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Health informatics — Identification of medicinal products — Data elements and structures for unique identification and exchange of regulated pharmaceutical product information

Informatique de santé — Identification des médicaments — Éléments de données et structures pour l'identification unique et l'échange d'informations réglementées sur les produits pharmaceutiques

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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 11616 was prepared by Technical Committee ISO/TC 215, *Health informatics*.

Introduction

This International Standard was developed in response to a worldwide demand for internationally harmonized specifications for medicinal products. It is one of five standards which together provide the basis for the unique identification of medicinal products. The group of standards comprises:

ISO 11615, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal product information*;

ISO 11616, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information*;

ISO 11238, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on substances*;

ISO 11239, *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*;

ISO 11240, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of units of measurement.*

The purpose of this International Standard is to present data elements, structures and their relationships in order to uniquely identify and exchange regulated pharmaceutical product information. This International Standard provides an accurate and consistent mechanism to fully represent the relationship of Pharmaceutical Product Identifier(s) (PhPID) with the following:

— Medicinal Product Identifier(s) (MPIDs);

— Investigational Medicinal Product Identifier(s) (IMPIDs).

These standards for the Identification of Medicinal Products (IDMP) support the activities of medicines regulatory agencies worldwide by jurisdiction. These include a variety of regulatory activities related to development, registration and life cycle management of medicinal products, as well as pharmacovigilance and risk management.

To meet the primary objectives of the regulation of medicines and pharmacovigilance, it is necessary to reliably exchange medicinal product information in a robust and reliable manner. The IDMP standards therefore support the following interactions:

— Regulatory Medicines Authority to Regulatory Medicines Authority;

— pharmaceutical company to Regulatory Medicines Authority;

— sponsor of a clinical trial to Regulatory Medicines Authority;

— Regulatory Medicines Authority to other stakeholders (as applicable);

— Regulatory Medicines Authority to worldwide-maintained data sources.

Unique identifiers produced in conformance with the IDMP standards are intended to support applications where it is necessary to reliably identify and trace the use of medicinal and pharmaceutical products.

Messaging specifications are included as an integral part of the IDMP standards. This is critical to describing and protecting the integrity of the interactions listed above for the submission of regulated medicinal product information in the context of unique product identification and acknowledgement of receipt (which includes the validation of transmitted information).

There are many terms in use to describe basic concepts in the regulatory and pharmaceutical standards development domain for different purposes and in different contexts. The terms and definitions described in this International Standard are to be applied for the concepts required to uniquely identify, characterize and exchange regulated medicinal products and associated information.

The terms and definitions adopted in this International Standard are intended to facilitate the interpretation and application of legal and regulatory requirements but they are without prejudice to any legally binding document. In case of doubt or potential conflict, the terms and definitions contained in legally binding documents prevail.

This International Standard has been developed in conjunction with the Common Product Model in HL7. It is anticipated that implementation will use HL7 V3 messaging to transmit information between stakeholders.

Health informatics — Identification of medicinal products — Data elements and structures for unique identification and exchange of regulated pharmaceutical product information

1 Scope

This International Standard is intended to provide specific levels of information relevant to the identification of a medicinal product or group of medicinal products. It defines the data elements, structures and relationships between data elements that are required for the exchange of regulated information, in order to uniquely identify pharmaceutical products. This identification is to be applied throughout the product lifecycle to support pharmacovigilance, regulatory and other activities worldwide. In addition, this International Standard is essential to ensuring that pharmaceutical product information is assembled in a structured format with transmission between a diverse set of stakeholders. This ensures interoperability and compatibility for both the sender and the recipient.

This International Standard is not intended to be a scientific classification for pharmaceutical products. Rather, it is a formal association of particular data elements categorized in prescribed combinations and uniquely identified when levelling degrees of information are incomplete. This allows for medicinal products to be unequivocally identified.

References to other normative IDMP and messaging standards for pharmaceutical product information are included in Clause 2, to be applied in the context of this International Standard.

Medicinal products for veterinary use are out of scope of this International Standard.

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 3166-1, *Codes for the representation of names of countries and their subdivisions — Part 1: Country codes*

ISO 11615, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal product information*

ISO 11238, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on substances*

ISO 11239, *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*

ISO 11240, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of units of measurement*

HL7 Version 3 Standard, *Common Clinical Product Model*

HL7 Version 3 Standard, *Common Product Model CMETS*

HL7 Version 3 Standard, *Regulated Product Submission*

HL7 Version 3 Standard, *Structured Product Labeling*

3 Terms, definitions and abbreviations

3.1 Terms and definitions

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

3.1.1
administrable dose form
pharmaceutical dose form as administered to the patient, after any necessary transformation of the packaged pharmaceutical dose form has been carried out

EXAMPLES Solution for injection, tablet for oral use, hard-capsule powder for inhalation.

3.1.2
adverse drug reaction
noxious and unintended response associated with the use of a drug in humans

NOTE 1 This can be post-approval (an adverse event that occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of diseases or for modification of physiological function) or pre-approval (an adverse event that occurs at any dose and where a causal relationship is at least a reasonable possibility).

NOTE 2 FDA 21 CFR 310.305 defines an adverse drug experience to include any adverse event, "whether or not considered to be drug-related." CDISC recognizes that current usage incorporates the concept of causality.

NOTE 3 Adapted from WHO Technical Report 498(1972); ICH E2A.

3.1.3
clinical trial
research investigation involving human subjects that is designed to answer specific questions about the safety and efficacy of a biomedical intervention (drug, treatment, device) or new ways of using a known drug, treatment, or device

[ICH E6 Glossary, Directive 2001/20/EC:2002, Version: 1-2009/04/19]

3.1.4
clinical trial registration number
registration number (identifier for tracking purposes) for a clinical trial as assigned by the Regulatory Medicines Authority

3.1.5
code value
result of applying a coding scheme to an element within a coded set

NOTE Adapted from ISO/IEC 2382-4:1999.

3.1.6
coding scheme
collection of rules that maps the elements of one set onto the elements of a second set

NOTE 1 The coding scheme applied in this International Standard refers to the following standards:

— ISO 11615, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal product information*;

— ISO 11238, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on substances*;

— ISO 11239, *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*;

— ISO 11240, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of units of measurement*.

NOTE 2 Adapted from ISO/IEC 2382-4:1999.

3.1.7
controlled vocabulary
finite set of values that represent the only allowed values for a data item

NOTE These values may be codes, text, or numeric.

[CDISC Clinical Research Glossary V8.0, 2009]

3.1.8
TermID
controlled vocabulary term identifier
concept identifier intended to be used as the preferred unique identifier for that concept in that code system and which is published by the author of a code system

NOTE 1 The TermID remains constant over time, independent of the particular version of the knowledge resource.

NOTE 2 Adapted from HL7 Core Principles.

3.1.9
designation
symbolic representation of a concept

NOTE Adapted from ISO 1087-1:2000.

3.1.10
dose form
pharmaceutical dose form
physical manifestation of a product that contains the active ingredient(s) and/or inactive ingredient(s) that are intended to be delivered to the patient

NOTE Pharmaceutical dose form may refer to the administered dose form or the packaged dose form, depending on the product it is describing.

3.1.11
globally unique identifier
identifier that is different from any other such identifier in any domain namespace

3.1.12
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

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

[ENV 1613:1995]

3.1.13
identifier
description that is sufficient to differentiate objects in a given environment

[ENV 12610]

NOTE In the context of this International Standard, this is a list of identifying characteristics that together unambiguously identify a medicinal product, pharmaceutical product, substance, detailed substance description, excipient, route of administration, dose form and any other element that requires to be uniquely identified.

3.1.14
investigational code
sponsor code
code assigned by a regulatory authority to a sponsor's investigational new drug application prior to the initiation of a clinical trial

3.1.15
investigational medicinal product
pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including products already with a marketing authorization but used or assembled (formulated or packaged) in a way different from the authorized form, or when used for an unauthorized indication, or when used to gain further information about the authorized form

3.1.16
jurisdiction
geographical area or subject matter to which the pharmaceutical legislative authority applies

3.1.17
manufactured dose form
pharmaceutical dose form as presented in the packaging by the manufacturer, before any necessary transformation has been carried out to yield the administered dose form

EXAMPLE Powder for solution for injection.

NOTE In many instances, there is no transformation necessary and the manufactured dose form is equal to the administered dose form.

3.1.18
medical device
any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

— diagnosis, prevention, monitoring, treatment or alleviation of disease;

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;

— investigation, replacement or modification of the anatomy or of a physiological process;

— control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

[EC Directive 2007/47 on Medical Devices]

NOTE This definition is applicable for the purposes of this and related standards alone (ISO 11238, ISO 11239, ISO 11240, ISO 11615 and this International Standard).

3.1.19
medicinal product
any substance or combination of substances, which may be administered to human beings for treating or preventing disease with the view to making a medical diagnosis or to restore, correct or modify physiological functions

[ENV 13607, ENV 12610]

NOTE 1 A medicinal product may contain one or more manufactured items and one or more pharmaceutical products.

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

3.1.20
pharmaceutical product
qualitative and quantitative composition of a medicinal product in the dose form authorized for administration by a regulatory authority, and as represented with any corresponding regulated product information

NOTE 1 A medicinal product may contain one or more pharmaceutical products.

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

3.1.21
packaged pharmaceutical product
qualitative and quantitative composition of the pharmaceutical product as contained in the package of the medicinal product

NOTE In many instances the packaged pharmaceutical medicinal product will be equal to the medicinal product. However, there are instances where, for example, the packaged pharmaceutical product(s) must be reconstituted before it can be administered to the patient (powder and solvent for solution for injection).

EXAMPLE Each vial of Fabrazyme contains a nominal value of 35 mg of agalsidase beta (packaged pharmaceutical product). After reconstitution with 7,2 ml of water for injections, each vial of Fabrazyme contains 5 mg/ml (35 mg/7 ml) of agalsidase beta (pharmaceutical product after reconstitution).

3.1.22
PHPID
pharmaceutical product identifier
globally unique identifier assigned to the pharmaceutical product(s)

3.1.23
pharmacovigilance
the process and science of monitoring the safety of medicines and taking action to reduce risks and increase benefits from medicines

NOTE 1 It is a key public health function.

EXAMPLE Pharmacovigilance includes:

— collecting and managing data on the safety of medicines;

— looking at the data to detect “signals” (any new or changing safety issue) and evaluating the data and making decisions with regard to safety issues;

— acting to protect public health (including regulatory action) and communicating with stakeholders;

— auditing, both of the outcomes of action taken and of the key processes involved.

NOTE 2 Those directly involved in pharmacovigilance include:

— patients as the users of medicines;

— doctors, pharmacists, nurses and all other healthcare professionals working with medicines and regulatory authorities responsible for monitoring the safety of medicines;

— pharmaceutical companies and companies importing or distributing medicines.

3.1.24
quantity value
value of a quantity number and unit (reference), together expressing magnitude of a quantity

NOTE 1 A quantity value expresses the magnitude of a quantity. This expression consists of a numerical value together with a unit of measurement. The unit of measurement represents a quantitative scale of reference that relates the measured (or estimated) quantity value to one or more reference quantity values. The numerical value is the result of comparing the measured quantity to this reference scale.

NOTE 2 The word “magnitude” is not defined in ISO/IEC Guide 99. However, this definition of quantity value indicates that “magnitude” is expressed as a quantity value, i.e. a quantity value is an expression of a magnitude and the same magnitude might be expressed in many quantity values.

NOTE 3 A reference can be a unit of measurement, a measurement procedure, a reference material, or a combination of such.

3.1.25
radiopharmaceutical kit
preparation to be reconstituted or combined with radionuclides in the final radiopharmaceutical, usually prior to its administration

NOTE In the context of a radiopharmaceutical kit, which is to be radio-labelled after supply by the manufacturer, the active substance/specified substance is considered to be that part of the formulation which is intended to carry or bind the radio-nuclide.

3.1.26
reference strength
substance(s) and/or specified substance(s) used as a reference to form the basis of strength of an investigational or authorized medicinal product

NOTE The reference strength refers to the strengths of the base, in case the strength of the substance is expressed as the salt or water for hydration.

3.1.27
specified substance
group of elements that describe multiple substance materials and specify further information on substances and multi-substance materials relevant to the description of medicinal products

NOTE 1 This could include grade, units of measure, physical form, constituents, manufacturer, critical manufacturing processes (i.e. extraction, synthetic, recombinant processes), specification and the analytical methods used to determine whether a substance is in compliance with a specification.

NOTE 2 There are four different groups of elements that can be used to define a given specified substance and specific relationships between each group of elements.

3.1.28
sponsor
individual, company, institution or organization which takes responsibility for the initiation, management and/or financing of a clinical trial

3.1.29
strength
quantitative composition
amount of substance or specified substance expressed quantitatively per dosage unit, per unit of mass or volume, according to the dosage form

NOTE 1 It is necessary for the quantitative composition of the substance(s)/specified substance descriptions of the finished authorized/investigational medicinal products, depending on the pharmaceutical form concerned, to specify the mass, or the number of units of biological activity, either per dosage unit or per unit of mass or volume, of each substance/specified substance.

NOTE 2 Substances/specified substance descriptions present in the form of compounds or derivatives are always designated quantitatively by their total mass and, if necessary or relevant, by the mass of active entity, or entities, of the molecule.

3.1.30
substance
matter of defined composition that has discrete existence, whose origin may be biological, mineral or chemical

NOTE 1 Substances may be either single substances or mixture substances.

NOTE 2 Single substances are always defined using a minimally sufficient set of data elements divided into five types: chemical, protein, nucleic acid, polymer and structurally diverse. Substances may be salts, solvates, free acids, free bases, or mixtures of related compounds that are either isolated or synthesized together.

NOTE 3 Pharmacopeial terminology and defining characteristics are used when available and appropriate. Defining elements are dependent on the type of substance.

NOTE 4 Discrete existence refers to the ability of a substance to exist independently of any other substance. Substances may either be well-defined entities containing definite chemical structures, synthetic (i.e. isomeric mixtures) or naturally-occurring (i.e. conjugated oestrogens) mixtures of chemicals containing definite molecular structures, or materials derived from plants, animals, microorganisms or inorganic matrices for which the chemical structure may be unknown or difficult to define.

3.1.31
unit of measurement
real scalar quantity, defined and adopted by convention, with which any other quantity of the same kind can be compared in order to express the ratio of the two quantities as a number

NOTE Depending on the nature of the reference scale, the unit of measurement expression may stand either for a physical unit of measurement that is related to a system of quantities (e.g. SI units) or for an arbitrarily defined unit of measurement, which may refer to a certain reference material, a standard measurement procedure, a material measure or even to a combination of those.

3.1.32
unit of presentation
qualitative term describing the unit in which the strength(s) of the manufactured item or pharmaceutical product is presented and described

NOTE 1 This is often used specifically at the point of delivery to the patient in cases where a quantitative unit of measurement is not applicable.

NOTE 2 A unit of presentation may have the same “display name” as in another controlled vocabulary, such as a pharmaceutical dose form, but the two concepts are not equivalent, and each has a unique controlled vocabulary term identifier.

EXAMPLE A tablet, spray or puff “contains 100 µg per spray” (unit of presentation = spray).

3.1.33
UDI
unique device identifier
unique identifier assigned to a medicinal product as defined by the International Medical Device Regulators’ Forum (IMDRF)

3.1.34
(vaccine) adjuvant
component that potentiates the immune response to an antigen and/or modulates it towards the desired immune response

3.1.35
vocabulary
terminological dictionary which contains designations and definitions from one or more specific subject fields

NOTE Adapted from ISO 1087-1:2000, definition 3.7.2.

3.2 Abbreviations

3.2.1
CV
Controlled Vocabulary

3.2.2
FDA
United States Food and Drug Administration

3.2.3
EP
European Pharmacopeia

3.2.4
IMDRF
International Medical Device Regulators’ Forum

3.2.5
ICH
International Conference on Harmonization

3.2.6
ICSR
Individual Case Safety Report

3.2.7
IMP
Investigational Medicinal Products

3.2.8
IMPID
Investigational Medicinal Product Identifier

3.2.9
MPID
Medicinal Product Identifier

3.2.10
PhPID
Pharmaceutical Product Identifier

3.2.11
UoM
Unit of Measurement

3.2.12
USP
United States Pharmacopeia

3.2.13
UDI
Unique Device Identification Code

3.2.14
HL7
Health Level Seven

3.2.15
TermID
Term Identifier (Controlled Vocabulary)

4 Requirements

4.1 Elements required for the unique identification of pharmaceutical products

This chapter describes the elements required to uniquely identify and characterize a pharmaceutical product. It provides the requirements to support pharmaceutical product identification.

Pharmaceutical Product Identification (PhPID) shall be based on the following subset of elements that describe the pharmaceutical product:

a) substance(s)/specified substance(s);

b) strength(s), strength units (units of measurement and/or unit of presentation);

c) reference strengths;

d) administrable dose form;

e) medical device, when it is a component of a medicinal product.

These elements are described in detail in ISO 11615. In addition, ISO 11615 describes manufactured items that require reconstitution prior to administration.

Pharmaceutical identifiers and elements shall represent pharmaceutical products as represented in a medicinal product per the authorization by a regulatory authority. Off-label usage of medicinal products is outside the scope of this International Standard.

This International Standard and the related IDMP standards shall not be a substitute for evidence to support broader claims of efficacy in relation to other medicinal products that are assigned identical PhPIDs as outlined in ISO 11615.

The data elements required for the generation of PhPIDs depend further on controlled vocabularies (CVs) as described in the following documents:

ISO 11615, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal product information*;

ISO 11238, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on substances*;

ISO 11239, *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*;

ISO 11240, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of units of measurement.*

4.2 Exchange of pharmaceutical product information

To successfully support information sharing in the exchange of regulated product information between the parties mentioned in the Introduction, the construct of the message shall be in a format that allows for full compatibility and interoperability between stakeholders upon implementation.

The HL7 Version 3 messaging standard shall be utilized for the exchange of medicinal product information emphasizing the importance of having a standardized method of exchanging medicinal product information in support of regulatory and pharmacovigilance activities.

5 Identifying characteristics for the identification of pharmaceutical products

5.1 Pharmaceutical product identification strata and levels

5.1.1 General

PhPIDs shall be represented within two strata (active substance stratum and specified substance stratum), both of which contain four PhPID identification levels, for each pharmaceutical product contained in a medicinal product.

PhPIDs shall be generated using the substance standard (see ISO 11238), the Strength and Administrable Dose Form section (see ISO 11239) and Unit(s) of Measurement standard (see ISO 11240) as illustrated below.

Reference strength shall be repeated in both PhPID strata. The reference strength shall be derived from the active substance and the specified substance depending on the specific product characteristics.

NOTE All the PhPID Strata can be described at four different levels from 1 to 4.

Table 1 — The four levels of PhPID

PhPID Active Substance Stratum	PhPID_SUB_L1 → Substance(s) Term PhPID_ SUB _L2 → Substance Term(s) + Strength + Reference Strength PhPID_ SUB _L3 → Substance Term(s) + Administrable Dose Form PhPID_ SUB _L4 → Substance(s) Term+ Strength + Reference Strength + Administrable Dose Form
PhPID Specified Substance Stratum	PhPID_SpSUB_L1 → Specified Substance(s) Term PhPID_SpSUB_L2 → Specified Substance(s) Term+ Strength + Reference Strength PhPID_SpSUB_L3 → Specified Substance(s) Term + Administrable Dose Form PhPID_SpSUB_L4 → Specified Substance(s) Term + Strength + Reference Strength + Administrable Dose Form

NOTE 1 A pharmaceutical product may refer to a drug that is associated with a medical device (e.g. drug/device, biologic/device). In this instance, the device term and term ID (unique device identifier) shall be displayed with the substance(s) and specified substance(s) terms for the product at all applicable PhPID levels. This association shall be made by directly associating the assigned PhPIDs to a medicinal product and its corresponding MPID and PCID as outlined in ISO 11615.

NOTE 2 Strength is not applicable to a device.

NOTE 3 A jurisdiction may further refine the requirements in relation to specification of the medical device as part of this International Standard at implementation so that this information is to be specified only if required.

NOTE 4 A pharmaceutical product may refer to a drug that is associated with an adjuvant (e.g. vaccine). In this instance, the adjuvant term and term ID shall be displayed with the substance(s) and specified substance(s) terms for the product at all applicable PhPID levels. This association shall be made by directly associating the assigned PhPIDs to a medicinal product and its corresponding MPID and PCID as outlined in ISO 11615.

Strength shall indicate quantity, unit of measurement and/or unit of presentation.

Administrable dose form is derived from the pharmaceutical product.

5.1.2 PhPID Specified Substance

As described in ISO 11238, specified substance(s) shall capture detailed characteristics of single substances or the composition of material that contains multiple substances or multiple physical forms.

The elements necessary to define specified substances shall be divided into four groups to facilitate implementation.

These groups are described as follows.

a) Group 1 Specified Substance. Elements shall be used to describe material that contains multiple substances, solvents used in the preparation of herbal or allergenic extracts, specific marker or signature substances present in plant or animal derived materials, the physical form of a substance, when relevant, and any properties essential to the description of the material.

   The element groups used to define a group 1 specified substance shall include constituents, physical form and property.

NOTE This grouping of elements allows for the definitions of many materials in commerce that are used in the formulation of medicinal products.

b) Group 2 specified substance. Group 2 elements shall be used to capture the manufacturer of either a substance or a group 1 specified substance along with minimal manufacturing information.

   The minimal manufacturing information shall include the overall production method type, (i.e. synthetic,

extractive, recombinant) production system type, (i.e. cell line, plant or animal tissue), production system (specific cell line).

NOTE Group 2 elements would allow the tracking of the substance to the manufacturer. It also allows the distinguishing of synthetic peptides from recombinant peptides and the capture of the product cell line.

c) Group 3 specified substance. Group 3 elements shall capture the grade of the material along with the source that defines the given grade.

Group 3 elements shall be used to distinguish specific pharmacopeial grades and technical grades of material.

The grade for each pharmacopeia shall be a separate substance if a pharmacopeial monograph related to a substance is not harmonized.

NOTE For most active pharmaceutical substances, typical grades are USP, EP or JP. For herbal substances, the grades would be standardized, quantified and unstandardized.

d) Group 4 Specified Substance. Group 4 elements shall contain the most detailed information on a substance. This information shall include critical manufacturing processes, specifications (impurities and related substance limits would be captured using constituents), unitage, reference material and analytical methods used for potency determination.

NOTE The specific information described for group 4 specified substances is often submitted in regulatory submissions in an unstructured manner that is difficult to capture and organize. The fields developed here will attempt to organize and structure the data in a manner that will facilitate its use in both review and compliance activities.

5.1.3 Pharmaceutical Product Specified Substance Identification (PhPID SpSub)

The PhPIDs for specified substance(s) shall be generated from three of the four groups (groups 1 to 3) identified within ISO 11238.

Groups 1, 2, and 3 contain necessary data elements for more detailed pharmaceutical product identification which supports the scope and purpose of this International Standard.

Groups 1 to 3, as assigned to an active substance(s) shall be utilized within this International Standard for pharmaceutical product identification with corresponding PhPIDs attributed as applicable.

Group 4 is a more comprehensive level of substance identification that is not necessary for the purposes of pharmaceutical product identification and shall not be utilized for PhPID generation.

Specified substance information shall be represented with the active substance(s) elements within a pharmaceutical product and within a group 1 specified substance, as applicable.

Groups 2 and 3 shall be associated directly with the active substance(s) of a pharmaceutical product and to a group 1 specified substance as applicable.

NOTE 1 An implementation guide addresses the assignment and association of specified substance groups for defined product classes. See ISO 11238 for detailed information related to substance and specified substance elements and identification.

NOTE 2 A jurisdiction may further refine the requirements in relation to specification of specified substances as part of this International Standard at implementation such that this information is to be specified only if required.

5.2 Cardinality

The relationships within the elements of a pharmaceutical product shall respect the following cardinality:

— a PhPID has one pharmaceutical dose form (cardinality relationship: 1..1);

— a PhPID may have zero to one unit of presentation (cardinality relationship: 0..1);

NOTE This is often used specifically at the point of delivery to the patient in cases where a quantitative unit of measurement is not applicable.

— a PhPID has one or more active substances (cardinality relationship: 1..*n*);

— a PhPID has one or more active specified substances (cardinality relationship: 1..n);

— a PHPID has one or more specified substances (cardinality relationship: 1..*n*);

— a PhPID has one strength (cardinality relationship: 1..1) based on one to many active substances or specified substances (cardinality relationship: 1..*n*); for liquid preparations, the unit volume (cardinality relationship: 1..1) and total volume per container (cardinality relationship: 1..1) shall both be represented;

— a PHPID has one reference strength (cardinality relationship: 1..1) but it can be composed from strength of one to many active substances or specified substances (cardinality relationship: 1..*n*).

5.3 Representation of strength concentration

For liquid preparations, strength shall be represented by both the total volume of the container as authorized by a Regulatory Medicines Authority and strength concentration per unit volume (e.g. 1 ml). For PhPID generation and assignment, the strength shall be expressed per total volume per container (MCID and PCID) with the corresponding strength concentration per unit volume represented in every instance of PhPID Levels 2 and 4. Both representations shall be considered mandatory elements when illustrating the strength of a pharmaceutical product.

EXAMPLE If two products contain the same strength per 1 ml, but with different container volumes represented, (Product A at 25 mg/5 ml and Product B at 50 mg/10 ml), different PhPIDs are assigned, with the strength per unit volume of 5 mg/ml represented within PhPID levels 2 and 4.

The strength concentration per unit volume shall be calculated from the strength per total volume of the container and presented at all PhPID levels where strength is represented in accordance with the product authorization by a regulatory authority.

The strength per unit volume shall be included as a data element and mapped to the strength per total volume at all applicable PhPID levels to support the interoperability and exchange of pharmaceutical product data.

The calculation and mapping of strength concentration per unit volume to the strength per total volume at all applicable PhPID levels shall be addressed during implementation and maintenance of this International Standard.

5.4 Pharmaceutical product identifier (PhPID)

The PhPID is a unique code assigned at the level of the pharmaceutical product and utilizes the identifying characteristics as outlined below. For products that need to be reconstituted in accordance with the authorization by a Regulatory Medicines Authority before they can be administered, the PhPID shall refer to the characteristics of the product after reconstitution.

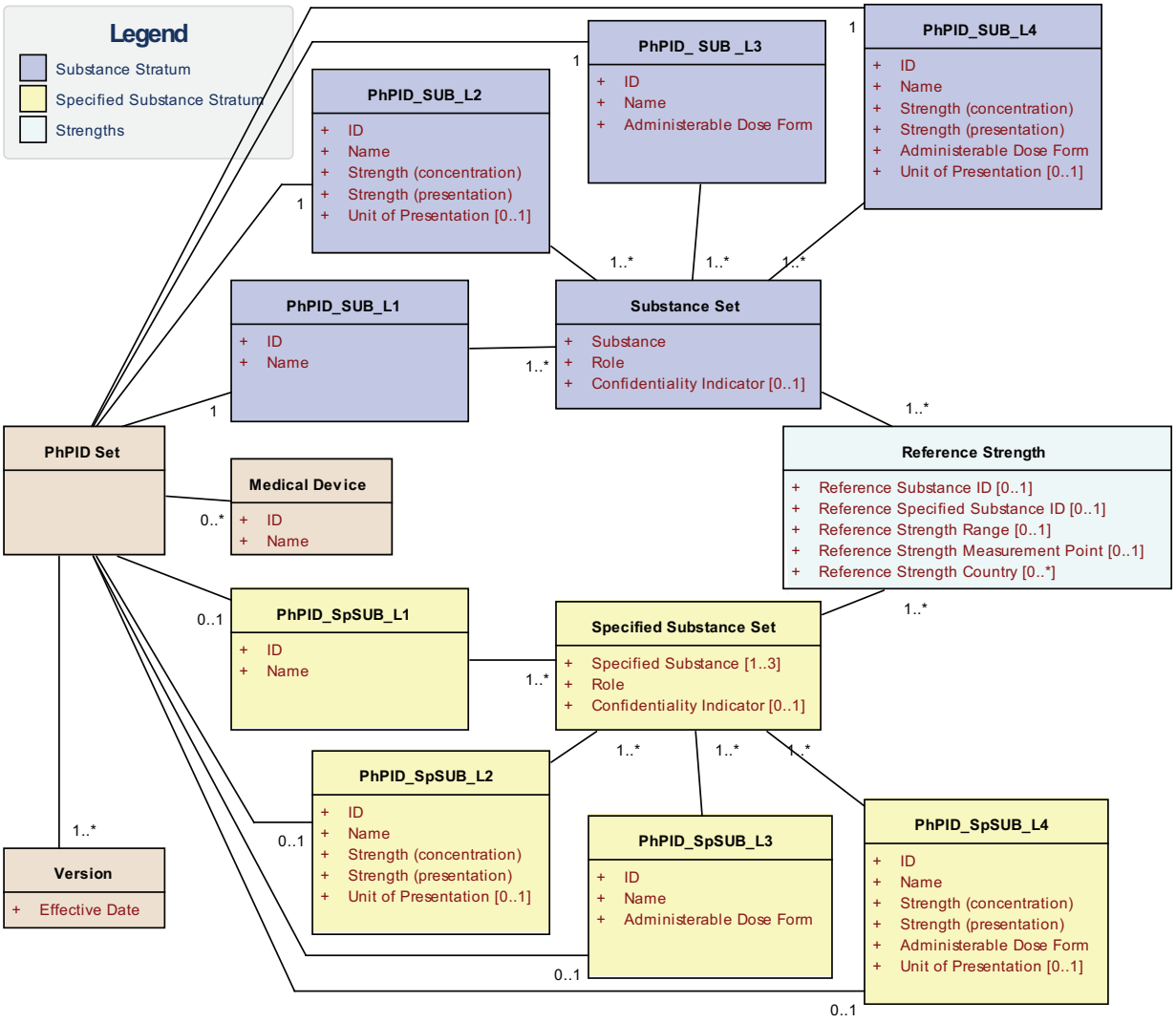

Figure 1 — Identifying characteristics for PhPIDs

NOTE For more detailed information regarding the specific data elements classifying a particular substance(s) and specified substance(s), see ISO 11238. The details of these elements are defining attributes for pharmaceutical product identification and assignment of PhPIDs.

5.5 Pharmaceutical product substance stratum elements (PhPID_SUB_Lx)

5.5.1 The construct of the pharmaceutical product substance stratum

The construct of the pharmaceutical product substance stratum utilizes the active substance(s) with strength, reference strength, administrable dose form and medical device (when applicable).

5.5.2 Substance Set

5.5.2.1 General

Each pharmaceutical product shall have one or more active substances. For each, the Substance and its Role shall be identified.

5.5.2.2 Substance

Each Substance is a value drawn from a value set specified in ISO 11238. It is to be specified using a CD data type.

5.5.2.3 Substance Term-ID

The Substance Term-ID of the pharmaceutical product shall be specified, based on a value drawn from the value set as defined in ISO 11238. The standard term identifier for the “Substance” (see ISO 11238) shall be described.

5.5.2.4 Substance Term

The Substance Term of the pharmaceutical product shall be specified, where applicable based on a value drawn from the value set as defined in ISO 11238. The standard term for the Substance (see ISO 11238) shall be described.

5.5.2.5 Role

The role that the substance plays in the product shall be specified. For instance “active ingredient”, “adjuvant”.

5.5.3 Administrable dose form

5.5.3.1 General

This shall describe the pharmaceutical dose form to be administered in accordance with the terms as authorized by a Regulatory Medicines Authority, after it has undergone any necessary reconstitution. It is a value drawn from a value set specified in ISO 11239. It is to be specified using a CD data type.

EXAMPLE Tablet, capsule, oral solution, suspension.

Each pharmaceutical product can have only one pharmaceutical form.

NOTE A medicinal product may have two manufactured items, one with a manufactured dose form of “powder” and the other with a manufactured dose form of “solution”, which is the solvent. These are then reconstituted to an administrable dose form “solution for injection” before being administered to a patient.

5.5.3.2 Administrable Dose Form Term-ID

The “Administrable Dose Form Term-ID” of the pharmaceutical product shall be specified on a value drawn from the value set as defined in ISO 11239. The standard term identifier for the administrable dose form (see ISO 11239) shall be described.

5.5.3.3 Administrable Dose Form Term

The Administrable Dose Form Term of the pharmaceutical product shall be specified on a value drawn from the value set as defined in ISO 11239. The standard term for the administrable dose form (see ISO 11239) shall be described.

5.5.4 Unit of presentation

5.5.4.1 General

Unit of presentation refers to the qualitative description of the unit in which the strength(s) of the pharmaceutical product is presented and described, often specifically at the point of delivery to the patient, in cases where a quantitative unit of measurement is not applicable. The unit of presentation standard term (see ISO 11239) shall be described.

EXAMPLE “Contains 100 µg per spray” (unit of presentation = spray).

5.5.4.2 Unit of Presentation Term-ID

The “Unit of Presentation Term-ID” of the pharmaceutical product shall be specified on a value drawn from the value set as defined in ISO 11239. The standard term identifier for the unit of presentation (see ISO 11239) shall be described.

5.5.4.3 Unit of Presentation Term

The “Unit of Presentation Term” of the pharmaceutical product shall be specified on a value drawn from the value set as defined in ISO 11239. The standard term for the unit of presentation (see ISO 11239) shall be described.

5.5.5 Medical device

When a medical device is a component of a pharmaceutical product, the following data elements apply.

5.5.5.1 Medical Device Term-ID

The Medical Device Term-ID of the pharmaceutical product shall be specified, when applicable, on a value drawn from a defined value set. The unique device identifier (UDI) shall be described based on an international reference terminology.

5.5.5.2 Medical Device Term

The Medical Device Term of the pharmaceutical product shall be specified, when applicable, on a value drawn from a defined value set. The medical device term shall be described based on an international reference terminology.

5.5.6 Confidentiality indicator

The confidentiality level of the organization information can be specified at all PhPID levels using an appropriate controlled vocabulary. The controlled term and a term identifier shall be specified.

EXAMPLE 1 Confidential.

EXAMPLE 2 No restriction.

5.6 Pharmaceutical Product Specified Substance Stratum Elements (PhPID_SpSUB_Lx)

5.6.1 The construct of the pharmaceutical product specified substance stratum

The construct of the pharmaceutical product specified substance stratum utilizes the specified substance(s) with strength, reference strength, administrable dose form, and medical device (when applicable).

NOTE A jurisdiction may wish to relax the requirement of the specification for specified substance as part of this International Standard at implementation so that this information is to be specified only if required.

5.6.2 Specified Substance Set

A pharmaceutical product shall have one or more specified substances. For each, the Specified Substance and its Role shall be identified. A specified substance shall reference one or more substances.

5.6.2.1 Specified Substance

5.6.2.1.1 Specified Substance Term-ID

Each Specified Substance is a value drawn from a value set specified in ISO 11238. It is to be specified using a CD data type.

The Specified Substance Term-ID of the pharmaceutical product shall be specified on a value drawn from the value set as defined in ISO 11238. The standard term identifier for the Substance (see ISO 11238) shall be described.

5.6.2.1.2 Specified Substance Term

The Specified Substance Term of the pharmaceutical product shall be specified on a value drawn from the value set as defined in ISO 11238. The standard term for the Specified Substance (see ISO 11238) shall be described.

5.6.2.2 Role

The role that the substance plays in the product shall be specified, for instance “active ingredient”, “adjuvant”.

5.6.3 Administrable dose form

This describes the pharmaceutical dose form to be administered in accordance with the terms as authorized by a Regulatory Medicines Authority, after it has undergone any necessary reconstitution. It is a value drawn from a value set specified in ISO 11239. It is to be specified using a CD data type.

EXAMPLES Tablet, capsule, oral solution, suspension. Each pharmaceutical product has only one pharmaceutical form.

NOTE A medicinal product may have two manufactured items, one with a manufactured dose form of “powder” and the other with a manufactured dose form of “solvent”. These are then reconstituted to an administrable dose form “solution for injection” before being administered to a patient.

5.6.3.1 Administrable Dose Form Term-ID

The Administrable Dose Form Term-ID of the pharmaceutical product shall be specified on a value drawn from the value set as defined in ISO 11239. The standard term identifier for the administrable dose form (see ISO 11239) shall be described.

5.6.3.2 Administrable Dose Form Term

The Administrable Dose Form Term of the pharmaceutical product shall be specified on a value drawn from the value set as defined in ISO 11239. The standard term for the Administrable Dose Form (see ISO 11239) shall be described.

5.6.4 Unit of presentation

Unit of presentation refers to the qualitative description of the unit in which the strength(s) of the pharmaceutical product is presented and described, often specifically at the point of delivery to the patient, in cases where a quantitative unit of measurement is not applicable. The unit of presentation standard term (see ISO 11239) shall be described.

EXAMPLE “Contains 100 mcg per spray” (unit of presentation = spray).

5.6.4.1 Unit of Presentation Term-ID

The Unit of Presentation Term-ID of the pharmaceutical product shall be specified on a value drawn from the value set as defined in ISO 11239. The standard term identifier for the Unit of Presentation (see ISO 11239) shall be described.

5.6.4.2 Unit of Presentation Term

The Unit of Presentation Term of the pharmaceutical product shall be specified on a value drawn from the value set as defined in ISO 11239. The standard term for the Unit of Presentation (see ISO 11239) shall be described.

5.6.5 Medical device

When a medical device is a component of a pharmaceutical product, the following data elements apply.

5.6.5.1 Medical Device Term-ID

The “Medical Device Term-ID” of the pharmaceutical product shall be specified, when applicable, based on a value drawn from a defined value set. The UDI shall be described based on an international reference terminology.

5.6.5.2 Medical Device Term

The Medical Device Term of the pharmaceutical product shall be specified, when applicable, based on a value drawn from a defined value set. The medical device term shall be described based on an international reference terminology.

5.7 Identifying characteristics to express strength

5.7.1 Expressing strength

Depending on the practices in a region or country, the strength description shall be the content of the active substance/specified substance description expressed quantitatively (e.g. per dosage unit, per unit of volume or per unit of weight, according to the pharmaceutical form or unit of presentation).

For a medicinal product with a different dose form before and after reconstitution, the pharmaceutical product section shall describe the strength of the actual pharmaceutical product after reconstitution or dilution in accordance with the regulatory product information.

NOTE 1 PhPIDs shall not include information related to dosing. The actual amount of product administered to a patient by a health care provider or self-administration is outside the scope of this International Standard.

For some pharmaceutical products, the exact dose strength cannot be indicated and therefore needs to be expressed as a range e.g. as “not greater than” or as “not less than” a particular value.

The strength indicated for the pharmaceutical product shall be identical to the strength after reconstitution to the volume as authorized by a Regulatory Medicines Authority.

EXAMPLE 1 Docetaxel concentrate 20 mg/0,5 ml including 1,5 ml solvent: the dose form and strength for the PhPID will be docetaxel solution for injection 20 mg/2 ml (10 mg/ml).

EXAMPLE 2 Abatacept powder for concentrate for solution for infusion does not contain solvent. The dose form and strength after dilution is stated in the product labelling, which shall be utilized as the dose form and strength of the PhPID: abatacept concentrate for solution for infusion 25 mg/ml.

NOTE 2 A description of strength is included Annex C.

5.7.2 Attributes for representation of strength in PhPID stratum elements

5.7.2.1 Strength (concentration)

The Strength (concentration) shall be specified as a quantity of the substance/specified substance present per one unit of the pharmaceutical product. For example “2 mg/1 ml”, “2 mg/1 tablet”. For solid dose forms this is generally the same as Strength (presentation). For liquid preparations, both the total volume of the container as authorized by a Regulatory Medicines Authority and strength concentration per unit volume shall be identified.

5.7.2.2 Strength (presentation)

The Strength (presentation) shall be specified as a quantity of the substance/specified substance present in a given quantity of the pharmaceutical product. For example “10 mg/5 ml”, “2 mg/1 tablet”.

5.7.2.3 Representation of Strength (concentration) and Strength (presentation)

The symbol and the symbol identifier for the unit of measure shall be specified as defined in ISO 11240 and its resulting controlled vocabulary.

Where the strength is defined on the basis of a Unit of Presentation, the term and term identifier shall be used as defined in ISO 11239 and its resulting controlled vocabulary.

The value and units of the strength range shall be specified using an RTO < PQ,PQ > data type. This supports the strength data to be given as a numerator and a denominator, each with units. It allows both a low and a high value to be specified as well as upper and lower ranges. If both low and high values are the same, the interval is equivalent to a single value. If the low value is zero or not valued, the range is interpreted as not greater than the high value. Similarly, if the high value is zero or not valued, the range is interpreted as not less than the low value.

The unit of measure symbol and the symbol identifier as defined in ISO 11240 and its resulting controlled vocabulary shall be specified.

Where the strength is defined on the basis of a “unit of presentation”, the term and term identifier shall be used as defined in ISO 11239 and its resulting controlled vocabulary.

5.7.2.3.1 Representing strength of multi-ingredient products

A product with two ingredients may have a strength described as the quantity of first ingredient plus quantity of second ingredient per unit of presentation. For example “15 mg + 850 mg/1 tablet”. In ISO 11615 this is expressed in detail by showing the strength associated with each ingredient but this level of detail is not required in ISO 11616. The RTO < PQ,PQ > data type allows a textual representation of the data and this should be used for these complex cases.

5.7.2.4 Reference strength

5.7.2.4.1 General considerations

There are two roles for substances and/or specified substances in the PHPID.

— The active substance/specified substance that is added to form the active basis of the product.

— To unambiguously link to the strength of the product. Each pharmaceutical product shall express strength associated with one or more substance(s) or specified substance(s). In addition, a reference strength for the product shall be expressed based on an anhydrous free acid, anhydrous free base or a substance “created” to express activity, where applicable.

EXAMPLE 1 Pancrelipase is an example where the expressed activity represents the reference strength. Pancrelipase (porcine) is identified as the active substance but there are three different substances upon which the strength of the product is based: pancrelipase lipase, pancrelipase protease, and pancrelipase amylase (see Annex B).

EXAMPLE 2 Morphine HCl·3H_2O: an injection that contains 5 mg morphine HCl·3H_2O per 1 ml, has a strength of 5 mg/ml morphine HCl·3H_2O and a reference strength of 3,80 mg/ml morphine base.

A substance(s) and/or specified substance(s) shall be used as a reference to form the basis of strength of an investigational or authorized medicinal product.

The reference strength of the substance(s) and/or specified substance(s) shall be described as a quantity of the substance present in a given quantity of the pharmaceutical product and shall be indicated using the Strength class.

5.7.2.4.2 Reference Strength Substance

If a Reference Strength Substance is specified, the value for the Reference Strength Substance shall be described using a term and a term identifier as defined in ISO 11238 and its resulting controlled vocabulary.

5.7.2.4.3 Reference Strength Specified Substance

If a Reference Strength Specified Substance is specified, the value for the Reference Strength Specified Substance shall be described using a term and a term identifier as defined in ISO 11238 and its resulting controlled vocabulary.

5.7.2.4.4 Reference Strength Range

The strength of the Reference Strength Substance or Reference Strength Specified Substance shall be specified as a quantity of the substance/specified substance present in a given quantity of the pharmaceutical product.

The symbol and the symbol identifier for the unit of measure shall be specified as defined in ISO 11240 and its resulting controlled vocabulary.

Where the strength is defined on the basis of a Unit of Presentation, the term and term identifier shall be used as defined in ISO 11239 and its resulting controlled vocabulary.

The value and units of the strength range shall be specified using an RTO < PQ,PQ > data type. This supports the strength data to be given as a numerator and a denominator, each with units. It allows both a low and a high value to be specified as well as upper and lower ranges. If both low and high values are the same, the interval is equivalent to a single value. If the low value is zero or not valued, the range is interpreted as not greater than the high value. Similarly, if the high value is zero or not valued the range is interpreted as not less than the low value.

The unit of measure symbol and the symbol identifier as defined in ISO 11240 and its resulting controlled vocabulary shall be specified.

Where the strength is defined on the basis of a Unit of Presentation, the term and term identifier shall be used as defined in ISO 11239 and its resulting controlled vocabulary.

5.7.2.4.5 Reference Strength Measurement Point

The Reference Strength Measurement Point, if applicable, can be described.

5.7.2.4.6 Reference strength country

The country or countries for which the Reference Strength Range and Measurement Point are valid can be specified using values from ISO 3166-1 alpha-2 code elements.

If a Measurement Point is specified, a country or countries should be described.

5.7.3 Representation of strength for a patch

For a patch, the strength shall be expressed as “per time unit” or “per each” patch in accordance with the approval by the medicines regulatory authority. If “per time unit” expression is not applicable, then the strength shall be expressed as “per each” patch.

When identifying the strength “per time unit” patch, the following principles are applied for PhPID generation:

— capture the rated release of the product (e.g. 1 μg/1 hour as authorized by the regulatory authority);

— capture the quantity released per total time unit (e.g., 24 μg/24 hour).

Where no rated release information is authorized, the quantity per each/contained by each but not delivered by each (e.g. 50 mg per each patch) shall be specified.

6 Relationship between MPID and PhPID

6.1 Concepts required for the unique identification of a medicinal product and the association with PhPIDs

Figure 2 shows the conceptual relationship between MPID and PhPID. The drawing is part of a larger conceptual drawing taken directly from ISO 11615, which should be consulted for detailed discussion of the classes presented.

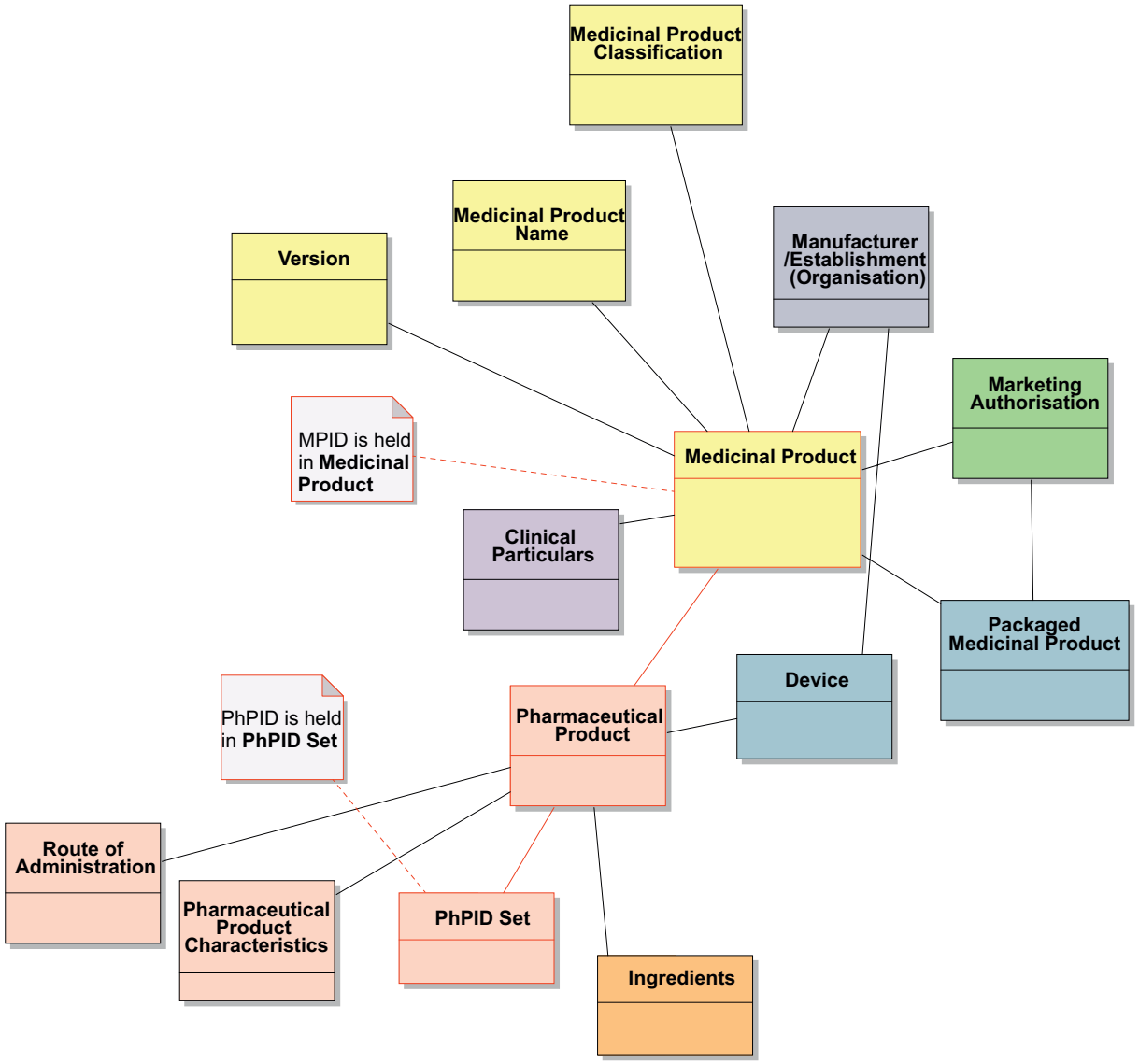

Figure 2 — Conceptual relationship between MPID and PhPID

This International Standard defines the concepts required to associate PHPID(s) with regulated medicinal products (authorized or under investigation in a clinical trial) as described in ISO 11615. Such association shall utilize the following principles.

a) A medicinal product may relate to one or more pharmaceutical products as part of a treatment regime [e.g. a kit, which might be a combination pack containing vaginal tablets (500 mg) and an external vaginal cream (10 %)].

b) The characterization of the pharmaceutical product(s) based on the active substance(s)/specified substance(s), the (reference) strength thereof, the pharmaceutical (administrable) dose form(s), and the medical device (e.g. a scaffolding for cell-based products) being part of the medicinal product.

c) The description of the pharmaceutical product(s) in the pharmaceutical dose form approved for administration, where applicable after reconstitution and as authorized in accordance with the regulated product information.

d) The association of the regulated (investigational) medicinal product and the pharmaceutical product(s) using the PhPID(s).

The PhPID standard is vital in associating products at this level of granularity e.g. to assist in product identification when a branded/proprietary name or MPID is unavailable. The elements defining the medicinal product identifier (MPID) are presented in the document ISO 11615.

The PhPID shall refer to one or more medicinal products, which contain the same administered pharmaceutical product.

A medicinal product shall refer to one or more PhPIDs as one to many PhPIDs may be associated with one or many MPIDs.

EXAMPLE If a medicinal product contains the same elements as defined for a particular PhPID level, they will share an identical PhPID. For example, medicinal product A with drug substance X will share a common PhPID1 level with medicinal product B containing the same drug substance X. Furthermore, if medicinal product A and B both contain substance X with an administrable dose form Y, but a different strength, PhPID1 and PhPID3 would be identical, but PhPID2 and PhPID4 levels would have a different PhPID assigned due to the differences in strength.

PhPIDs shall refer to a medicinal product being tested in a clinical trial(s) throughout all phases of development and after authorization by a regulatory authority within a particular jurisdiction. A change to any of the PhPID elements associated with a change to the medicinal product shall warrant the generation of a new MPID.

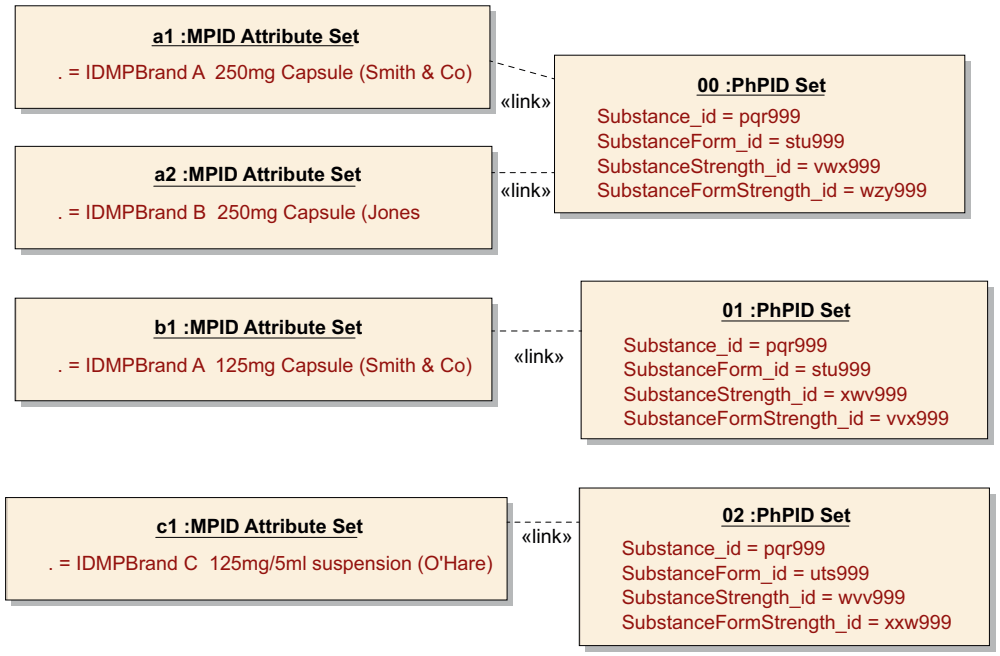

Figure 3 — Illustration of the relationship between MPID and PhPID

6.2 Pharmaceutical product identification criteria

6.2.1 General considerations

This subclause specifies how PhPIDs shall be generated.

6.2.2 Multiple products packaged as a kit and administered as separate medicinal products

A product that is constituted of units with different substances, strengths or dose form(s) that are intended to be administered independently of each other (e.g. a kit with tablets and cream to be taken at different time intervals in a particular order, or tablets of different strengths in one blister) shall be assigned separate PhPIDs for each product contained within the kit (see A.4).

6.2.3 Multiple products packaged as a kit for reconstitution and administered as one medicinal product

Multiple products packaged as a kit (combination pack) with the intent of being administered as one medicinal product shall be assigned one overarching PhPID for the medicinal product at the level of the kit.

EXAMPLE A product may be supplied as two items, a powder for solution for injection, and a solvent for solution for injection. One PhPID shall be assigned with the administrable dose form of solution for injection (see Annex B).

Products without solvents (single products) will also have the dose form after reconstitution. Products that are already solutions, e.g. products with dose form “powder” without solvents and products with dose form “powder” with solvents, where the reconstituted products are identical, shall share the same PhPIDs.

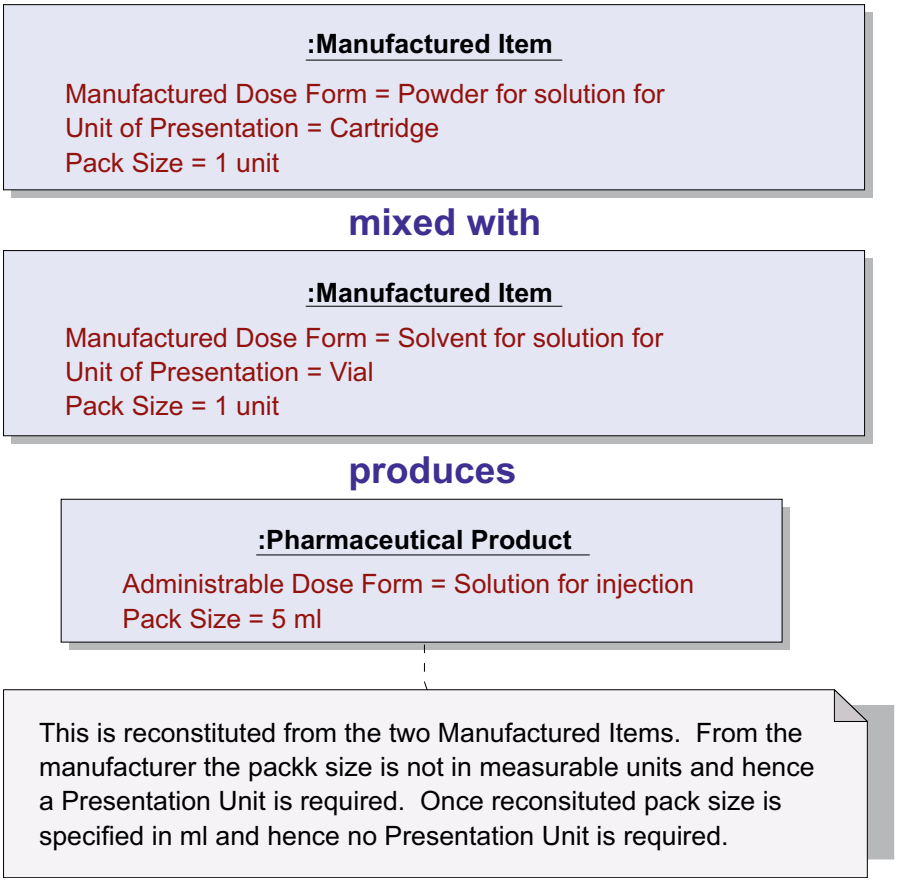

Figure 4 — Reconstituted kit example

6.2.4 Components of kits which are not packaged together (e.g. radiopharmaceutical kits)

A medicinal product authorized to be marketed as a kit with all components to be reconstituted and intended to be administered as one product (as approved by a regulatory authority) shall be assigned one PhPID as reconstituted.

For radiopharmaceutical kits, there may be instances where, due to safety reasons, the radiopharmaceutical components of the kit would not be packaged together. This will not trigger the generation of an additional PhPID if the product was authorized as a radiopharmaceutical kit to be administered as one product. The description of the manufacturing method of radiopharmaceutical kits shall include details of the manufacture of the kit and details of its recommended final processing to produce the radioactive medicinal product. The necessary specifications of the radio-nuclide need to be described in accordance, where relevant, with the general monograph or specific monographs of the applicable pharmacopoeia. In addition, any compounds essential for the radio-labelling shall be described. The structure of the radio-labelled compound shall also be described. For radio-nuclides, the nuclear reactions involved shall be described.

6.2.5 Different representations of strength in two or more regions for identical products

One PhPID shall be generated for a product that is authorized in two or more regions and contains multiple representations of an identical strength.

Different regional representations that are synonymous for identifying a particular strength in an identical product shall have the identical PhPIDs assigned, regardless of region.

Mapping of the different terms of each region that are synonymous with a particular strength can be addressed in maintenance and implementation.

6.2.6 Representation of PhPID for a patch

For a patch, the strength shall be expressed as amount per each patch and per time unit (when applicable). In addition to identifying the amount per each patch, the following principles shall be applied when generating PhPIDs for a patch (see Annex B):

— capture the rated release of the product (as authorized by the regulatory authority);

— capture the quantity released per time unit (e.g., 24 μg/24 hour).

Where no rated release information is authorized, capture the quantity per each/contained by each but not delivered by each (e.g. 50 mg per each patch).

7 Relationship between IMPID and PhPID

Investigational medicinal products refer to the medicinal product being tested in a clinical trial throughout all phases of development prior to its authorization by a regulatory authority within the region in which the product is intended to being marketed.

The IMPID is using a common attribute set related to an investigational medicinal product, which when all of them have a value, define a specific IMPID concept. The pattern is:

— Country Code Segment [ISO 3166-1 alpha-2 code elements];

— Sponsor [Organization Identifier] Code Segment;

— Sponsor Product Code and/or Regulator Product Code (depending on regional requirements) Segment.

Figure 5 shows the conceptual relationship between IMPID and PhPID. The figure is part of a larger conceptual drawing taken directly from ISO 11615, which should be consulted for a detailed discussion of the classes presented.

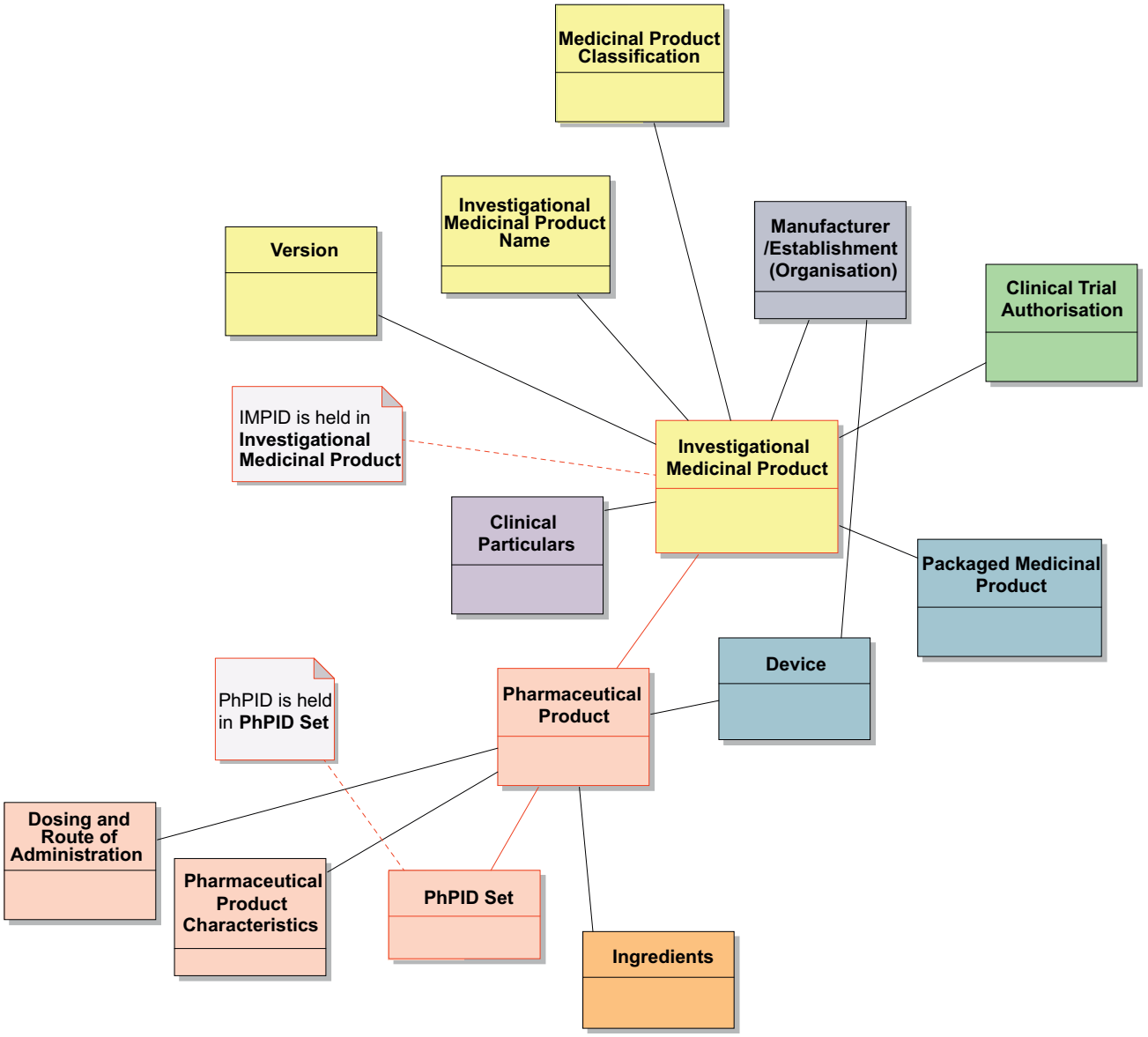

Figure 5 — Conceptual relationship between IMPID and PhPID

PhPIDs shall refer to an investigational medicinal product being tested in a clinical trial(s) throughout all phases of development prior to its authorization by a regulatory authority within a particular jurisdiction. A change to any of the PhPID elements associated with a change to the medicinal product shall warrant the generation of a new IMPID.

The principles for assigning a PhPID to an investigational medicinal product are identical to their assignment for authorized medicinal products. However, there may be dissimilarities between regulators or when PhPID levels are to be assigned to an investigational medicinal product (e.g. different phases of development). As stated, this International Standard accommodates the generation and assignment of PhPIDs for investigational medicinal products, but the timing and utilization of PhPID levels for investigational medicinal products shall be addressed in regional implementations of this International Standard.

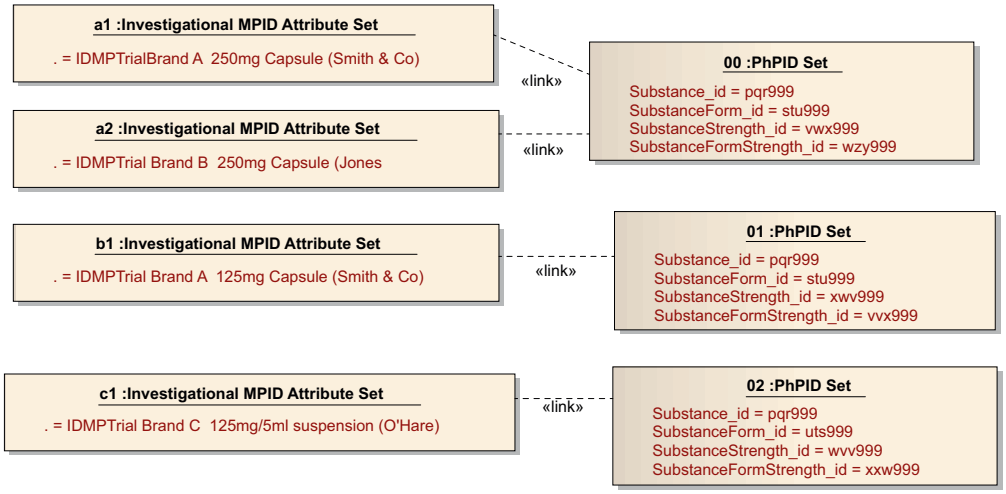

Figure 6 — High-level example of the relationship between IMPID and PhPID

8 Conceptual model

The composition of the pharmaceutical product as authorized by a Regulatory Medicines Authority shall be captured in a structured format. To illustrate this point, a high-level conceptual model related to the pharmaceutical product is presented in Figure 7 along with representative examples (in Annex A) for pharmaceutical product identification assignment.

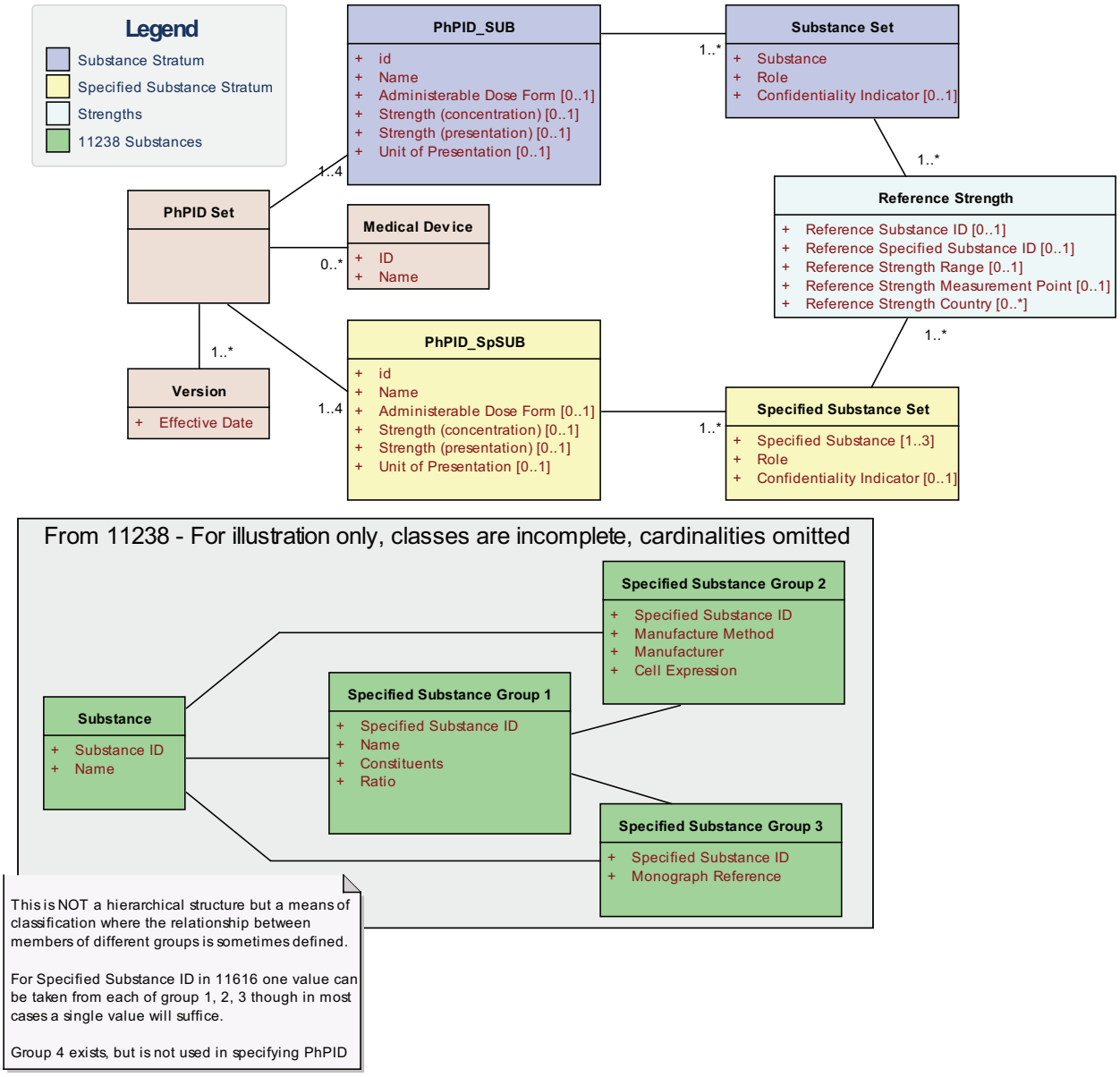

Figure 7 — High-level conceptual model of pharmaceutical product identification

Annex A
(informative)

Examples

A.1 General

As presented in this International Standard, the following illustrations represent the foundational data elements for generation of pharmaceutical product identifiers (PhPIDs).

A.2 PhPID model (Figure A.1)

Figure A.1 shows a modelled representation of PhPID data elements for an adjuvanted H1N1 influenza vaccine. The detailed MPID data elements for this model can be found in ISO 11615, Annex B for the MPID data elements.

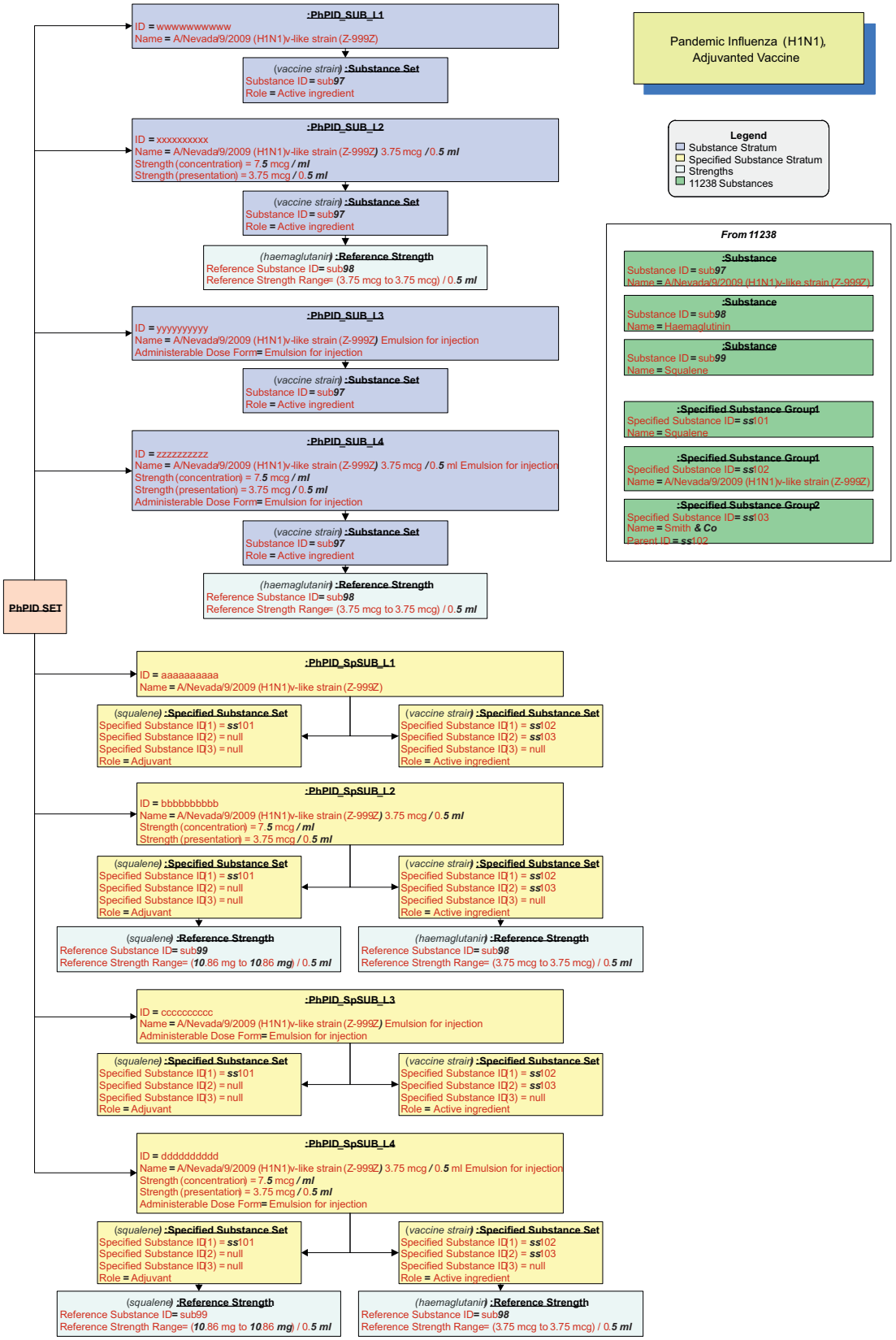

Figure A.1 — PhPID Model: Pandemic influenza (H1N1), adjuvanted vaccine

A.3 Solid oral (Figure A.3)

Invented brand name: LITHDRUG® (lithium carbonate, pharmacopeia), extended-release tablets 300 mg, ISO IDMP Manufacturer Alpha.

Components: 1

Strength/dosage form: 300 mg tablet

Active substances: lithium carbonate

Reference strength: lithium ion, 8,1 mmol

Table A.1 — Strata and levels

PhPID Active Substance Stratum	PhPID_SUB_L1 → lithium carbonate PhPID_SUB_L2 → lithium carbonate 300 mg (lithium ion, 8,1 mmol)* PhPID_ SUB _L3 → lithium carbonate, tablet, extended release PhPID_ SUB _L4 → lithium carbonate 300 mg (lithium ion, 8,1 mmol), tablet, extended-release
PhPID Specified Substance Stratum	PhPID_SpSUB_L1 → ISO IDMP Manufacturer Alpha, (USP, EP Monograph) lithium carbonate PhPID_SpSUB_L2 → ISO IDMP Manufacturer Alpha, (USP, EP Monograph) lithium carbonate 300 mg (lithium ion, 8,1 mmol) PhPID_SpSUB_L3 → ISO IDMP Manufacturer Alpha, (USP, EP Monograph) lithium carbonate, tablet, extended-release PhPID_SpSUB_L4 → ISO IDMP Manufacturer Alpha, (USP, EP Monograph) lithium carbonate 300 mg (lithium ion, 8 mmol), tablet, extended-release

NOTE 1 The strength and reference strength are different in this example.

NOTE 2 See ISO 11238 for the detailed data elements defining a substance/specified substance (e.g. source, grade, additional manufacturing information).

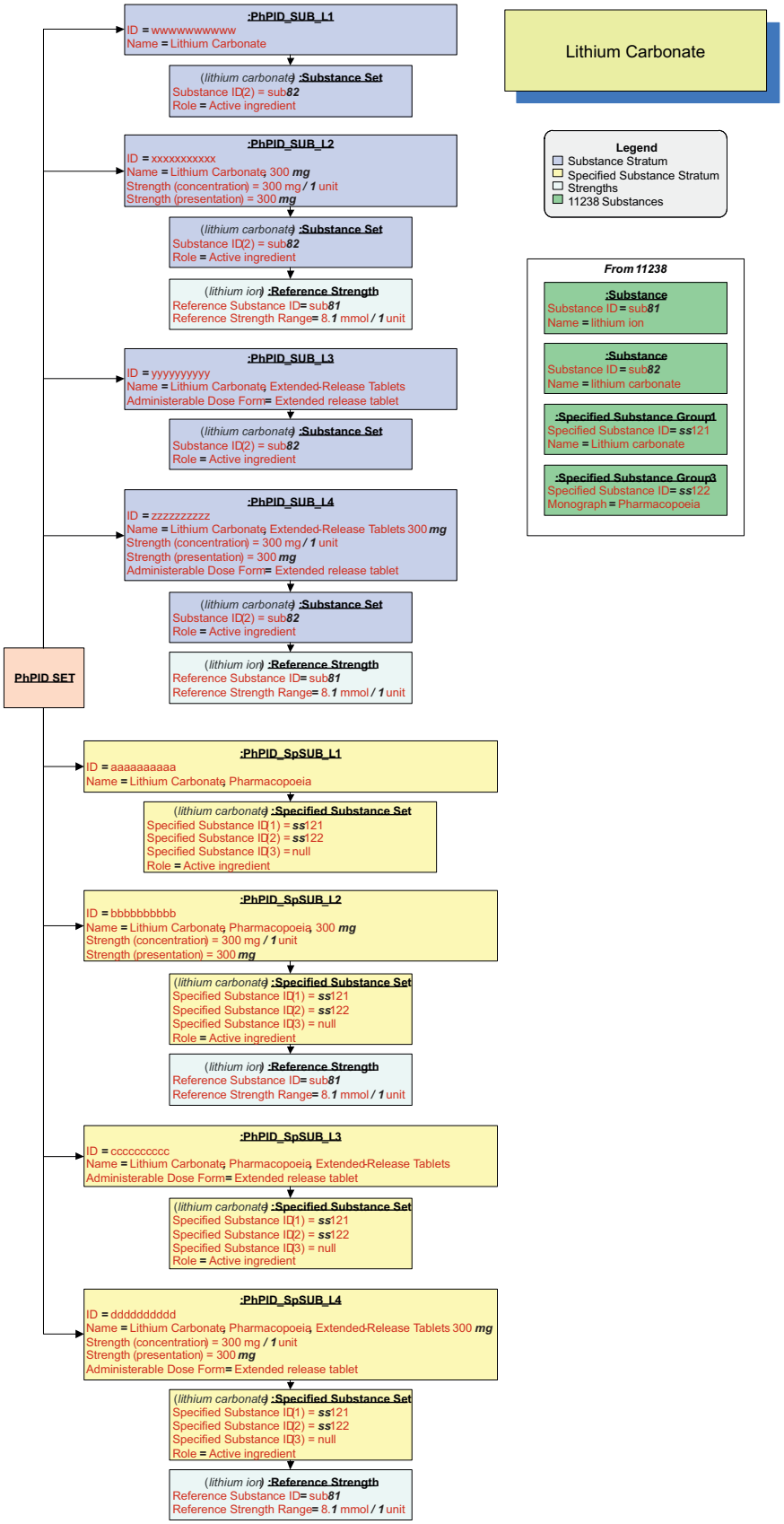

Figure A.2 — PhPID model: LITHDRUG® (lithium carbonate, pharmacopeia)

A.4 Multiple products packaged as a kit and administered as separate medicinal products

Invented brand name: COMBIDRUG™ combination pack (vaginal tablets 500 mg and cream 1 %), ISO IDMP Manufacturer Bravo

Components: 2

Strength/dosage form: 500 mg tablet and 1 % external cream

Active substances: clotrimazole tablet/clotrimazole cream

Reference strength: 500 mg clotrimazole/1 % clotrimazole

Table A.2 — Strata and levels

PhPID Active Substance Stratum	PhPID_SUB_L1 → clotrimazole PhPID_SUB_L2 → clotrimazole 500 mg (clotrimazole 500mg) PhPID_ SUB _L3 → clotrimazole tablet PhPID_ SUB _L4 → clotrimazole 500 mg tablet (Clotrimazole 500mg)
PhPID Specified Substance Stratum	PhPID_SpSUB_L1 → (ISO IDMP Manufacturer Bravo) clotrimazole PhPID_SpSUB_L2 → (ISO IDMP Manufacturer Bravo) clotrimazole 500 mg (clotrimazole 500 mg) PhPID_SpSUB_L3 → (ISO IDMP Manufacturer Bravo) clotrimazole tablet PhPID_SpSUB_L4 → (ISO IDMP Manufacturer Bravo) clotrimazole 500 mg tablet (clotrimazole 500 mg)
PhPID Active Substance Stratum	PhPID_SUB_L1 → clotrimazole PhPID_SUB_L2 → clotrimazole 1 % (clotrimazole 1 %) PhPID_ SUB _L3 → clotrimazole external cream PhPID_ SUB _L4 → clotrimazole 1 % external cream (clotrimazole 1 %)
PhPID Specified Substance Stratum	PhPID_SpSUB_L1 → (ISO IDMP Manufacturer Bravo) clotrimazole PhPID_SpSUB_L2 → (ISO IDMP Manufacturer Bravo) clotrimazole 1 % (clotrimazole 1 %) PhPID_SpSUB_L3 → (ISO IDMP Manufacturer Bravo) clotrimazole external cream PhPID_SpSUB_L4 → (ISO IDMP Manufacturer Bravo) clotrimazole 1 % external cream (clotrimazole 1 %)

NOTE See ISO 11238 for the detailed data elements defining a substance/specified substance (e.g. source, grade, additional manufacturing information).

A.5 Multiple products packaged as a kit for reconstitution and administered as one medicinal product

Invented brand name: ANTIHEMODRUG© (antihaemophilic factor, recombinant human) kit, ISO IDMP Manufacturer Charlie

Components: 2 (antihaemophilic factor, powder for solution and Sterile Water for Injection)

Strength/dosage form: 250 iU/10 ml (25 iU/ml), solution for injection

Active substances: antihaemophilic factor, recombinant human

Reference strength: antihaemophilic factor, 25 iU/ml

Table A.3 — Strata and levels

PhPID Active Substance Stratum	PhPID_SUB_L1 → antihaemophilic factor, recombinant human PhPID_SUB_L2 → antihaemophilic factor, recombinant human, 250 iU/10 ml (25 iU/ml)*, PhPID_ SUB _L3 → antihaemophilic factor, recombinant human, solution for injection PhPID_ SUB _L4 → antihaemophilic factor, recombinant human, 250 iU/10 ml (25 iU/ml), solution for Injection
PhPID Specified Substance Stratum	PhPID_SpSUB_L1 → ISO IDMP Manufacturer Charlie antihaemophilic factor, recombinant human, PhPID_SpSUB_L2 → ISO IDMP Manufacturer Charlie antihaemophilic factor, recombinant human, 250 iU/10ml (25 iU/ml), PhPID_SpSUB_L3 → ISO IDMP Manufacturer Charlie antihaemophilic factor, recombinant human, solution for injection PhPID_SpSUB_L4 → ISO IDMP Manufacturer Charlie antihaemophilic factor, recombinant human, 250 iU/10 ml (25 iU/ml), solution for injection

NOTE 1 The strength and the reference strength are identical in this example.

NOTE 2 See ISO 11238 for the detailed data elements defining a substance/specified substance (e.g. source, grade, additional manufacturing information).

A.6 Patch

Brand Name: NICODRUG© (nicotine transdermal patch extended release), ISO IDMP Manufacturer Delta

Components: 1

Strength (per each and per time unit)/dosage form: patch, 25 mg/24 hours

Active substances: nicotine

Reference strength: nicotine, 25 mg

Table A.4 — Strata and levels

PhPID Active Substance Stratum	PhPID_SUB_L1 → nicotine PhPID_SUB_L2 → nicotine, 25mg/24hrs (nicotine 25 mg)* PhPID_ SUB _L3 → nicotine transdermal patch PhPID_ SUB _L4 → nicotine transdermal patch, 25 mg/24 hrs, (nicotine 25 mg)
PhPID Specified Substance Stratum	PhPID_SpSUB_L1 → ISO IDMP Manufacturer Delta Nicotine PhPID_SpSUB_L2 → ISO IDMP Manufacturer Delta Nicotine, 25 mg/24 hrs (nicotine 25 mg) PhPID_SpSUB_L3 → ISO IDMP Manufacturer Delta Nicotine, transdermal patch PhPID_SpSUB_L4 → ISO IDMP Manufacturer Delta Nicotine transdermal patch, 25 mg/24 hrs, (nicotine 25 mg)

NOTE 1 The strength and the reference strength are identical in this example.

NOTE 2 See ISO 11238 for the detailed data elements defining a substance/specified substance (e.g. source, grade, additional manufacturing information).

A.7 Reference strength

Brand name: PANCREADRUG®, pancrelipase (lipase, protease, amylase), ISO IDMP Manufacturer Echo

Components: 1

Strength/dosage form: 200 mg capsule

Active substances: pancrelipase

Reference strength: lipase, 5 000 iU, protease, 10,000 iU, amylase, 15,000 iU.

Table A.5 — Strata and levels

PhPID Active Substance Stratum	PhPID_SUB_L1 → pancrelipase PhPID_SUB_L2 → pancrelipase 200 mg (lipase, 5 000 iU, protease, 10,000 iU, amylase, 15,000 iU)* PhPID_ SUB _L3 → pancrelipase capsule PhPID_ SUB _L4 → pancrelipase 200 mg capsule (lipase, 5 000 iU, protease, 10,000 iU, amylase, 15,000 iU)
PhPID Specified Substance Stratum	PhPID_SpSUB_L1 → ISO IDMP Manufacturer Echo- pancrelipase, PhPID_SpSUB_L2→ ISO IDMP Manufacturer Echo - pancrelipase, 200 mg, (lipase, 5 000 iU, protease, 10,000 iU, amylase, 15,000 iU) PhPID_SpSUB_L3 → ISO IDMP Manufacturer Echo - pancrelipase, capsule PhPID_SpSUB_L4 → ISO IDMP Manufacturer Echo - pancrelipase, 200 mg capsule, (lipase, 5 000 iU, protease, 10,000 iU, amylase, 15,000 iU capsule)

NOTE 1 The strength and the reference strength are different in this example.

NOTE 2 See ISO 11238 for the detailed data elements defining a substance/specified substance (e.g. source, grade, additional manufacturing information).

A.8 Multi ingredient (Figure A.8)

Invented brand name: GLUBRAVA® (pioglitazone and metformin), capsules 15 mg + 850 mg, ISO IDMP Manufacturer Foxtrot Co.

Components: 1

Strength/dosage form: pioglitazone 15 mg + metformin 850 mg, capsule

Active substances: pioglitazone; metformin

Reference strength: pioglitazone 15 mg per tablet; metformin 850 mg per tablet

Table A.6 — Strata and levels

PhPID Active Substance Stratum	PhPID_SUB_L1 →pioglitazone + metformin PhPID_SUB_L2 → pioglitazone 15 mg + metformin 850 mg PhPID_ SUB _L3 → pioglitazone + metformin capsule PhPID_ SUB _L4 → pioglitazone 15 mg + metformin 850 mg capsule
PhPID Specified Substance Stratum	PhPID_SpSUB_L1 → ISO IDMP Manufacturer Foxtrot, pioglitazone + metformin PhPID_SpSUB_L2 → ISO IDMP Manufacturer Foxtrot, pioglitazone 15 mg + metformin 850 mg PhPID_SpSUB_L3 → ISO IDMP Manufacturer Foxtrot, pioglitazone + metformin capsule PhPID_SpSUB_L4 → ISO IDMP Manufacturer Foxtrot, pioglitazone 15 mg + metformin 850 mg capsule

NOTE See ISO 11238 for the detailed data elements defining a substance/specified substance (e.g. source, grade, additional manufacturing information).

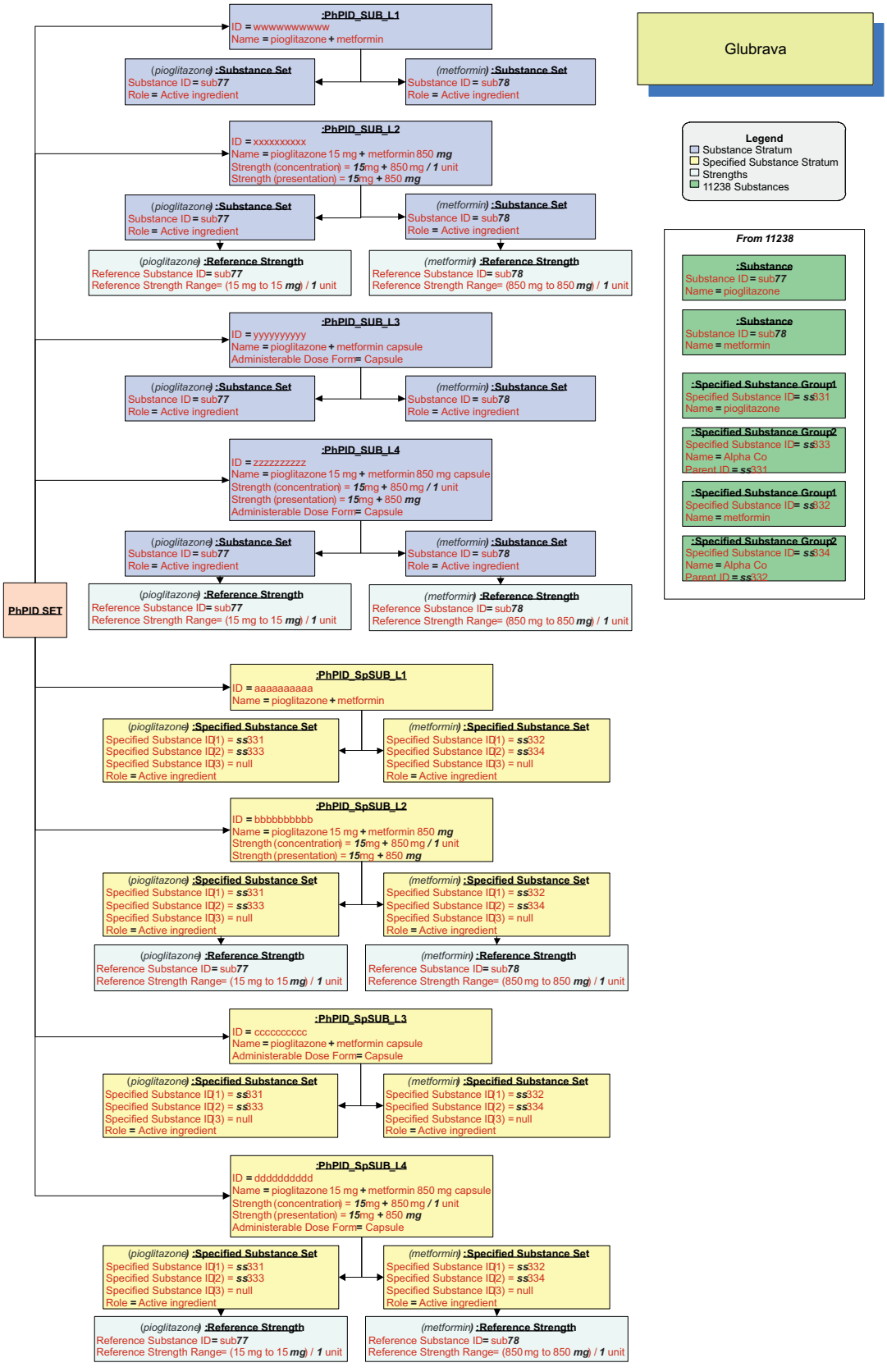

Figure A.3 — PhPID model: GLUBRAVA® (pioglitazone and metformin)

Annex B
(informative)

Tabled examples

B.1 Example of representation of strength

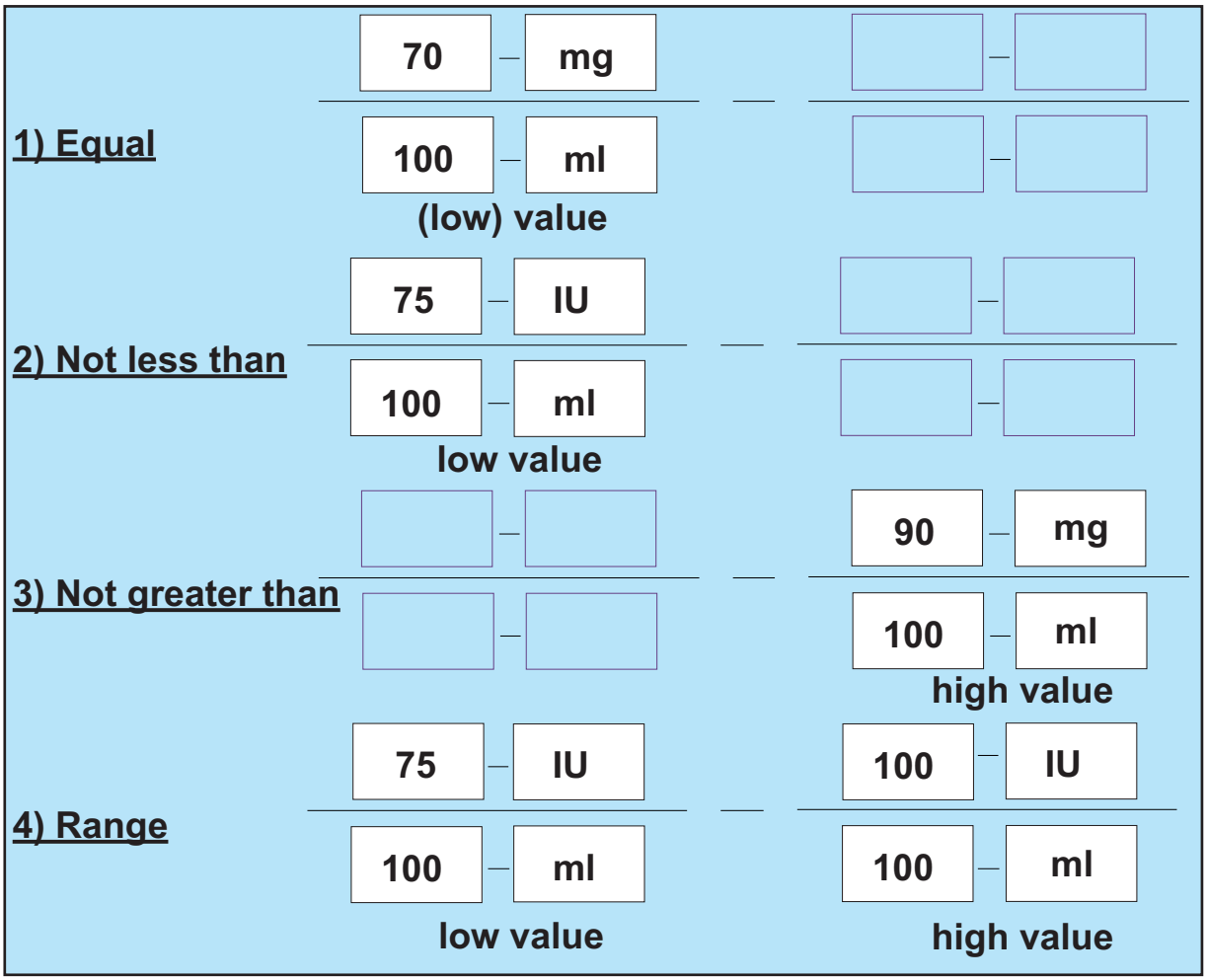

Figure B.1 — Modelled example for representation of strength

B.2 Example of representation of strength for medicinal product types[1)]

Table B.1 — Conventions on the representation of strength

Non-injection unit dose [solid, (semi)liquid]						
	Case	**Example**	**Numerator value**	**Numerator unit**	**Denominator value**	**Denominator unit of presentation**
Oral solid	[unit]/Each	$\frac{25[\text{unit}]}{1\text{Each}}$	number	[unit]	1	Each
Non-injection continuous dose (liquid or semisolid)						
	Case	**Example**	**Numerator value**	**Numerator unit**	**Denominator value**	**Denominator unit of presentation**
Non-injection liquid 1 ml or greater	[unit]/ML	$\frac{25[\text{unit}]}{10\,\text{ML}}$	number	[unit]	number	ML
Non-injection liquid less than 1 ml	[unit]/ML	$\frac{25[\text{unit}]}{0{,}1\text{ML}}$	number	[unit]	Number (<1)	ML
Non-injection continuous dose (solid)						
	Case	**Example**	**Numerator value**	**Numerator unit**	**Denominator value**	**Denominator unit of presentation**
Non-injection solid 1 gram or greater	[unit]/GM*)	$\frac{25[\text{unit}]}{10\,\text{ML}}$	number	[unit]	number	GM
Non-injection solid less than 1 gram	[unit]/GM*)	$\frac{25[\text{unit}]}{0{,}1\text{ML}}$	number	[unit]	Number (<1)	GM
Parenteral unit dose (the unit dose is given in total)						
	Case	**Example**	**Numerator value**	**Numerator unit**	**Denominator value**	**Denominator unit of presentation**
Injection unit dose	[unit]/Each	$\frac{25[\text{unit}]}{1\text{Each}}$	number	[unit]	1	Each
Parenteral continuous dose (including partial use of a unit dose vial)						
	Case	**Example**	**Numerator value**	**Numerator unit**	**Denominator value**	**Denominator unit of presentation**
injection liquid 1 ml or greater	[unit]/ML	$\frac{25[\text{unit}]}{10\,\text{ML}}$	number	[unit]	number	ML
injection liquid less than 1 ml	[unit]/ML	$\frac{25[\text{unit}]}{0{,}1\text{ML}}$	number	[unit]	Number (<1)	ML
Inhaler						
	Case	**Example**	**Numerator value**	**Numerator unit**	**Denominator value**	**Denominator unit of presentation**

1) Calculation and mapping of PhPIDs with concentrations of strength per unit volume shall be addressed during implementation and maintenance of this International Standard.

Table B.1 *(continued)*

Non-injection unit dose [solid, (semi)liquid]						
Inhaler - powder	[unit]/dose	$\frac{25\,[\text{unit}]}{1\,\text{Each}}$	number	[unit]	1	dose
Inhaler – liquid single dose	[unit]/Each	$\frac{25\,[\text{unit}]}{1\,\text{Each}}$	number	[unit]	1	Each
Inhaler - liquid multidose 1 ml or greater	[unit]/ML	$\frac{25\,[\text{unit}]}{10\,\text{ML}}$	number	[unit]	number	ML
Inhaler – liquid less than 1 ml	[unit]/ML	$\frac{25\,[\text{unit}]}{0{,}1\,\text{ML}}$	number	[unit]	Number (<1)	ML
Topical, patch						
Transdermal patch	[unit]/Per Time or Each	$\frac{25\,[\text{unit}]}{1\,\text{Each}}$	number	[unit]	1	time or each

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[49] Appendix3 DCL Appendix4 Template of SGML

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