Content

Introduction to the Identification of Medicinal Products (IDMP)

https://www.idmp1.com has started the first terminology browser for health professionals in the eSubmission of medicinal products – named the IDMP Term Browser. Furthermore under https://www.idmp1.com you will find a free IDMP Wiki.

The IDMP Term Browser includes terminology of the eXtended Eudravigilance Medicinal Product Dictionary (XEVMPD) and of the Identification of Medicinal Products (IDMP) which is required by the European Medicines Agency (EMA) for the Electronic Submission of Medicinal Product Information in the EU (eSubmission) between regulators and pharmaceutical companies.

Furthermore it is most likely that the Food and Drug Administration (FDA) will take over this IDMP Standard in the near future. So the FDA´s "Structured Product Labeling" (SPL) Terminology also is integrated in the IDMP Term Browser.

What is the legal base for IDMP?

- The Implementation of Electronic Submission of Medicinal Product Information in the EU (Article 57(2) Requirements of the New Pharmacovigilance Legislation)
- IDMP will become mandatory latest by 1st July 2016

Who is affected by IDMP?

- Regulatory affairs staff of pharmaceutical companies
- Representatives of IT departments of medicines regulatory authorities, pharmaceutical companies, and service providers
- EU Qualified Persons responsible for Pharmacovigilance (EU QPPVs)
- Pharmacovigilance staff of pharmaceutical companies and medicines regulatory authorities
- Medicinal product management software vendors
- Sponsors of clinical trials

Current regulations in the US and Europe

Current regulations in the US and Europe require substantially different technologies, terminologies and vocabularies for registration of medicinal products. In the US, the FDA requires a "Structured Product Labeling" (SPL). In Europe, the European Medical Agency (EMA) initiated a new standard called IDentification of Medicinal Products (IDMP). It is most likely that FDA will take-over these standards in near future. IDMP raised the bar significantly by requiring information be sent in specific form for each country and language and coded with an ISO Code.

Implications for Marketing Authorisation Holders (MAHs)

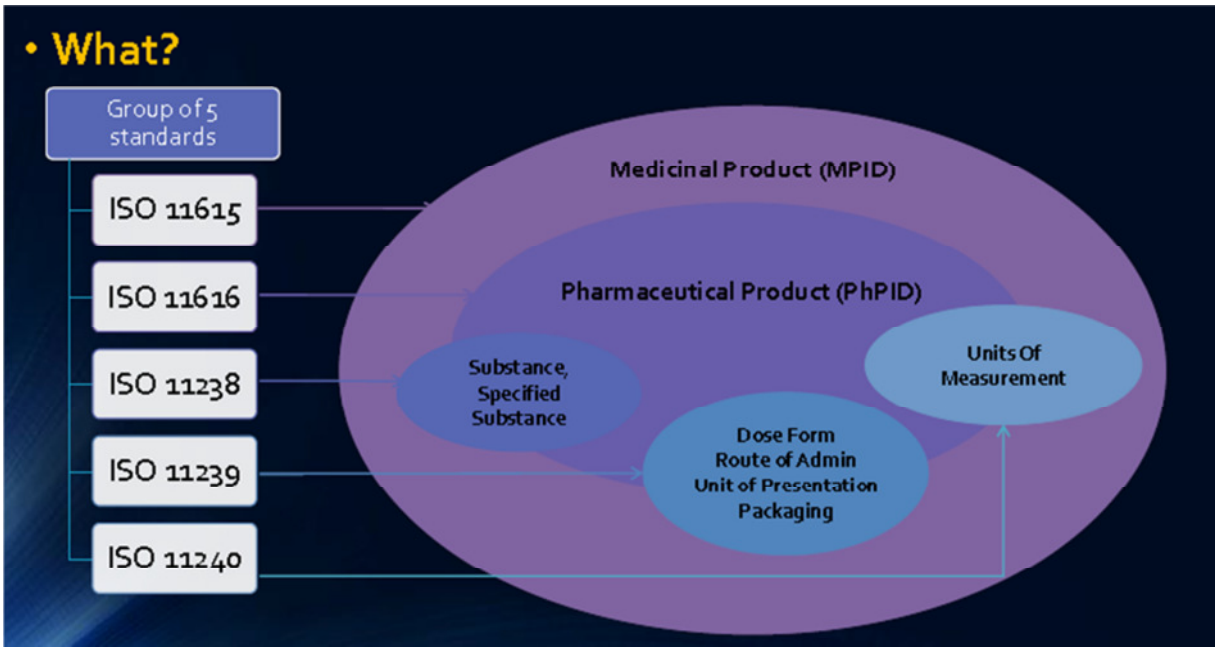
In order to submit the data all branches of a company should share a common language, from pharmacovigilance to product supply to comply with the controlled vocabulary dedicated. The structured substance information, and controlled vocabularies for pharmaceutical dose forms, units of presentation, routes of administration, and packaging will be challenging to integrate.

Furthermore the terminology needs to be aligned throughout the company.

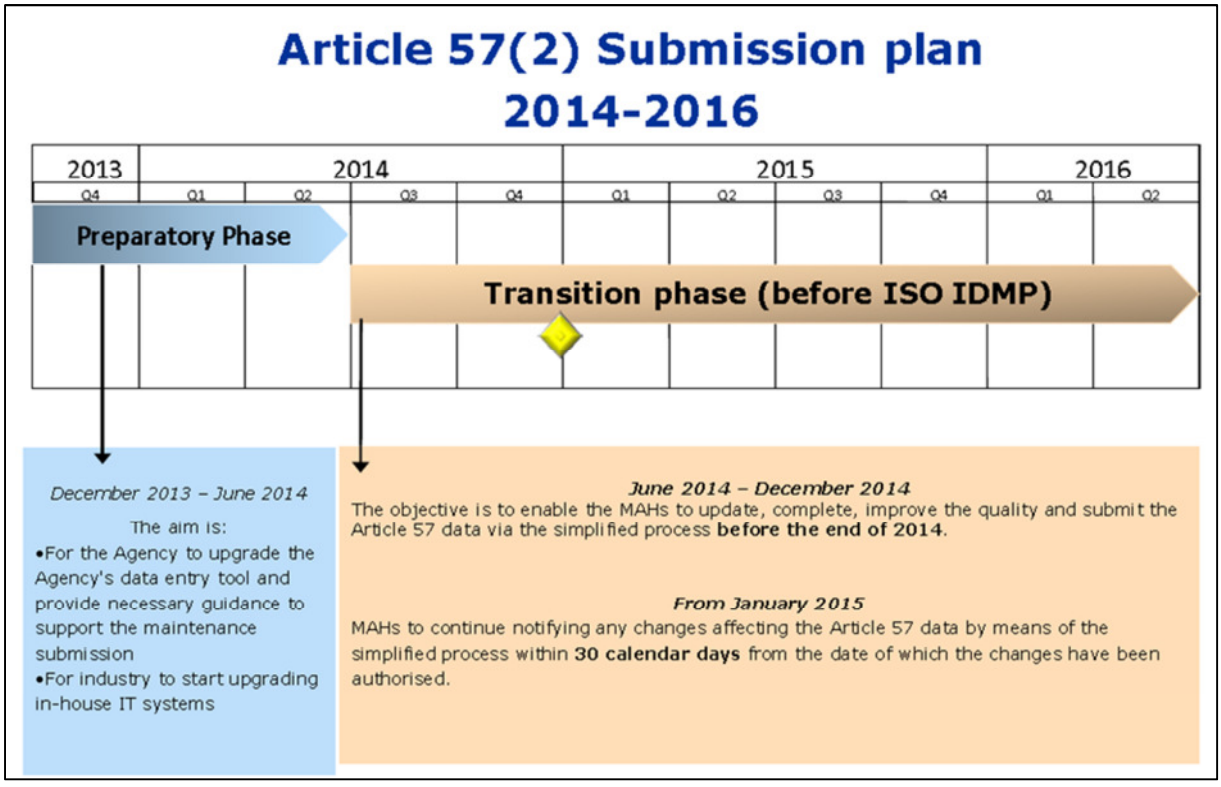
ISO IDMP and XEVPMD Controlled Vocabularies (CVs)

The official standard term lists controlled vocabularies is maintained either by EMA or by external maintenance organisation. The use of this CVs is today in XEVMPD on a voluntary base for certain areas but will become mandatory with IDMP latest by 1st July 2016.

In some areas it is not yet decided which vocabulary EMA might require. However EMA agreed on the components of Identification IDMP.



Controlled Vocabularies Submission Plan 2014 – 2016



The European Medicines Agency's commitment to meeting the 16 July 2016 legislative deadline for implementing the Identification of Medicinal Products (IDMP) —has created disquiet in the regulatory community. Companies know that the IDMP is a far broader set of standards than the eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD), which it replaces. And given the problems companies have faced in preparing to meet the XEVMPD, their concerns are understandable.

The good news, however, is that even though the IDMP will require significant time and resource commitments, it is better designed than the XEVMPD; and because it eases the exchange of data by means of standardisation, it also presents an opportunity for companies to improve their own regulatory information management (RIM).

The IDMP Term Browser is keeping its finger on the pulse of developments around XEVMPD and the IDMP controlled vocabularies and the related coding issues. Our experience with helping other industries adapt their terminology to such controlled vocabulary has given us a deeper level of insight into helping you leap from worry to successful adaptation. To learn more, see the [pharmazie.com] Web site on IDMP.

The IDMP Browser helps make your coding projects a success.

Content of the IDMP Term Browser

EMA – XEVMPD

As part of the efforts to provide high quality Article 57(2) data, the IDMP Term Browser makes available EMA´s XEVMPD Controlled Vocabulary (CV). The different CVs and related links are as follows:

XEVMPD Routes of Administration

The standard route of administration controlled vocabulary is populated and maintained by EMA. The XEVMPD value is the EDQM standard term value whilst the unique identifiers (i.e. EV Codes) are randomly and automatically assigned by the EV system upon request.

Term	Lang	Role	Code	Type	Source
Epiduraal gebruik	NL	ST	20009000	SYN	EDQM
Epiduraaliseen antoon	FI	ST	20009000	SYN	EDQM
Epiduraalne	ET	ST	20009000	SYN	EDQM
Epidural användning	SV	ST	20009000	SYN	EDQM
Epidural anvendelse	DA	ST	20009000	SYN	EDQM
Epidural bruk	NO	ST	20009000	SYN	EDQM
EPIDURAL USE	EN	**PT**	ADR00008MIG	ROA	EMA

XEVMPD Units of Measurement

Unit of measurement description

The following lists serve the description of the strength of the medicinal product:

- XEVMPD amount prefix unit

- XEVMPD amount numerator unit

– XEVMPD amount denominator unit

The values and codes of the above lists are published and maintained by the Unified Code for Units of Measure (UCUM) and are freely available at http://unitsofmeasure.org/.

ISO 11240 describes the SI (International System) of units, and creates data structures for communicating values and units for electronic messaging.

Distinct in the ISO 11240 methodology is splitting the unit type (e.g. “grams”) from the scale (e.g. “milli”), so instead of just measuring in “mg”, the standard specifies “M” and “G” as separate terms.

XEVMPD Substances

Following the validation performed by the Agency to provide high quality Article 57(2) data, the XEVMPD substance controlled vocabulary contains the complete list of the substance assessment and mapping data. Specifically, the purpose of this data is to allow Marketing Authorisation Holders (MAHs) submitting Article 57 medicinal product information via EMA Gateway to perform an analysis and plan for the implementation of the remapping of substance names in their in-house systems. In addition, the actions to be performed by EVWEB users (where applicable) are also explained.

Synonym Details:

Term	Lang	Role	Code	Type	Source
[3aS(3aalpha,4beta,6aalpha)]-5-(Hexahydro-2-oxo-1H-thieno[3,4-d] imidazol-4-yl)valeriansäure	N/A	SY	219700	SUB	ABDATA
5-[(3aS,4S,6aR)-2-Oxohexahydro-1H-thieno[3,4-d]imidazol-4-yl]pentanoic acid	N/A	SY	219700	SUB	ABDATA
5-[(3aS,4S,6aR)-2-Oxohexahydrothieno[3,4-d]imidazol-4-yl]pentansäure	N/A	SY	219700	SUB	ABDATA
beta-Biotin	N/A	SY	219700	SUB	ABDATA
Bioepiderm	N/A	SY	219700	SUB	ABDATA
Bios II	N/A	SY	219700	SUB	ABDATA
BIOTIINI	FI	ST	SUB05841MIG	SUB	EMA
Biotin	**N/A**	**PT**	**219700**	**SUB**	**ABDATA**
Biotin	DE	ST	A11HA05	ATC	WHO
Biotin	**EN**	**PT**	**A11HA05**	**ATC**	**WHO**
Biotin	**EN**	**PT**	**6SO6U10H04**	**SUB**	**FDA**
Biotin	**EN**	**PT**	**1035**	**SUB**	**FDB**
Biotin	**N/A**	**PT**	**SUB05841MIG**	**SUB**	**EMA**
Biotin	DA	ST	SUB05841MIG	SUB	EMA
Biotin	DE	ST	SUB05841MIG	SUB	EMA
Biotin	HU	ST	SUB05841MIG	SUB	EMA
Biotin	NO	ST	SUB05841MIG	SUB	EMA
Biotin	SV	ST	SUB05841MIG	SUB	EMA
BIOTÍN	SK	ST	SUB05841MIG	SUB	EMA
BÍÓTÍN	IS	ST	SUB05841MIG	SUB	EMA

XEVMPD Pharmaceutical Dose Forms

Synonym Details:

Term	Lang	Role	Code	Type	Source
Capsulă moale rectală	RO	ST	11014000	SYN	EDQM
Cápsula rectal	ES	ST	11014000	SYN	EDQM
Capsula rettale	IT	ST	11014000	SYN	EDQM
Capsule rectale	FR	ST	11014000	SYN	EDQM
Capsule voor rectaal gebruik	NL	ST	11014000	SYN	EDQM
Endaþarmshylki	IS	ST	11014000	SYN	EDQM
Kapsula għar-rektum	MT	ST	11014000	SYN	EDQM
kapsula za rektum	HR	ST	11014000	SYN	EDQM
Kapsulë rektale	SQ	ST	11014000	SYN	EDQM
Kapsułka doodbytnicza	PL	ST	11014000	SYN	EDQM
Peräpuikko, kapseli	FI	ST	11014000	SYN	EDQM
RECTAL CAPSULE	EN	**PT**	11014000	SYN	EDQM
RECTAL CAPSULE	EN	**PT**	PHF00215MIG	PHF	EMA

XEVMPD Units of Presentation

Term	Lang	Role	Code	Type	Source
blister	**EN**	**PT**	**1{BLISTER}**	**PRE**	**EMA**
blister	HR	ST	30007000	SYN	EDQM
blister	ET	ST	30007000	SYN	EDQM
blister	SV	ST	30007000	SYN	EDQM
blister	ES	ST	30007000	SYN	EDQM
blister	SR	ST	30007000	SYN	EDQM
blister	RO	ST	30007000	SYN	EDQM
blister	PT	ST	30007000	SYN	EDQM
blister	TR	ST	30007000	SYN	EDQM
blister	PL	ST	30007000	SYN	EDQM
blister	DA	ST	30007000	SYN	EDQM
blister	**EN**	**PT**	**30007000**	**SYN**	**EDQM**
blister	IT	ST	30007000	SYN	EDQM
blister	**EN**	**PT**	**C54564**	**PRE**	**FDA**
Blistër	SQ	ST	30007000	SYN	EDQM
Blisterpackung	DE	ST	30007000	SYN	EDQM

XEVMPD Company Code

The MAH´s name and Headquarter organisation ID (i.e. the ID specified by the organisation during the registration process to uniquely identify each organisation in EudraVigilance. This ID is used to send/receive product/safety reports as per the organisation's profile.)

Term	Lang	Role	Code	Type	Source
BOEHRINGER INGELHEIM AUSTRIA GMBH	**EN**	**PT**	**ORG8827**	**ORG**	**EMA**

XEVMPD Reference Source

Official reference sources for substance names, synonyms and translations.

Term	Lang	Role	Code	Type	Source
EUROPEAN PHARMACOPOEIA	EN	PT	SRC574	REF	EMA

ATC (WHO)

The ATC list is published and maintained by the WHO Collaborating Centre for Drug Statistics Methodology. Summary of changes for each ATC version are published by WHO.

In addition to the ATC standard term list, the values "NOTASSIGN" and "NOTAPPLIC" were added to the official list to allow the selection of such values when the ATC code is not assigned or not applicable to the authorised/registered medicinal product.

Type	Code	Descr
ATC	A07EA04	Antidiarrheals, intestinal antiinflammatory/antiinfective agents Intestinal antiinflammatory agents Corticosteroids acting locally Betamethasone
ATC	C05AA05	Vasoprotectives Agents for treatment of hemorrhoids and anal fissures for topical use Corticosteroids Betamethasone
ATC	D07AC01	Corticosteroids, dermatological preparations Corticosteroids, plain Corticosteroids, potent (group III) Betamethasone
ATC	D07XC01	Corticosteroids, dermatological preparations Corticosteroids, other combinations Corticosteroids, potent, other combinations Betamethasone
ATC	H02AB01	Corticosteroids for systemic use Corticosteroids for systemic use, plain Glucocorticoids Betamethasone
ATC	R01AD06	Nasal preparations Decongestants and other nasal preparations for topical use Corticosteroids Betamethasone

ISO Country Code

The Country Code is maintained by ISO (ISO-3166).

Term	Lang	Role	Code	Type	Source
France	EN	PT	FR	ISO	EMA
France	EN	PT	FRA	ISO	FDA

ISO Two-Letter Language Code

The Two-Letter Language Code is maintained by ISO (ISO 639-1).

Term	Lang	Role	Code	Type	Source
French	EN	PT	fr	ISO	EMA

FDA - Structured Product Labeling (SPL)

UNII Substances

Unique Ingredient Identifier - a non-proprietary, free, unique, unambiguous, nonsemantic, alphanumeric identifier based on a substance's molecular structure and/or descriptive information.

The FDA requires a “Stuctured Product Labeling” (SPL) for the registration of medicinal products. The substances are to be coded by a UNII code.

Aspirin	N/A	SY	SUB12730MIG	SUB	EMA
Aspirin	N/A	SY	104201	SUB	ABDATA
Aspirin	**EN**	**PT**	**R16CO5Y76E**	**SUB**	**FDA**
ASS	N/A	SY	104201	SUB	ABDATA

SPL Country Codes

SPL represents countries with ISO 3166-1 Alpha-3 country codes

Term	Lang	Role	Code	Type	Source
Switzerland	**EN**	**PT**	**CH**	**ISO**	**EMA**
Switzerland	**EN**	**PT**	**CHE**	**ISO**	**FDA**

SPL - Drug Route of Administration Terminology

Terminology used for representation of the information on pharmaceutical product route of administration in the framework of the Structured Product Labeling documents.

Term	Lang	Role	Code	Type	Source
Dilaltı uygulama	TR	ST	20067000	SYN	EDQM
Kielen alle	FI	ST	20067000	SYN	EDQM
Përdorim nën gjuhë	SQ	ST	20067000	SYN	EDQM
Podání pod jazyk	CS	ST	20067000	SYN	EDQM
Podanie podjęzykowe	PL	ST	20067000	SYN	EDQM
Sublinguaal gebruik	NL	ST	20067000	SYN	EDQM
Sublingual	DE	ST	20067000	SYN	EDQM
Sublingual	**EN**	**PT**	**C38300**	**ROA**	**FDA**
Sublingual användning	SV	ST	20067000	SYN	EDQM
Sublingual anvendelse	DA	ST	20067000	SYN	EDQM
SUBLINGUAL USE	**EN**	**PT**	**ADR00060MIG**	**ROA**	**EMA**

SPL Pharmaceutical Dosage Form Terminology

Terminology used for representation of the information on pharmaceutical product dosage form in the framework of the Structured Product Labeling documents.

Term	Lang	Role	Code	Type	Source
TABLET, FILM COATED	**EN**	**PT**	**C42931**	**PHF**	**FDA**

SPL Package Type Terminology

Terminology used for representation of the information on pharmaceutical product package type in the framework of the Structured Product Labeling documents.

Term	Lang	Role	Code	Type	Source
BOTTLE, GLASS	**EN**	**PT**	**C43172**	**PAC**	**FDA**

SPL Unit of Presentation Terminology

Terminology that encompasses dosage form, package type, and unit of measurement (aka potency) terms used in supporting regulatory submissions in electronic format such as drug establishment

registration and drug listing.

Term	Lang	Role	Code	Type	Source
PIECE	EN	PT	C89446	PRE	FDA

SPL Unit of Measure Terminology

Terminology that represents units of measure in supporting regulatory submissions in electronic format such as drug establishment registration and drug listing.

Term	Lang	Role	Code	Type	Source
MICROGRAM	EN	PT	C48152	MEA	FDA

Additional Information

XEVMPD and MedDRA

The Medical Dictionary for Regulatory Activities Terminology (MedDRA) is an international standard terminology used to classify adverse event information and indications associated with the use of biopharmaceuticals and other medical products. In some areas it is not yet decided which vocabulary EMA might require e.g. for indications and adverse reactions but MedDRA is one of the candidates for this purpose (besides SNOMED CT see below).

MedDRA was developed under the auspices of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) owns MedDRA as trustee for ICH, and the Maintenance and Support Services Organization (MSSO) serves as the repository, maintainer, and distributor.

MedDRA is updated bi-annually (March and September).

As MedDRA requires a specific license and is not yet required, it is not integrated in the IDMP Term Browser.

AdverseReaction(s) as MedDRA Code

Example:
MedDRA=10027714
="Mitral and aortic valve diseases, unspecified"

FDA and SNOMED CT

Systematized Nomenclature of Medicine-Clinical Terms (SNOMED CT) provides core general terminology for the electronic health record (EHR). Concepts have unique meanings and formal logic-based definitions organized into hierarchies. Each international release includes the core of the terminology (concepts, descriptions, and relationships), together with resources to support the implementation and use of SNOMED CT, including subsets, cross maps to existing classifications and coding schemes, and an extensive set of guidelines. SNOMED CT includes more than 311,000 unique concepts. There are almost 800,000 descriptions in SNOMED CT, including synonyms that can be used to refer to a concept. In addition, there are approximately 1,360,000 links or semantic relationships between the SNOMED CT concepts.

SNOMED is FDA´s favourite to be used to code indications and adverse reactions in IDMP (instead of MedDRA). But up to now it is not yet decided and discussions are going on.

ABDA and International Substance List

The International Substance List includes data on more than 40,000 ingredients and plants with more than 65,000 synonyms and more than 150,000 drugs in 54 countries.

EDQM and Synonyms / Translations

EMA references the European Directorate for the Quality of Medicines & Healthcare (EDQM) concerning Standard Terms.

Get a Test Account to the IDMP Term Browser

You are kindly invited to explore the beta version of the first terminology browser in pharmazie.com for Health Professionals in the eSubmission.

Get a test-account: http://www.pharmazie.com/dacon32/landingpages/idmp.htm