAL, PATENT DELIVERY SYSTEM
57	VIAL, PHARMACY BULK PACKAGE
58	VIAL, PIGGYBACK

59	VIAL, PLASTIC
60	VIAL, SINGLE-DOSE
61	VIAL, SINGLE-USE

Table 20. Route of Administration

Value	Description
1	AURICULAR USE
2	BUCCAL USE
3	CUTANEOUS USE
4	DENTAL USE
5	ENDOCERVICAL USE
6	ENDOSINUSIAL USE
7	ENDOTRACHEOPULMONARY USE
8	EPIDURAL USE
9	EPILESIONAL USE
10	EXTRAAMNIOTIC USE
11	EXTRACORPOREAL USE
12	GASTRIC USE
13	GASTROENTERAL USE
14	GINGIVAL USE
15	HAEMODIALYSIS
16	IMPLANTATION
17	INFILTRATION
18	INHALATION USE
19	INTESTINAL USE
20	INTRAAMNIOTIC USE
21	INTRAARTERIAL USE
22	INTRAARTICULAR USE
23	INTRABURSAL USE
24	INTRACAMERAL USE
25	INTRACARDIAC USE
26	INTRACARTILAGINOUS USE
27	INTRACAVERNOUS USE
28	INTRACEREBRAL USE
29	INTRACERVICAL USE
30	INTRACHOLANGIOPANCREATIC USE
31	INTRACISTERNAL USE
32	INTRACORONARY USE
33	INTRADERMAL USE
34	INTRADISCAL USE
35	INTRAEPIDERMAL USE
36	INTRAGLANDULAR USE
37	INTRALESIONAL USE
38	INTRALYMPHATIC USE
39	INTRAMUSCULAR USE
40	INTRAOCULAR USE
41	INTRAOSSEOUS USE
42	INTRAPERICARDIAL USE
43	INTRAPERITONEAL USE
44	INTRAPLEURAL USE
45	INTRAPORTAL USE
46	INTRAPROSTATIC USE

47	INTRASTERNAL USE
48	INTRATHECAL USE
49	INTRATUMORAL USE
50	INTRAUTERINE USE
51	INTRAVENOUS USE
52	INTRAVESICAL USE
53	INTRAVITREAL USE
54	IONTOPHORESIS
55	LARYNGOPHARYNGEAL USE
56	NASAL USE
57	OCULAR USE
58	ORAL USE
59	OROMUCOSAL USE
60	OROPHARYNGEAL USE
61	PERIARTICULAR USE
62	PERINEURAL USE
63	PERIODONTAL USE
64	PERIOSSEOUS USE
65	PERITUMORAL USE
66	POSTERIOR JUXTASCLERAL USE
67	RECTAL USE
68	RETROBULBAR USE
69	ROUTE OF ADMINISTRATION NOT APPLICABLE
70	SKIN SCARIFICATION
71	SUBCONJUNCTIVAL USE
72	SUBCUTANEOUS USE
73	SUBLINGUAL USE
74	SUBMUCOSAL USE
75	TRANSDERMAL USE
76	URETHRAL USE
77	VAGINAL USE

Table 21. Dose form type

Value	Description
1	ANTICOAGULANT AND PRESERVATIVE SOLUTION FOR BLOOD
2	BATH ADDITIVE
3	BLADDER IRRIGATION
4	BUCCAL FILM
5	BUCCAL TABLET
6	CACHET
7	CAPSULE, HARD
8	CAPSULE, SOFT
9	CHEWABLE CAPSULE, SOFT
10	CHEWABLE TABLET
11	CHEWABLE/DISPERSIBLE TABLET
12	COATED TABLET
13	COLLODION
14	COMPRESSED LOZENGE
15	CONCENTRATE FOR CUTANEOUS SOLUTION
16	CONCENTRATE FOR CUTANEOUS SPRAY, EMULSION

17	CONCENTRATE FOR DISPERSION FOR INFUSION
18	CONCENTRATE FOR EMULSION FOR INFUSION
19	CONCENTRATE FOR GARGLE
20	CONCENTRATE FOR HAEMODIALYSIS SOLUTION
21	CONCENTRATE FOR HAEMODIALYSIS SOLUTION
22	CONCENTRATE FOR INTRAVESICAL SOLUTION
23	CONCENTRATE FOR ORAL SOLUTION
24	CONCENTRATE FOR ORAL SUSPENSION
25	CONCENTRATE FOR ORAL/RECTAL SOLUTION
26	CONCENTRATE FOR ORAL/RECTAL SOLUTION
27	CONCENTRATE FOR RECTAL SOLUTION
28	CONCENTRATE FOR SOLUTION FOR INFUSION
29	CONCENTRATE FOR SOLUTION FOR INJECTION
30	CONCENTRATE FOR SOLUTION FOR INJECTION/INFUSION
31	CONCENTRATE FOR SOLUTION FOR INTRAOCULAR IRRIGATION
32	CONCENTRATE FOR SOLUTION FOR PERITONEAL DIALYSIS
33	CREAM
34	CUTANEOUS EMULSION
35	CUTANEOUS FOAM
36	CUTANEOUS LIQUID
37	CUTANEOUS PASTE
38	CUTANEOUS PATCH
39	CUTANEOUS POWDER
40	CUTANEOUS SOLUTION
41	CUTANEOUS SOLUTION/CONCENTRATE FOR OROMUCOSAL SOLUTION
42	CUTANEOUS SOLUTION/CONCENTRATE FOR OROMUCOSAL SOLUTION
43	CUTANEOUS SPRAY, EMULSION
44	CUTANEOUS SPRAY, OINTMENT
45	CUTANEOUS SPRAY, POWDER
46	CUTANEOUS SPRAY, SOLUTION
47	CUTANEOUS SPRAY, SUSPENSION
48	CUTANEOUS STICK
49	CUTANEOUS SUSPENSION
50	CUTANEOUS/NASAL OINTMENT
51	CUTANEOUS/NASAL OINTMENT
52	DENTAL CEMENT
53	DENTAL EMULSION
54	DENTAL GEL
55	DENTAL PASTE
56	DENTAL POWDER
57	DENTAL SOLUTION
58	DENTAL STICK
59	DENTAL SUSPENSION
60	DENTURE LACQUER
61	DISPERSIBLE TABLET

62	DISPERSIBLE TABLETS FOR DOSE DISPENSER
63	DISPERSION
64	DISPERSION FOR INFUSION
65	DISPERSION FOR INJECTION
66	EAR CREAM
67	EAR DROPS, EMULSION
68	EAR DROPS, SOLUTION
69	EAR DROPS, SUSPENSION
70	EAR GEL
71	EAR OINTMENT
72	EAR POWDER
73	EAR SPRAY, EMULSION
74	EAR SPRAY, SOLUTION
75	EAR SPRAY, SUSPENSION
76	EAR STICK
77	EAR TAMPON
78	EAR WASH, EMULSION
79	EAR WASH, SOLUTION
80	EAR/EYE DROPS, SOLUTION
81	EAR/EYE DROPS, SOLUTION
82	EAR/EYE DROPS, SUSPENSION
83	EAR/EYE DROPS, SUSPENSION
84	EAR/EYE OINTMENT
85	EAR/EYE OINTMENT
86	EAR/EYE/NASAL DROPS, SOLUTION
87	EAR/EYE/NASAL DROPS, SOLUTION
88	EAR/EYE/NASAL DROPS, SOLUTION
89	EAR/NASAL DROPS, SUSPENSION
90	EAR/NASAL DROPS, SUSPENSION
91	EFFERVESCENT GRANULES
92	EFFERVESCENT POWDER
93	EFFERVESCENT TABLET
94	EFFERVESCENT VAGINAL TABLET
95	EMULSION FOR INFUSION
96	EMULSION FOR INJECTION
97	EMULSION FOR INJECTION/INFUSION
98	ENDOCERVICAL GEL
99	ENDOSINUSIAL WASH, SUSPENSION
100	ENDOTRACHEOPULMONARY INSTILLATION, POWDER FOR SOLUTION
101	ENDOTRACHEOPULMONARY INSTILLATION, SOLUTION
102	ENDOTRACHEOPULMONARY INSTILLATION, SUSPENSION
103	EYE CREAM
104	EYE DROPS, EMULSION
105	EYE DROPS, PROLONGED-RELEASE
106	EYE DROPS, SOLUTION

107	EYE DROPS, SOLVENT FOR RECONSTITUTION
108	EYE DROPS, SUSPENSION
109	EYE GEL
110	EYE LOTION
111	EYE LOTION, SOLVENT FOR RECONSTITUTION
112	EYE OINTMENT
113	FILM-COATED TABLET
114	GARGLE
115	GARGLE, POWDER FOR SOLUTION
116	GARGLE, TABLET FOR SOLUTION
117	GARGLE/MOUTHWASH
118	GARGLE/NASAL WASH
119	GARGLE/NASAL WASH
120	GASTROENTERAL EMULSION
121	GASTROENTERAL SOLUTION
122	GASTROENTERAL SUSPENSION
123	GASTRO-RESISTANT CAPSULE, HARD
124	GASTRO-RESISTANT CAPSULE, SOFT
125	GASTRO-RESISTANT GRANULES
126	GASTRO-RESISTANT GRANULES FOR ORAL SUSPENSION
127	GASTRO-RESISTANT TABLET
128	GEL
129	GEL FOR INJECTION
130	GINGIVAL GEL
131	GINGIVAL PASTE
132	GINGIVAL SOLUTION
133	GRANULES
134	GRANULES FOR ORAL SOLUTION
135	GRANULES FOR ORAL SUSPENSION
136	GRANULES FOR ORAL/RECTAL SUSPENSION
137	GRANULES FOR ORAL/RECTAL SUSPENSION
138	GRANULES FOR RECTAL SUSPENSION
139	GRANULES FOR SYRUP
140	GRANULES FOR VAGINAL SOLUTION
141	HERBAL TEA
142	IMPLANT
143	IMPLANTATION CHAIN
144	IMPLANTATION MATRIX
145	IMPLANTATION SUSPENSION
146	IMPLANTATION TABLET
147	IMPREGNATED DRESSING
148	IMPREGNATED PAD
149	IMPREGNATED PLUG
150	INHALATION POWDER
151	INHALATION POWDER, HARD CAPSULE

152	INHALATION POWDER, PRE-DISPENSED
153	INHALATION POWDER, TABLET
154	INHALATION SOLUTION
155	INHALATION VAPOUR, CAPSULE
156	INHALATION VAPOUR, EFFERVESCENT TABLET
157	INHALATION VAPOUR, EMULSION
158	INHALATION VAPOUR, IMPREGNATED PAD
159	INHALATION VAPOUR, IMPREGNATED PLUG
160	INHALATION VAPOUR, LIQUID
161	INHALATION VAPOUR, OINTMENT
162	INHALATION VAPOUR, POWDER
163	INHALATION VAPOUR, SOLUTION
164	INHALATION VAPOUR, TABLET
165	INSTANT HERBAL TEA
166	INTESTINAL GEL
167	INTRAPERITONEAL SOLUTION
168	INTRAUTERINE DELIVERY SYSTEM
169	INTRAUTERINE FOAM
170	INTRAVESICAL SOLUTION
171	INTRAVESICAL SOLUTION/SOLUTION FOR INJECTION
172	INTRAVESICAL SOLUTION/SOLUTION FOR INJECTION
173	IRRIGATION SOLUTION
174	KIT FOR RADIOPHARMACEUTICAL PREPARATION
175	LIVING TISSUE EQUIVALENT
176	LOZENGE
177	MEDICATED CHEWING-GUM
178	MEDICATED CHEWING-GUM
179	MEDICATED NAIL LACQUER
180	MEDICATED PLASTER
181	MEDICATED SPONGE
182	MEDICATED THREAD
183	MEDICATED VAGINAL TAMPON
184	MEDICINAL GAS, COMPRESSED
185	MEDICINAL GAS, CRYOGENIC
186	MEDICINAL GAS, LIQUEFIED
187	MODIFIED-RELEASE CAPSULE, HARD
188	MODIFIED-RELEASE CAPSULE, SOFT
189	MODIFIED-RELEASE GRANULES
190	MODIFIED-RELEASE GRANULES FOR ORAL SUSPENSION
191	MODIFIED-RELEASE TABLET
192	MOUTHWASH
193	MOUTHWASH, POWDER FOR SOLUTION
194	MOUTHWASH, TABLET FOR SOLUTION
195	MUCO-ADHESIVE BUCCAL TABLET

196	NASAL CREAM
197	NASAL DROPS, EMULSION
198	NASAL DROPS, SOLUTION
199	NASAL DROPS, SUSPENSION
200	NASAL GEL
201	NASAL OINTMENT
202	NASAL POWDER
203	NASAL SPRAY, EMULSION
204	NASAL SPRAY, POWDER FOR SOLUTION
205	NASAL SPRAY, SOLUTION
206	NASAL SPRAY, SOLUTION/OROMUCOSAL SOLUTION
207	NASAL SPRAY, SOLUTION/OROMUCOSAL SOLUTION
208	NASAL SPRAY, SUSPENSION
209	NASAL STICK
210	NASAL WASH
211	NASAL/OROMUCOSAL SOLUTION
212	NASAL/OROMUCOSAL SOLUTION
213	NASAL/OROMUCOSAL SPRAY, SOLUTION
214	NASAL/OROMUCOSAL SPRAY, SOLUTION
215	NEBULISER EMULSION
216	NEBULISER SOLUTION
217	NEBULISER SUSPENSION
218	OINTMENT
219	OPHTHALMIC INSERT
220	OPHTHALMIC STRIP
221	ORAL DROPS, EMULSION
222	ORAL DROPS, GRANULES FOR SOLUTION
223	ORAL DROPS, LIQUID
224	ORAL DROPS, POWDER FOR SUSPENSION
225	ORAL DROPS, SOLUTION
226	ORAL DROPS, SUSPENSION
227	ORAL EMULSION
228	ORAL GEL
229	ORAL GUM
230	ORAL LIQUID
231	ORAL LYOPHILISATE
232	ORAL PASTE
233	ORAL POWDER
234	ORAL SOLUTION
235	ORAL SOLUTION/CONCENTRATE FOR NEBULISER SOLUTION
236	ORAL SOLUTION/CONCENTRATE FOR NEBULISER SOLUTION
237	ORAL SUSPENSION
238	ORAL/RECTAL SOLUTION
239	ORAL/RECTAL SOLUTION

240	ORAL/RECTAL SUSPENSION
241	ORAL/RECTAL SUSPENSION
242	ORODISPERSIBLE FILM
243	ORODISPERSIBLE TABLET
244	OROMUCOSAL CAPSULE
245	OROMUCOSAL CREAM
246	OROMUCOSAL DROPS
247	OROMUCOSAL GEL
248	OROMUCOSAL OINTMENT
249	OROMUCOSAL PASTE
250	OROMUCOSAL PATCH
251	OROMUCOSAL SOLUTION
252	OROMUCOSAL SPRAY, EMULSION
253	OROMUCOSAL SPRAY, SOLUTION
254	OROMUCOSAL SPRAY, SUSPENSION
255	OROMUCOSAL SUSPENSION
256	OROMUCOSAL/LARYNGOPHARYNGEAL SOLUTION
257	OROMUCOSAL/LARYNGOPHARYNGEAL SOLUTION/SPRAY, SOLUTION
258	PASTILLE
259	PERIODONTAL GEL
260	PERIODONTAL INSERT
261	PERIODONTAL POWDER
262	PESSARY
263	PILLULES
264	PILLULES
265	PLASTER FOR PROVOCATION TEST
266	POUCH
267	POULTICE
268	POWDER FOR BLADDER IRRIGATION
269	POWDER FOR CONCENTRATE FOR DISPERSION FOR INFUSION
270	POWDER FOR CONCENTRATE FOR INTRAVESICAL SUSPENSION
271	POWDER FOR CONCENTRATE FOR SOLUTION FOR HAEMODIALYSIS
272	POWDER FOR CONCENTRATE FOR SOLUTION FOR HAEMODIALYSIS
273	POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION
274	POWDER FOR CONCENTRATE FOR SOLUTION FOR INJECTION/INFUSION
275	POWDER FOR CUTANEOUS SOLUTION
276	POWDER FOR DENTAL CEMENT
277	POWDER FOR DENTAL SOLUTION
278	POWDER FOR DISPERSION FOR INFUSION
279	POWDER FOR EPILESIONAL SOLUTION
280	POWDER FOR IMPLANTATION SUSPENSION
281	POWDER FOR INTRAVESICAL SOLUTION
282	POWDER FOR INTRAVESICAL SOLUTION/SOLUTION FOR INJECTION
283	POWDER FOR INTRAVESICAL SOLUTION/SOLUTION FOR INJECTION

284	POWDER FOR INTRAVESICAL SUSPENSION
285	POWDER FOR NEBULISER SOLUTION
286	POWDER FOR NEBULISER SUSPENSION
287	POWDER FOR ORAL SOLUTION
288	POWDER FOR ORAL SUSPENSION
289	POWDER FOR ORAL/RECTAL SUSPENSION
290	POWDER FOR ORAL/RECTAL SUSPENSION
291	POWDER FOR PROLONGED-RELEASE SUSPENSION FOR INJECTION
292	POWDER FOR RECTAL SOLUTION
293	POWDER FOR RECTAL SUSPENSION
294	POWDER FOR SOLUTION FOR INFUSION
295	POWDER FOR SOLUTION FOR INJECTION
296	POWDER FOR SOLUTION FOR INJECTION/INFUSION
297	POWDER FOR SOLUTION FOR INTRAOCULAR IRRIGATION
298	POWDER FOR SOLUTION FOR IONTOPHORESIS
299	POWDER FOR SUSPENSION FOR INJECTION
300	POWDER FOR SYRUP
301	PRESSURISED INHALATION, EMULSION
302	PRESSURISED INHALATION, SOLUTION
303	PRESSURISED INHALATION, SUSPENSION
304	PROLONGED-RELEASE CAPSULE, HARD
305	PROLONGED-RELEASE CAPSULE, SOFT
306	PROLONGED-RELEASE GRANULES
307	PROLONGED-RELEASE GRANULES FOR ORAL SUSPENSION
308	PROLONGED-RELEASE SUSPENSION FOR INJECTION
309	PROLONGED-RELEASE TABLET
310	RADIONUCLIDE GENERATOR
311	RADIOPHARMACEUTICAL PRECURSOR
312	RADIOPHARMACEUTICAL PRECURSOR, SOLUTION
313	RECTAL CAPSULE
314	RECTAL CREAM
315	RECTAL EMULSION
316	RECTAL FOAM
317	RECTAL GEL
318	RECTAL OINTMENT
319	RECTAL SOLUTION
320	RECTAL SUSPENSION
321	RECTAL TAMPON
322	SEALANT
323	SEALANT MATRIX
324	SEALANT POWDER
325	SHAMPOO
326	SOLUBLE TABLET
327	SOLUTION FOR BLOOD FRACTION MODIFICATION

328	SOLUTION FOR CARDIOPLEGIA
329	SOLUTION FOR DENTAL CEMENT
330	SOLUTION FOR HAEMODIAFILTRATION
331	SOLUTION FOR HAEMODIAFILTRATION
332	SOLUTION FOR HAEMODIALYSIS
333	SOLUTION FOR HAEMODIALYSIS
334	SOLUTION FOR HAEMODIALYSIS/HAEMOFILTRATION
335	SOLUTION FOR HAEMODIALYSIS/HAEMOFILTRATION
336	SOLUTION FOR HAEMOFILTRATION
337	SOLUTION FOR HAEMOFILTRATION
338	SOLUTION FOR INFUSION
339	SOLUTION FOR INJECTION
340	SOLUTION FOR INJECTION/INFUSION
341	SOLUTION FOR INTRAOCULAR IRRIGATION
342	SOLUTION FOR IONTOPHORESIS
343	SOLUTION FOR ORGAN PRESERVATION
344	SOLUTION FOR PERITONEAL DIALYSIS
345	SOLUTION FOR PROVOCATION TEST
346	SOLUTION FOR PROVOCATION TEST
347	SOLUTION FOR PROVOCATION TEST
348	SOLUTION FOR SEALANT
349	SOLUTION FOR SKIN-PRICK TEST
350	SOLUTION FOR SKIN-SCRATCH TEST
351	SOLVENT FOR PARENTERAL USE
352	SOLVENT FOR SOLUTION FOR INFUSION
353	SOLVENT FOR SOLUTION FOR INTRAOCULAR IRRIGATION
354	STOMACH IRRIGATION
355	SUBLINGUAL FILM
356	SUBLINGUAL SPRAY, EMULSION
357	SUBLINGUAL SPRAY, SOLUTION
358	SUBLINGUAL SPRAY, SUSPENSION
359	SUBLINGUAL TABLET
360	SUPPOSITORY
361	SUSPENSION FOR INJECTION
362	SYRUP
363	TABLET
364	TABLET FOR RECTAL SOLUTION
365	TABLET FOR RECTAL SUSPENSION
366	TABLET FOR VAGINAL SOLUTION
367	TOOTHPASTE
368	TRANSDERMAL GEL
369	TRANSDERMAL PATCH
370	TRANSDERMAL SOLUTION
371	TRANSDERMAL SPRAY, SOLUTION

372	TRANSDERMAL SYSTEM
373	URETHRAL GEL
374	URETHRAL STICK
375	VAGINAL CAPSULE, HARD
376	VAGINAL CAPSULE, SOFT
377	VAGINAL CREAM
378	VAGINAL DELIVERY SYSTEM
379	VAGINAL EMULSION
380	VAGINAL FOAM
381	VAGINAL GEL
382	VAGINAL OINTMENT
383	VAGINAL SOLUTION
384	VAGINAL SUSPENSION
385	VAGINAL TABLET
386	WOUND STICK

Table 22. Legal status

Code	Description
NR	NON RENEWABLE
R	RENEWABLE
PO	PHARMACY ONLY
GS	GENERAL SALE