Bundesverband der Arzneimittel-Hersteller e.V. B.A.H
beraten • analysieren • handeln

IDMP
IDENTIFICATION OF MEDICINAL PRODUCTS

18. DGRA Jahreskongress

16. Juni 2016

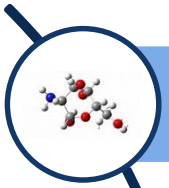
Dr. Andreas Franken

AGENDA / CONTENT

- Introduction to IDMP as a means of identification of products
  - IDMP – what is it ? And why ?
  - Hierarchy of identifiers and simplified view of use cases for these identifiers
  - Initial scope of data associated to each identifier

- IDMP from a business process perspective
  - Setting the scene
  - Time lines and overall goal
  - Implementation: Global – Europe – Member States
  - Industry involvement
  - Future Vision and Lessons Learned

WHAT MAKES UP A “PRODUCT”?



Multiple Specified Substances go into a…

Pharmaceutical Product which is…

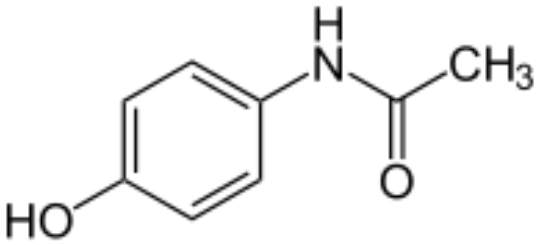
presented as a specific Packaged Product

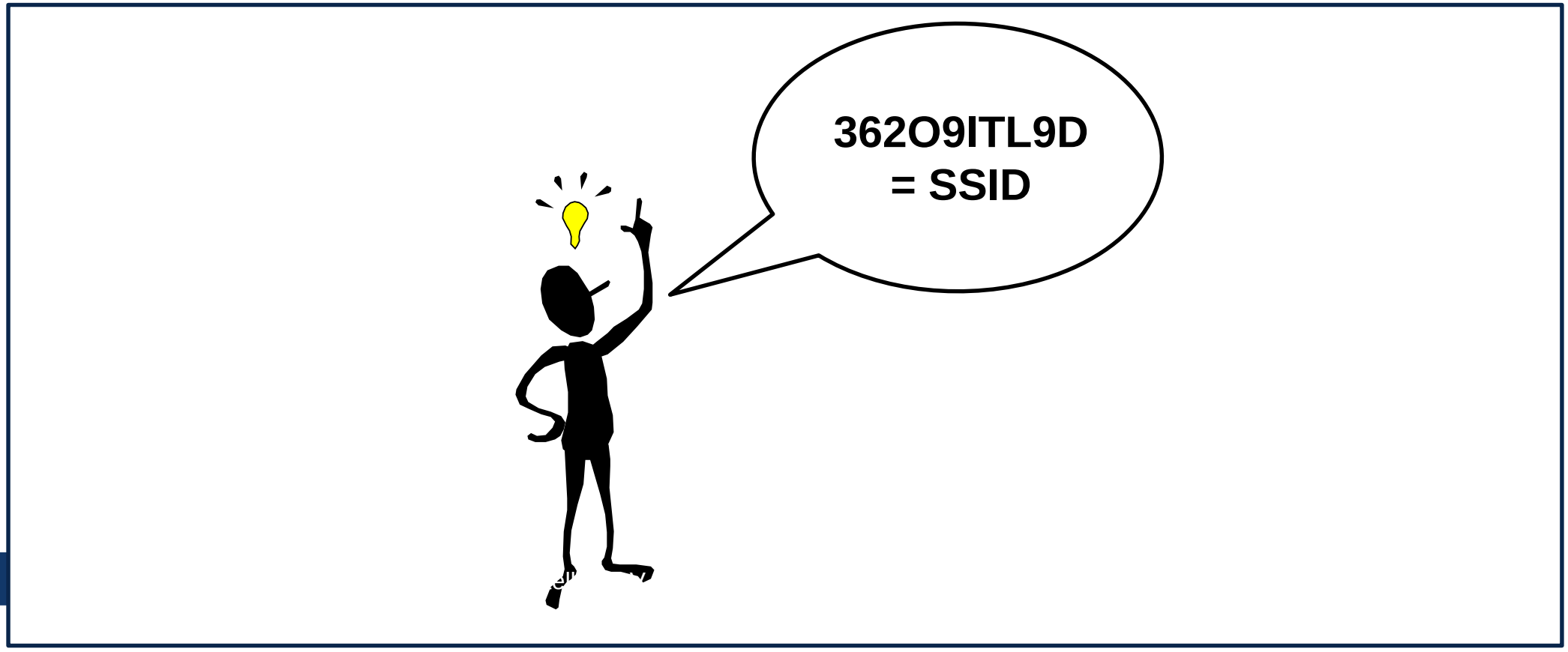
which is manufactured in batches

and has regulator approval as a Medicinal Product

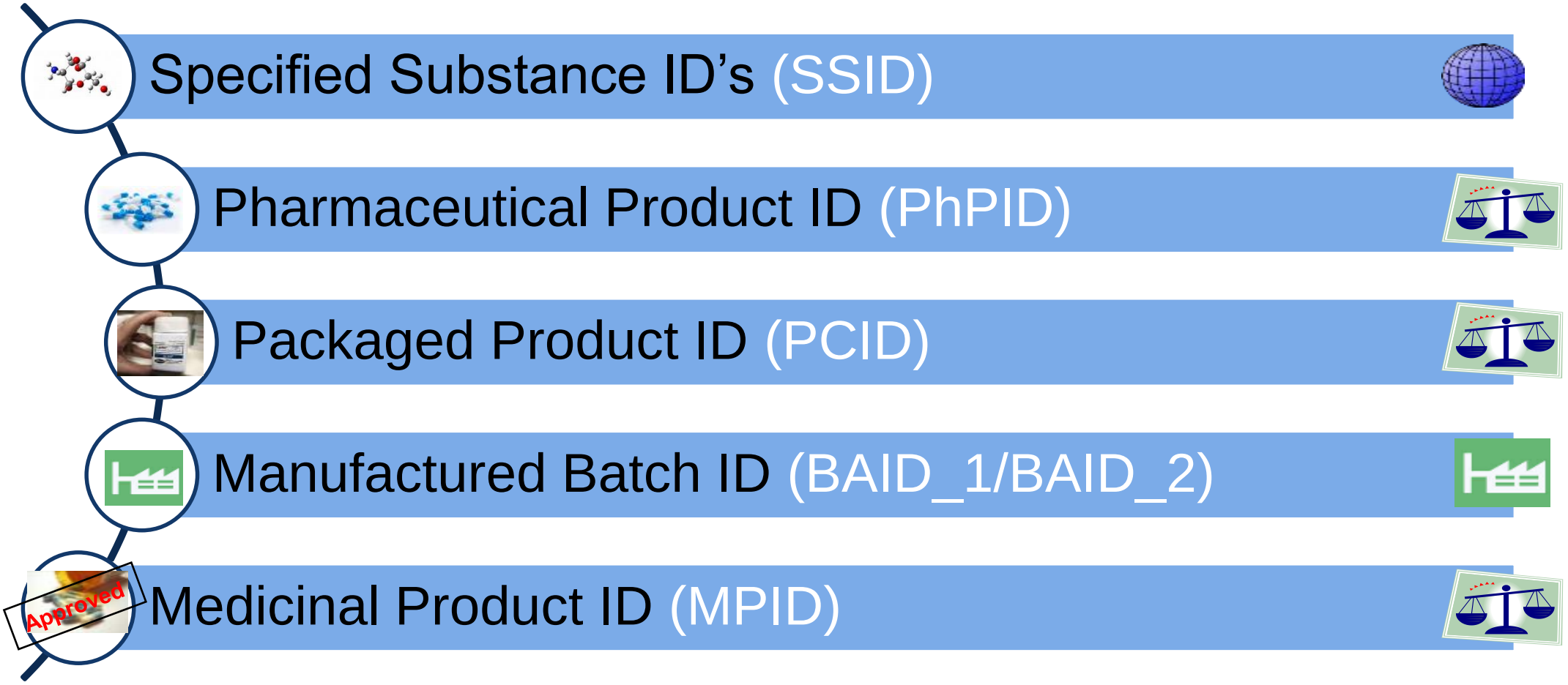
SETTING THE SCENE

Multiple Specified Substances go into a…





IN IDMP EACH OF THESE ENTITIES HAS AN IDENTIFIER



IDENTIFICATION OF MEDICINAL PRODUCT (IDMP)

Where does it come from?

- 5 ISO standards to uniquely identify a medicinal product
- 4 Implementation Guides to bring theory into real life
- Maintenance organisation(s) to assign unique identifiers
- A set of control vocabularies and terms
- A messaging standard to exchange data

IDMP

Identification of Medicinal Products

IG 19844

Substances

ISO 11238

Data elements and structures for the unique identification and exchange of regulated information on substances

This norm distinguishes Substances (defined based on its main, general characteristics ; can have different roles e.g. active, adjuvant, basis of strength, excipient) and Specified Substances (More granular, specific description of a substance e.g. including manufacturing information, purity, grade ; allows for the specification of multiple substances ("Intermediate Products" e.g. AS03 - adjuvant composed of squalene (10.69 milligrams), DL-α-tocopherol (11.86 milligrams) and polysorbate 80 (4.86 milligrams)

IG 20440

Dose forms, etc.

ISO 11239

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

Identifies for example injection solution, Injection suspension, Infusion solution (or a less granular regional term linked to these)

IG 20443

MPID

ISO 11615

Data elements and structures for the unique identification and exchange of regulated Medicinal Product information

Defines, characterizes and uniquely identifies regulated medicinal products for human use during their entire life cycle (Development, authorization, post-marketing and renewal or withdrawal from the market) ; Establishes definitions and concepts ; Describes data elements and their structural relationships required for the detailed description and unique identification of medicinal products

Units of mesurement

ISO 11240

Data elements and structures for the unique identification and exchange of units of measurement

Specify rules for the usage of units of measurement for IDMP ; Define requirements for traceability to metrological standards ; Establish reference code system for units ; Provide structures and rules for mapping between different unit vocabularies and language translations, linking to existing systems, dictionaries and repositories

PhPID

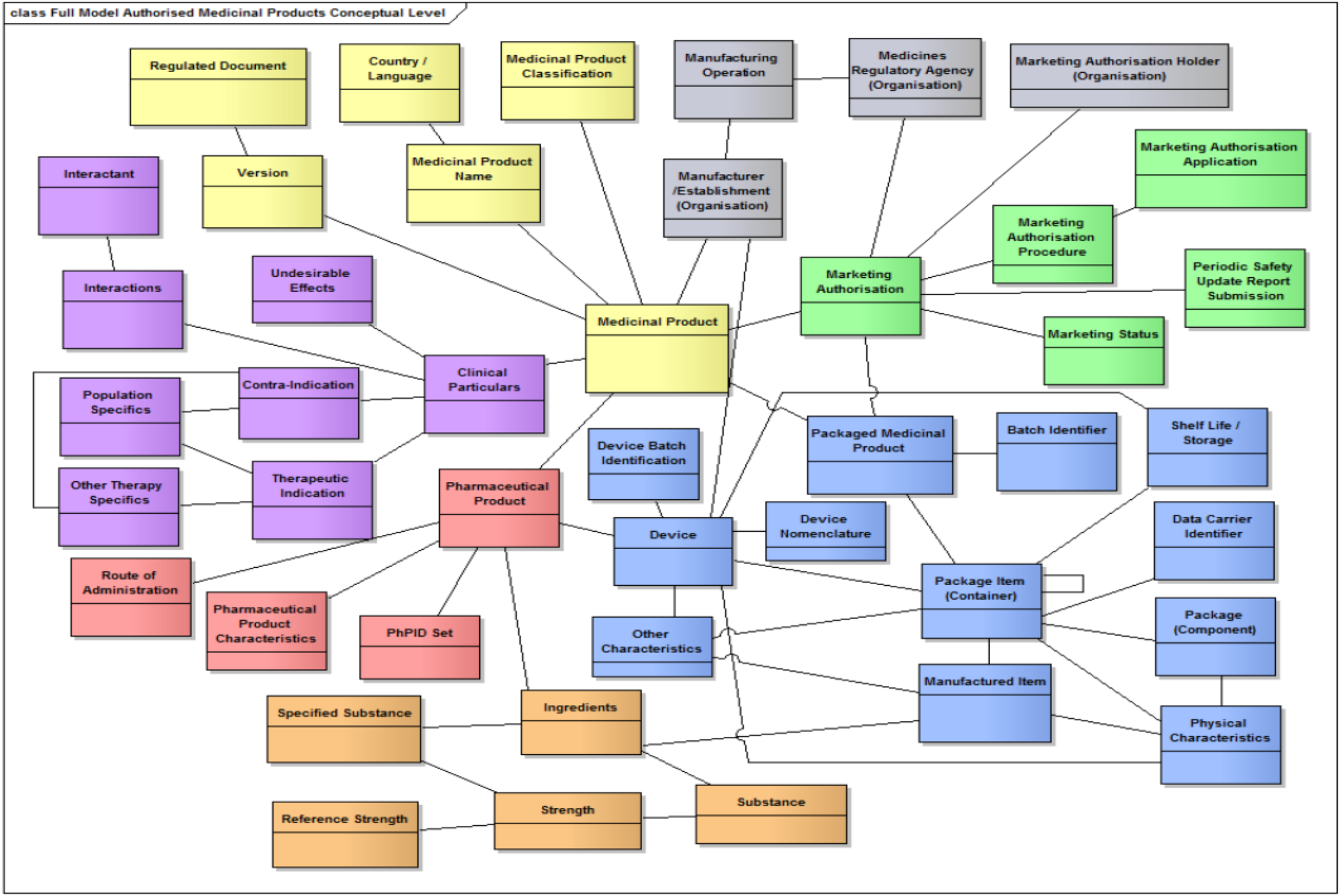
ISO 11616

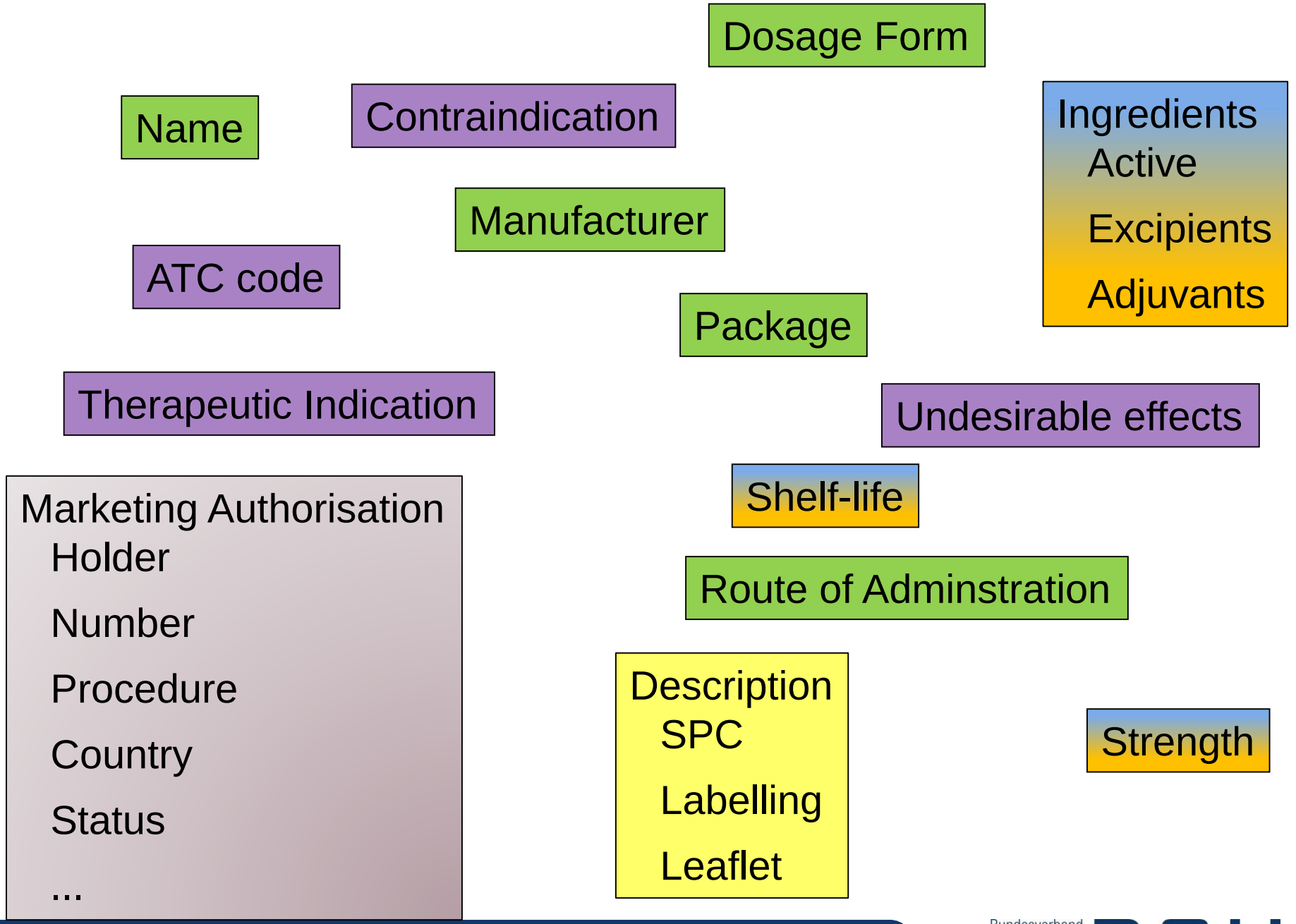
IG 20451

Data elements and structures for the unique identification and exchange of regulated Medicinal Product information

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

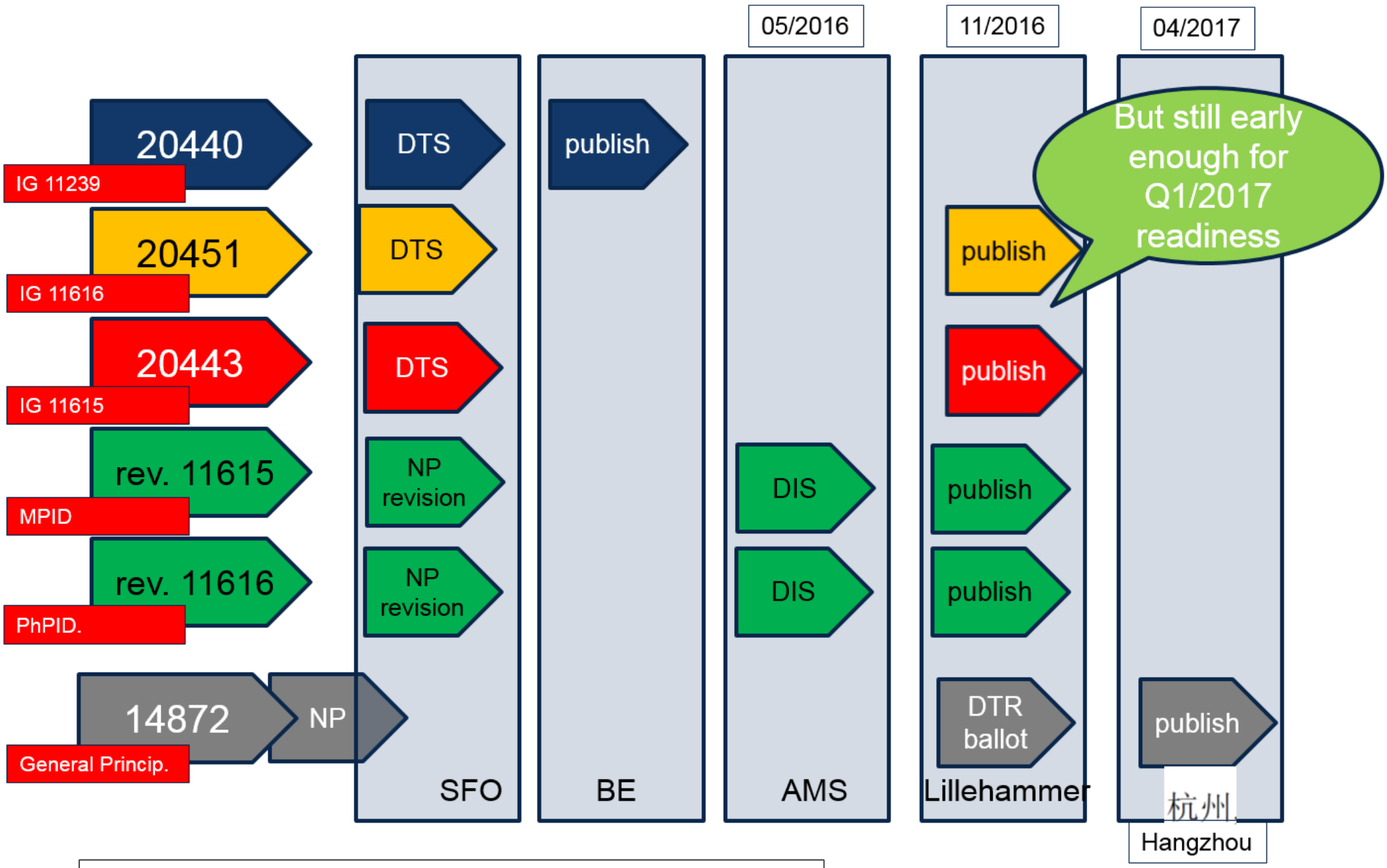
- Substance(s)/Specified Substance(s)
- Strength(s) - Strength units (units of measurement and/or unit of presentation)
- Reference Strengths
- Administrable Dose Form


class Full Model Authorised Medicinal Products Conceptual Level
Regulated Document
Country / Language
Medicinal Product Classification
Manufacturing Operation
Medicines Regulatory Agency (Organisation)
Marketing Authorisation Holder (Organisation)
Interactant
Version
Medicinal Product Name
Manufacturer /Establishment (Organisation)
Marketing Authorisation Application
Marketing Authorisation Procedure
Interactions
Undesirable Effects
Medicinal Product
Marketing Authorisation
Periodic Safety Update Report Submission
Marketing Status
Clinical Particulars
Population Specifics
Contra-Indication
Packaged Medicinal Product
Batch Identifier
Shelf Life / Storage
Device Batch Identification
Other Therapy Specifics
Therapeutic Indication
Pharmaceutical Product
Device
Device Nomenclature
Data Carrier Identifier
Route of Administration
Pharmaceutical Product Characteristics
PhPID Set
Other Characteristics
Package Item (Container)
Package (Component)
Manufactured Item
Specified Substance
Ingredients
Physical Characteristics
Reference Strength
Strength
Substance


Dosage Form
Name
Contraindication
Ingredients
Active
Excipients
Adjuvants
Manufacturer
ATC code
Package
Therapeutic Indication
Undesirable effects
Shelf-life
Marketing Authorisation
Holder
Number
Procedure
Country
Status
...
Route of Adminstration
Description
SPC
Labelling
Leaflet
Strength

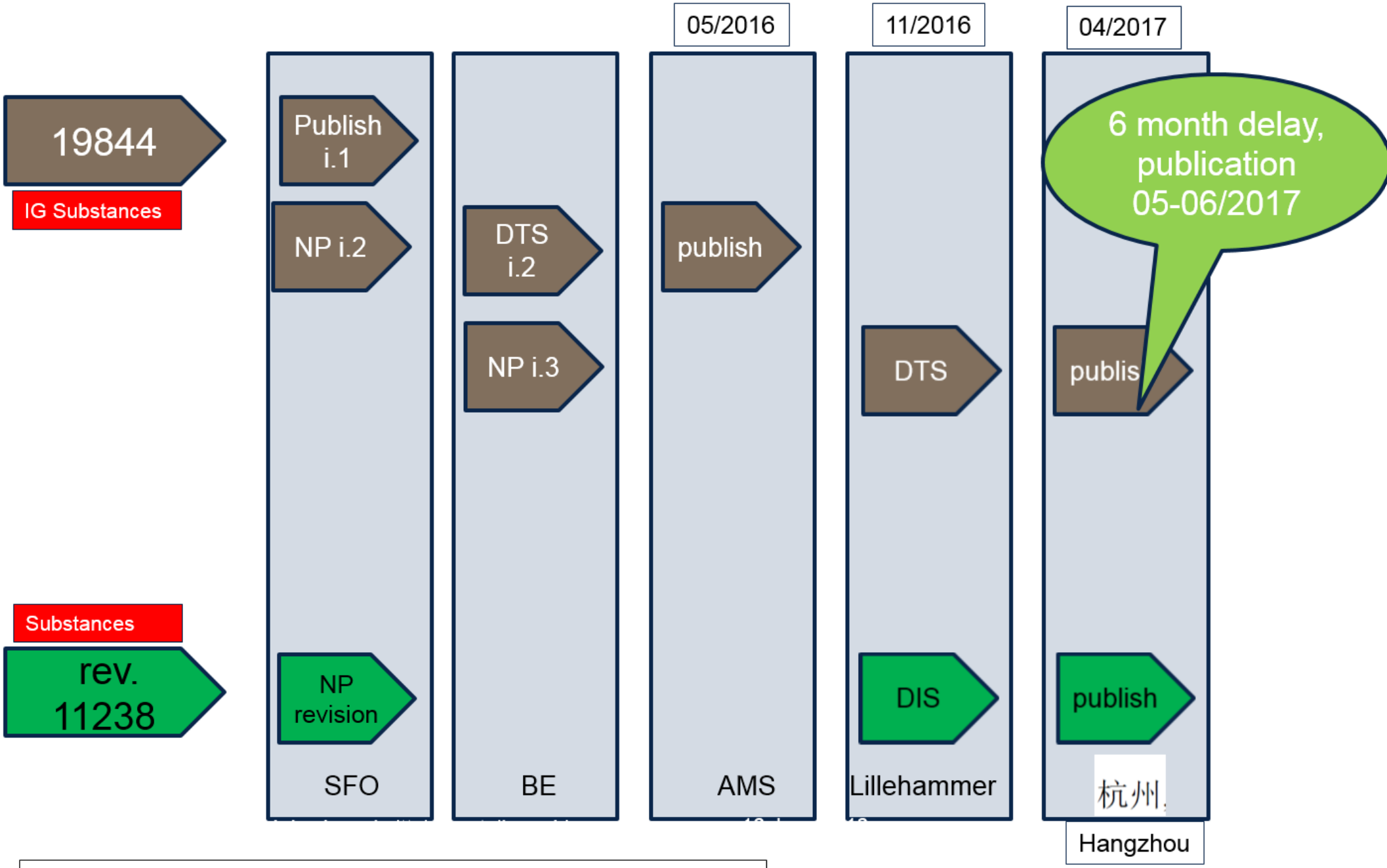
ISO IDMP TIMELINES

IDMP ROADMAP – MAY 2016



Source: Presentation by Christian Hay; ISO Amsterdam May 2016

IDMP ROADMAP - SUBSTANCES



Source: Presentation by Christian Hay; ISO Amsterdam May 2016

SO? WHEN IS IT COMING?

Full set of ISO Implementation Guides and **all basic standards** revised to be **complete and published** by

Q2 2017

(up to know !!!)

„THE DEADLINE CONFUSION“ – ART 40

- The obligation on the part of **marketing authorisation holders**, **national competent authorities** and **the Agency** to use the terminology provided for in points (c) to (g) of Article 25 shall apply from
  - **1 July 2016**

- BUT:
  “The European Commission, the European Union (EU) Network Data Board and the EU ISO IDMP Task Force have endorsed a **phased implementation** of the ISO IDMP standards. The phased implementation will commence in July 2016 with the release of terminologies, or so-called **controlled vocabularies**, and **organisation identifiers**.”

SPOR (IDMP) TIMELINES

SPOR ???

"Every time you've learned all the answers, they change all the questions.“

Oliver Otis Howard (1830-1909), American founder of the Howard University, Washington D.C.

Article 57 Database: **Content** (1)

EUROPEAN MEDICINES AGENCY

Substance Information:
- S1: Substance names
- S2: Substance Translations
- S3: Substance synonyms
- S4: Substance class
- S5: Reference source
- S6: International Codes

Business Service Substance: S

Reference Terminology:
- R1: Pharmaceutical form
- R2: Route of Administration
- R3: ATC codes
- R4: Units of Measurement
- R5: Units of presentation
- R6: Reference source

Business Service Referentials: R

Organisation information:
- O1: MAH (Legal Entity)
- O2: QPPV
- O3: PhV Enquiries
- O4: PhV System Master File

Business Service Organisation: O

Structured Medicinal Product Information:
- P1: MAH (Legal Entity)
- P2: QPPV
- P3: PhV Enquiries
- P4: PSMF
- P5: Authorisation country code
- P6: Authorisation procedure
- P7: Authorisation status
- P8: Authorisation number
- P9: Authorisation date
- P10: MRP/DCP/EU number
- P11: Date of withdrawal/revocation/suspension
- P12: Package description
- P13: Orphan drug designation
- P14: Comments (e.g. paediatric use)
- P15: Medicinal product name
- P16: Medicinal product invented name
- P17: Product generic name
- P18: Product company name
- P19: Product strength name
- P20: Product form name
- P21: Pharmaceutical Form
- P22: Route of administration(s)
- P23: Active ingredient(s), Adjuvant(s)
- P24: Excipients
- P25: Medical device(s)
- P26: Strength of active ingredient(s)/adjuvant(s)
- P27: Therapeutic Indication(s)
- P28: ATC code

Unstructured Medicinal Product Information:
- P29: Summary of Medicinal Product Characteristics

Business Service Product: P

EMA

(Source: presentation by Ilaria Del Seppia, EMA; 2015-04-22)

Implementing ISO IDMP through SPOR

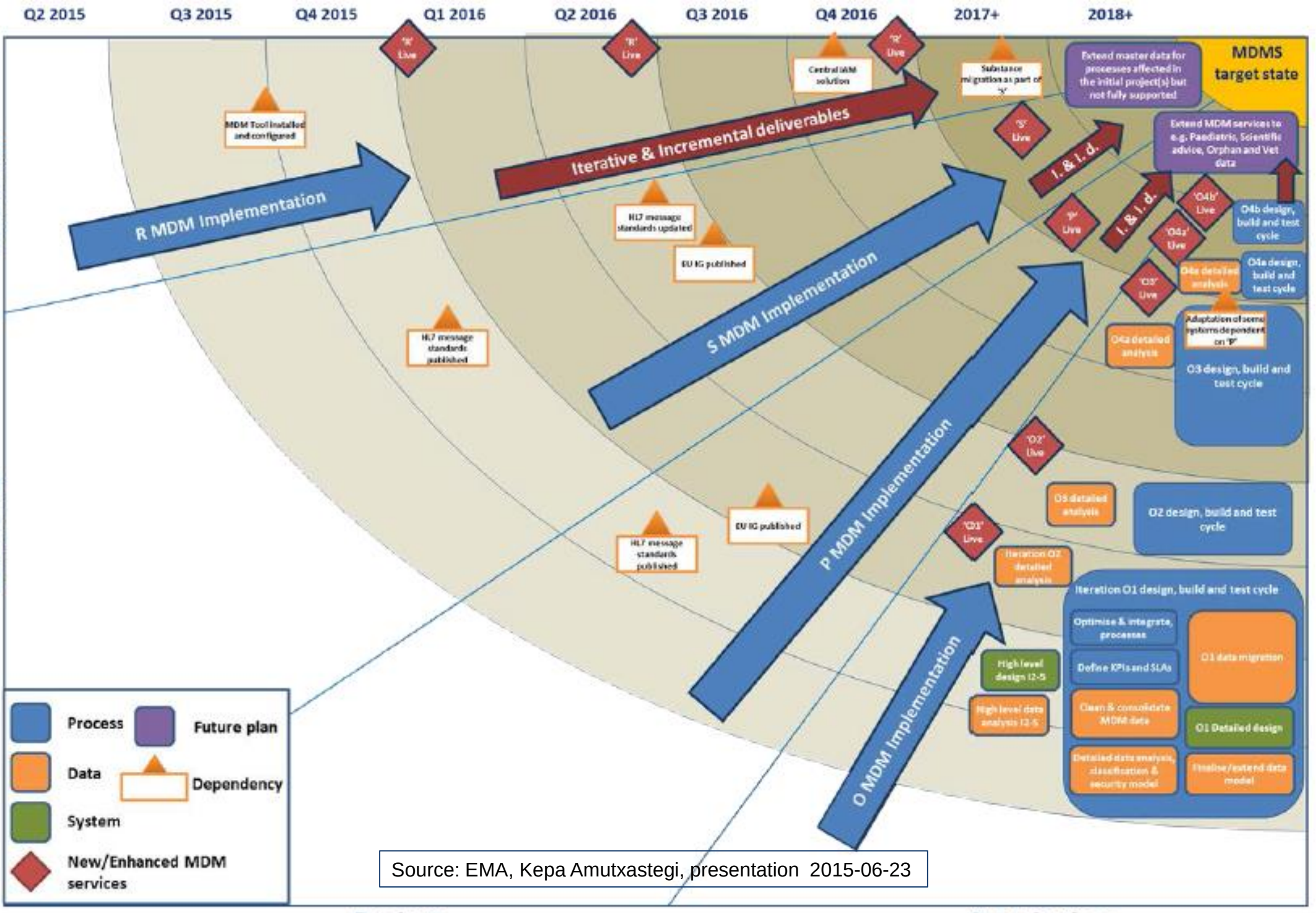
*Master data is any information that is considered to play a key role in the core operation of a business

The 5 new ISO IDMP standards are all about **master data***

In the case of the regulated EU pharmaceutical industry, there are four domains of master data:

1. **Substances:** Data that describes the ingredients that make up the medicinal product
2. **Products:** Data that describes the marketing and medicinal information relating to a product
3. **Organisations:** Data about the organisations that develop, own and manufacture the products e.g. pharmaceutical company names, their addresses, their plants, distribution centres, their regulatory agencies, and persons related to these organisations
4. **Referentials:** Lists of terms used to describe attributes of products eg. lists of dosage forms, country codes, package codes, weight codes

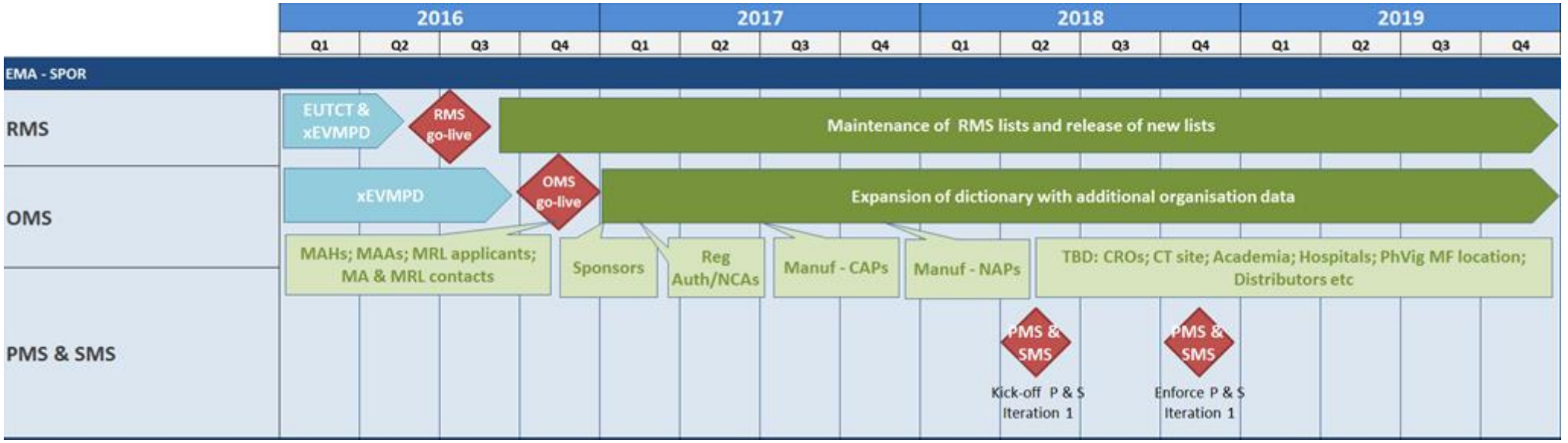
The SPOR programme has been established to implement services that centralise management of the four domains of master data. The programme will be a phased implementation of 4 projects; 1 for each of the domains:



Source: EMA, Kepa Amutxastegi, presentation 2015-06-23

Roll-out plan

We will be using a **phased approach** to implement the new ISO IDMP standards. RMS and OMS will be the **first projects to go live** since the Referentials and Organisations data provide the foundations for implementing PMS and SMS.

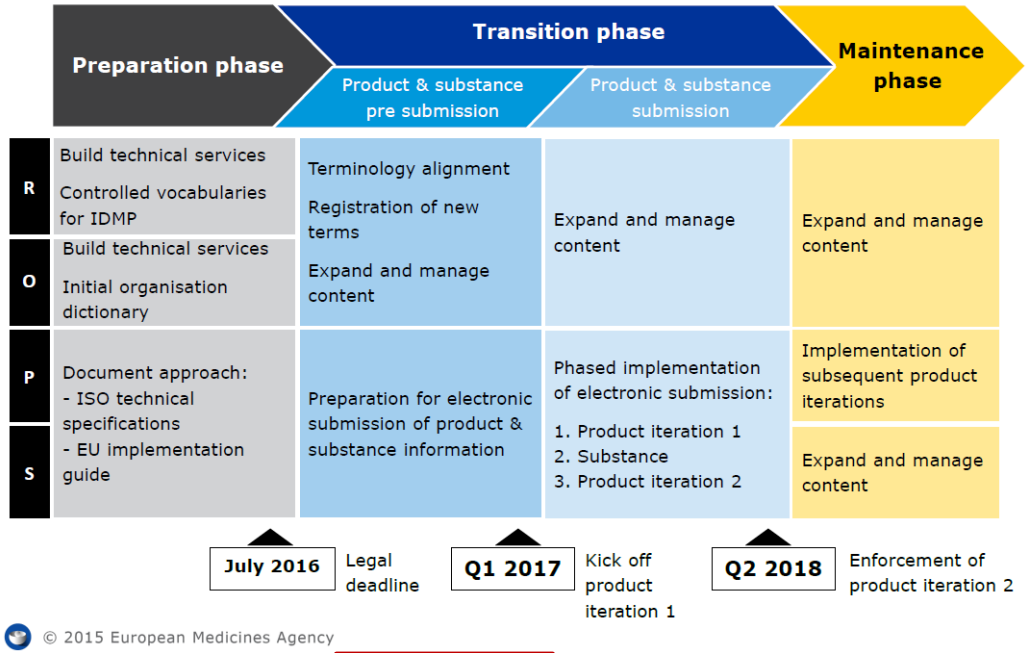


RELATIVE TIMELINE FOR IG AND ITERATION

TIME SHIFT (EVERY 3 MONTH?)

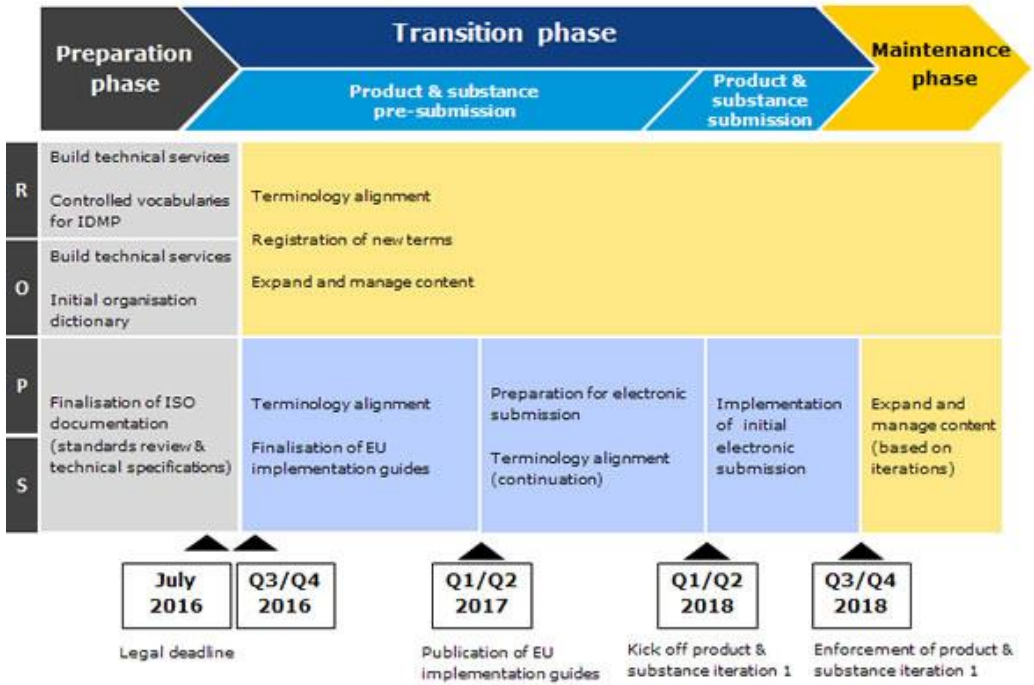
EMA webpage: Human regulatory/Data submission on medicines/Implementation of ISO IDMP standards

Overall high level plan for SPOR



Jan 2016

Overall high level plan for SPOR



Apr 2016

12 month time shift

BASIC PRINCIPLES OF INITIAL DATA SCOPE

Data fields required to identify product at the various levels

+

Current attributes submitted to XEVMPD under Article 57

(Art 57 project closed at the Agency since April 2016 and whole activity is in operation and maintenance – 10.000 products coming every month)

Recommendation for PMS Iteration 1

Medicinal Product
MPID
Combined Pharmaceitical Dose Form
IMPID Corss-Reference
Additional monitoring indicator
Orphan Designation Status
Name (Med.Product)
Invented Name Part
Scientific Name Part
Strength Name Part
Pharmaceutical Dose Form Part
Formulation Part
Intended Use Part
Target Population Part
Container or Pack Part
Device Name Part
Trademark or Company Name Part
Time/Period Part
Flavour Part
Classification System
Classification System Value
Version Date
Version Identifier
Document Type
Document Identifier
Regulated Document
Document Effective Date
Country
Language

Marketing Authorisation
Marketing Authorisation Number
Country
Legal Status of Supply
Authorisation Status
Authorisation Status Date
Date of First Authorisation
Procedure Identifier/Number (e.g. MRP number)
Procedure Type (e.g. MRP/DCP)
Country (national authorisation)
Marketing Authorization Number (national authorisation)

Organisation (e.g. MAH, QPPV, PSMFL)
Identifier
Role
Location Address
Location Role
Entity Identifier (according to Role e.g. PSMF ID)

Marketing information
Country
Marketing Status
Marketing Date
Risk of shortage supply
Risk of shortage supply comment

Indication
Indication Text
Indication as "Disease/ Symptom/ Procedure"
Co-Morbidity
Intended Effect

Pharmaceutical Products
Administrable Dose Form
Unit of Presentation
Route of Administration
PhPID Identifier Sets
Device Type (combined medical device ATMP)
Device Trade Name (combined medical device ATMP)

Ingredient
Ingredient Role
Substance
Specified Substance
Confidentiality Indicator
Strength Range (Presentation)
Strength Range (Concentration)
Reference Strength Substance
Reference Strength Specified Substance
Reference Strength Range

Package description
PCID
Package Description
Package Item (Container) Type
Package Item (Container) Quantity
Material
Component Type
Component Material
Manufactured Dose Form
Unit of Presentation
Manufactured Item Quantity
Device Type
Device Trade Name

16

- Around 20 data elements were removed/ streamlined/ re-modelled
- It is agreed to include 5 data elements to cover Shortage and Marketing information

  → **Total 80 Data elements in PMS Iteration 1**

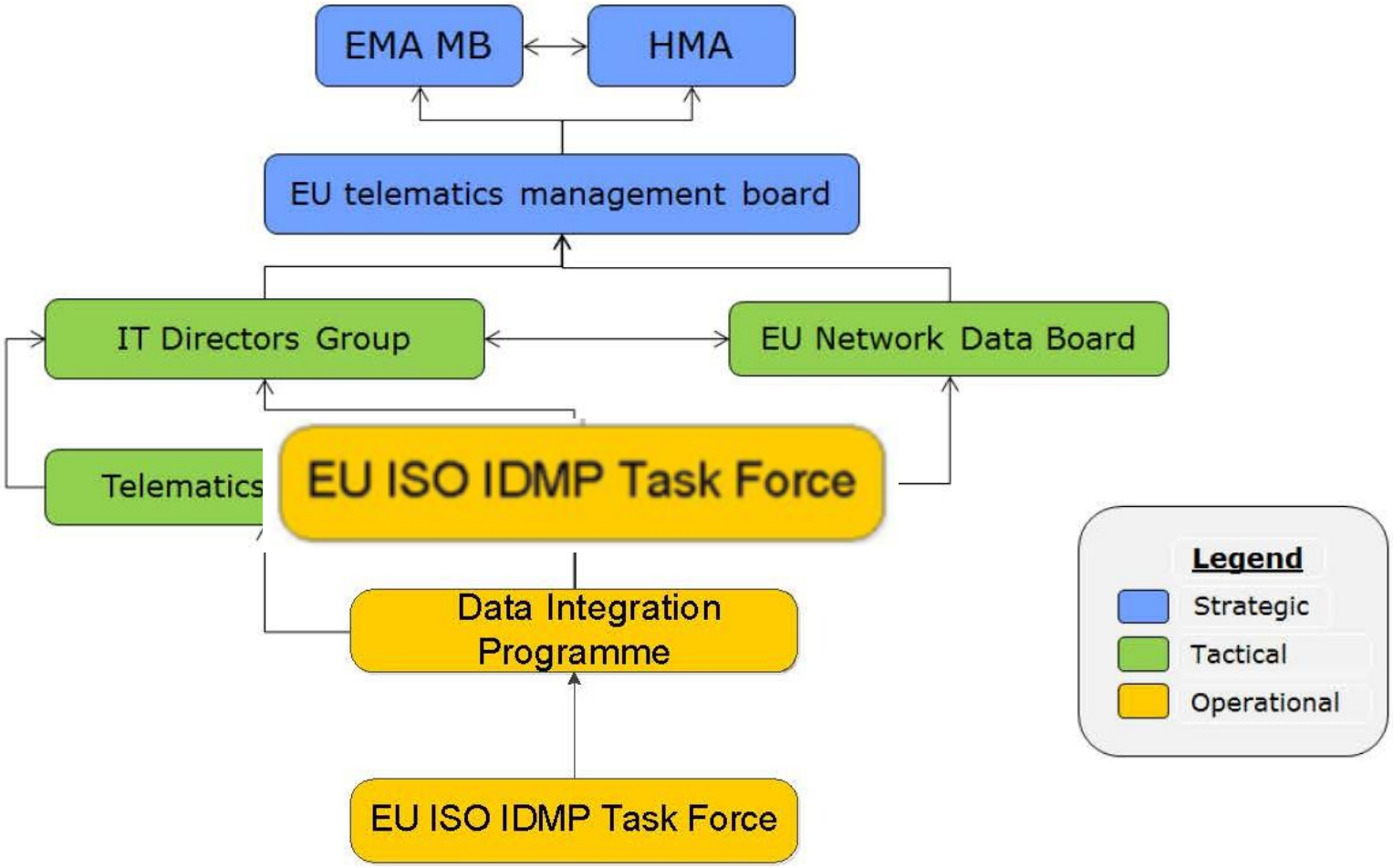
ITERATION 1 IMPLEMENTATION GUIDE

EU IDMP Implementation Guide
Modular Table of Content
(DRAFT)

Iteration	
Description	RMS v1
Date	3Q 2016
Overall EU IG Version	v0.1
Data Elements (High Level)	
Cross Reference	

Guide	Module/Process	Chapters	#	Author	
'Interim Process'	Interim Process	Interim process plan	1.1	S&P?	
		interim process timelines	1.2	S&P?	
		Interim Process (initial +maintenance)	1.3	S&P?	
	Migration Guide	Mapping Strategy	1.4	S&P?	
		Migration Process	1.5	S&P?	
S.P.O.R. Documentation	S.P.O.R. User Manual	User Manual (System Functionality)	2.1	EMA	
	S.P.O.R. Technical Documents	Technical Specification	2.2	EMA	
		Application Programming Interface (API)	2.3	EMA	
		SPOR Messaging Format	2.4	EMA	
Quality Control	Quality Control Methodology	Complete List of Content Fields and Controlled Vocabularies for EU IG	2.5	S&P?	
		Data Quality Assurance Process	2.6	S&P?	v1
		Data Access, Monitoring and Reporting	2.7	RMS	v1
"To Be Process" Target Operating Model	Set Up	Registering an Organisation (Org_ID & Org_Location_ID)	3.1	OMS	
		Maintain Organisation Information	3.2	OMS	
		Registering a Substance (SID & SSID)	3.3	S&P?	
		Maintaining Substance Information	3.4	S&P?	
		Requesting a new/updated Referential Term	3.5	RMS	v1
	Pre-Trial	Applying for new Scientific Advice	3.6	S&P?	
	Development	Applying for Clinical Trial Application (CTA-IMPID, PhPID)	3.7	S&P?	
		Amending a Clinical Trial Application	3.8	S&P?	
		Requesting an ATC/INN	3.9	RMS	v1
		Submitting a PIP	3.10	S&P?	
		Submitting a PSP	3.11	S&P?	
		Submitting a DSUR	3.12	S&P?	
		Maintaining IDMP Information during Development	3.13	S&P?	
	Marketing Authorisation Application	Applying for Marketing Authorisation (PCID)	4.1	S&P?	
		Maintaining IDMP in a Marketing Authorisation during Review	4.2	S&P?	
		Specific Cases relating to MAAs (e.g. PRIME)	4.3	S&P?	
		Linguistic Review (CAP)	4.4	S&P?	
		Post Approval/Pre-Launch Activities (BAID)	4.5	S&P?	
	Life Cycle Management	Submiting a Variation e.g. Safety/CMC	5.1	S&P?	
		Submitting an ICSR	5.2	S&P?	
		Maintaining Post Approval Commitments	5.3	S&P?	
		File new MAA in EU	5.4	S&P?	
		Apply for IIS	5.5	S&P?	
		Apply for License Renewal	5.6	S&P?	
		Maintaining Marketing Status for Shortage of Supply	5.7	S&P?	
		Apply for License Transfer	5.8	S&P?	
		Withdraw Product License	5.9	S&P?	
Integration Guide (Out of Scope)		Serialization (FMD) updates to EU Data Hub		S&P?	
		XEVMPD		S&P?	
		NCA Guide for how to receive/evaluate IDMP Information		?	

GOVERNANCE UNDER THE EMA

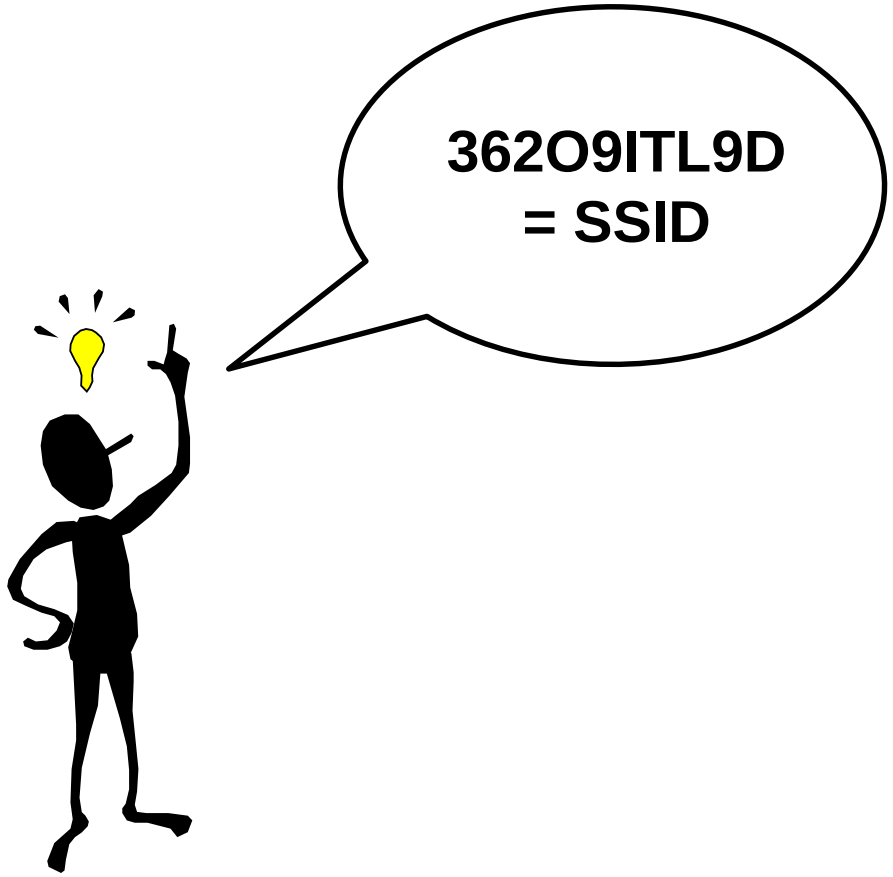


MEMBERSHIP OF ISO IDMP TASKFORCE

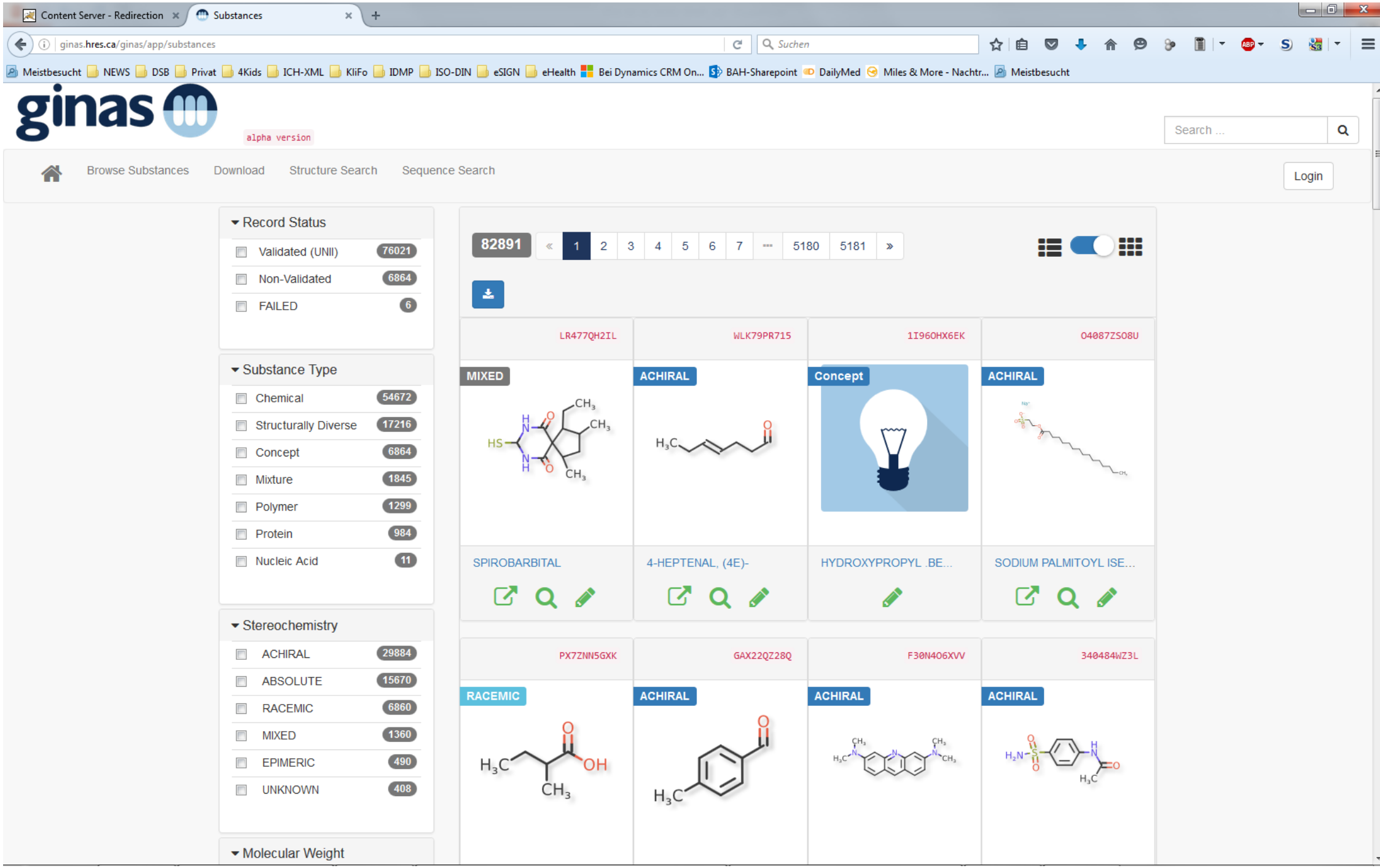
- 6 from EMA:
  - 3 representing business
  - 3 representing IT
- 20 from the EU Regulatory Network (EUNDB):
  - 8 NCAs, 1 European Commission, 1 EDQM
  - Up to 10 additional experts
- 24 from Industry Associations (up to 3 reps each)
  - Incl. AESGP, EFPIA, EuropaBio, EGA
- 10 interested parties:
  - EDQM, EU Commission, SwissMedic, Veterinary MP
  - experts from software vendors, service providers, medical product dictionary/ database solution developers
  - FDA representatives !! (learning and contributing)

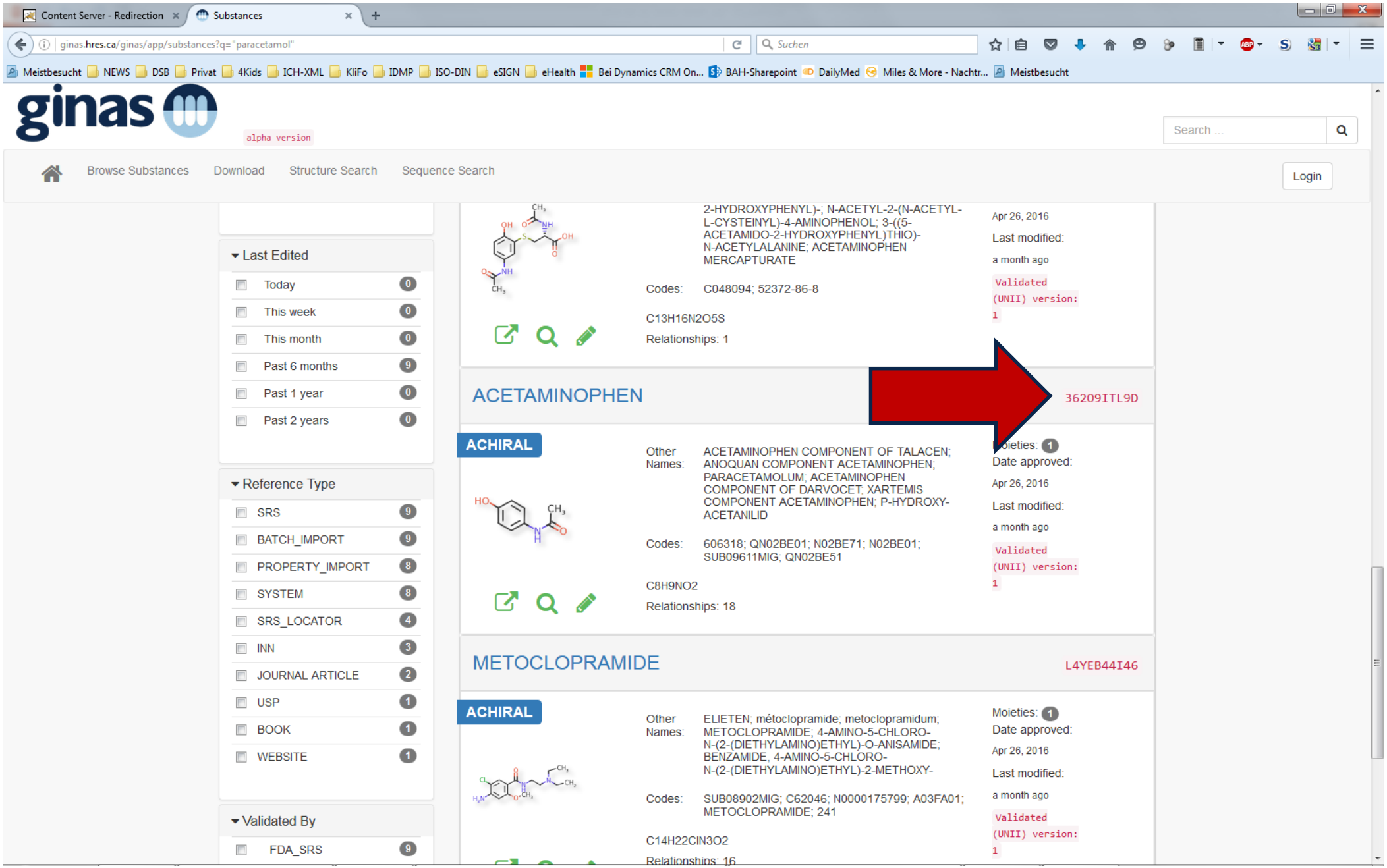
EVER SEEN AN IDMP CODE ???

SSID ??
GINAS PROJECT



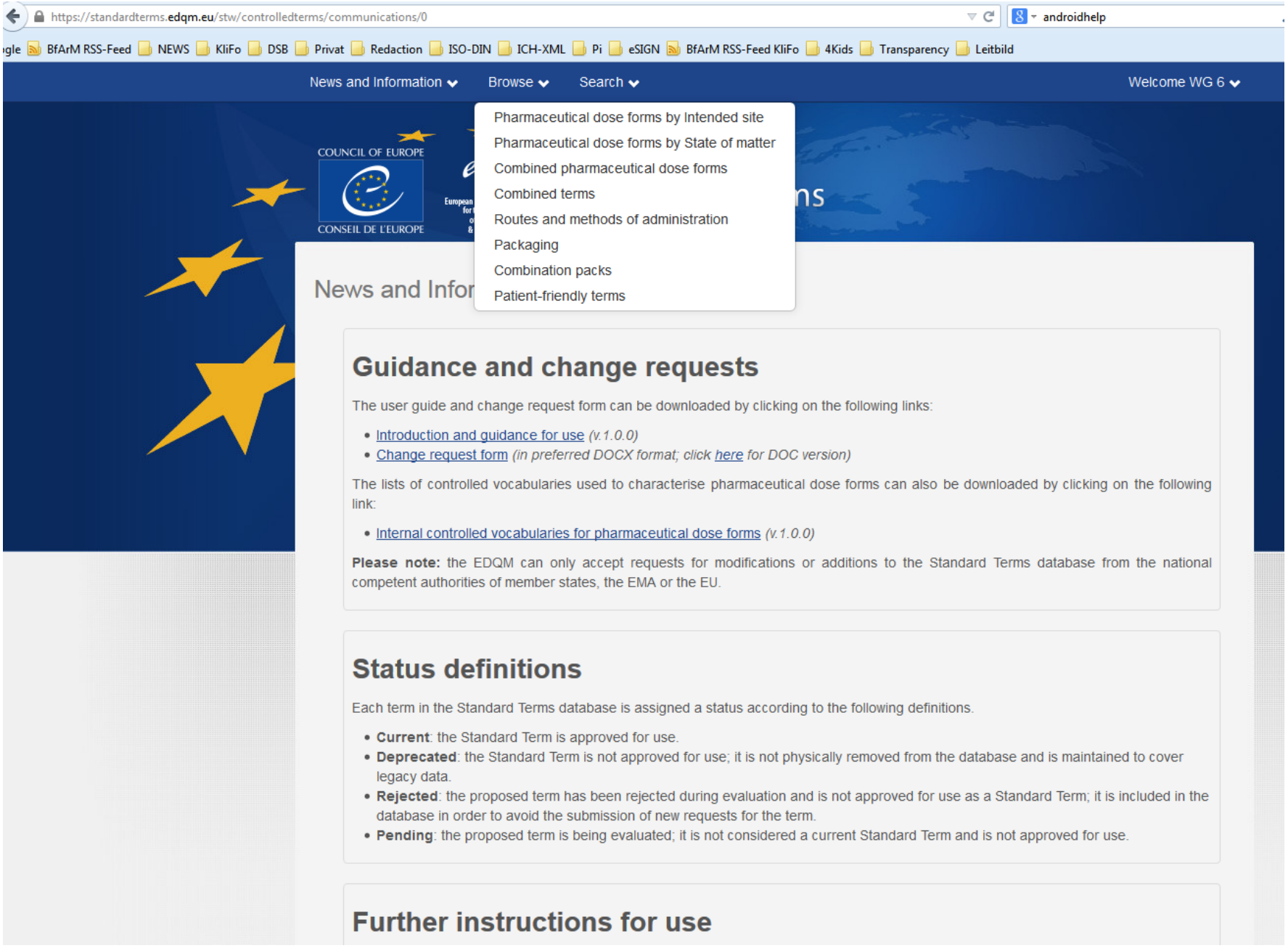
http://tripod.nih.gov/ginas/ http://ginas.hres.ca/ginas/





EDQM – DATABASE FOR STANDARD TERMS

https://standardterms.edqm.eu



Current	Effervescent granules	Human and Veterinary
Pending	Effervescent granules for oral suspension	Human and Veterinary
Current	Effervescent powder	Human and Veterinary
Current	Effervescent tablet	Human and Veterinary
Rejected	Film coated gastro-resistant tablet	Human and Veterinary
Current	Film-coated tablet	Human and Veterinary
Current	Gastro-resistant capsule, hard	Human and Veterinary
Current	Gastro-resistant capsule, soft	Human and Veterinary
Deprecated	Gastro-resistant coated tablet	Human and Veterinary
Current	Gastro-resistant granules	Human and Veterinary
Current	Gastro-resistant granules for oral suspension	Human and Veterinary
Deprecated	Gastro-resistant prolonged-release tablet	Human and Veterinary

Details | Characteristics | Translations | Summary sheets

Concept Code	50026250
Term	Gastro-resistant prolonged-release tablet
Comment	Use discouraged. The important characteristic is that the tablet is a prolonged-release formulation.
Concept class	pharmaceutical dose form
Domain	Human and Veterinary
Concept Status	Deprecated
Replacement Coded Concepts	Prolonged-release tablet
Version Number	2
Version creation date	2014-09-04 13:19:39
Modification made	Coded Concept Change: replacement coded concept added.
Language	English
Expanded code	PDF-50026250-EN-GB
Concept creation date	2010-08-09 09:56:55

Current	Gastro-resistant tablet	Human and Veterinary

BASIC DOSE FORM „TABLET“

Table 5 – Example code term pairs for the basic dose form category ‘Tablet’

code	BDF-0069-EN-GB	BDF-0069-FR-FR	BDF-0069-JA-JP
term	tablet	comprimé	錠剤
definition	category of solid pharmaceutical dose forms that are usually compressed volumes of particulate solids (but may be obtained by other means), formed into a shape that is appropriate for their intended use	catégorie des formes pharmaceutiques solides qui sont généralement des volumes compressés des particules solides (mais qui peuvent être obtenues par d’autres moyens), créées dans une forme qui est appropriée pour l’usage prévu	固形製剤の分類は、通常、固体粒子を圧縮し（なお、他の製造方法を用いる場合もある）、使用目的に適した形状に成形する。
languageCode	EN	FR	JA
regionCode	GB	FR	JP

Table 6 – Example coded concept for the basic dose form category ‘Tablet’

code	BDF-0069
value	BDF-0069-EN-GB
translation	BDF-0069-FR-FR BDF-0069-JA-JP

Remember: tablet = BDF-0069

„PROLONGED-RELEASE TABLET“

Coded concept for the pharmaceutical dose (PDF) form ‘Prolonged-release tablet’

code	PDF-10226000
value	PDF-10226000-EN-GB
translation	PDF-10226000-FR-FR PDF-10226000-JA-JP

Example coded concept for the release characteristic (RCA) ‘Prolonged’

code	RCA-0045
value	RCA-0045-EN-GB
translation	RCA-0045-FR-FR RCA-0045-JA-JP

Example coded concept for the intended site characteristic (ISI) ‘Oral’

code	ISI-0031
value	ISI-0031-EN-GB
translation	ISI-0031-FR-FR ISI-0031-JA-JP

Example coded concept for the administration method characteristic (AME) ‘Swallowing’

code	AME-0019
value	AME-0019-EN-GB
translation	AME-0019-FR-FR AME-0019-JA-JP

Summary of pharmaceutical dose form ‘Prolonged-release tablet’ and its attributes

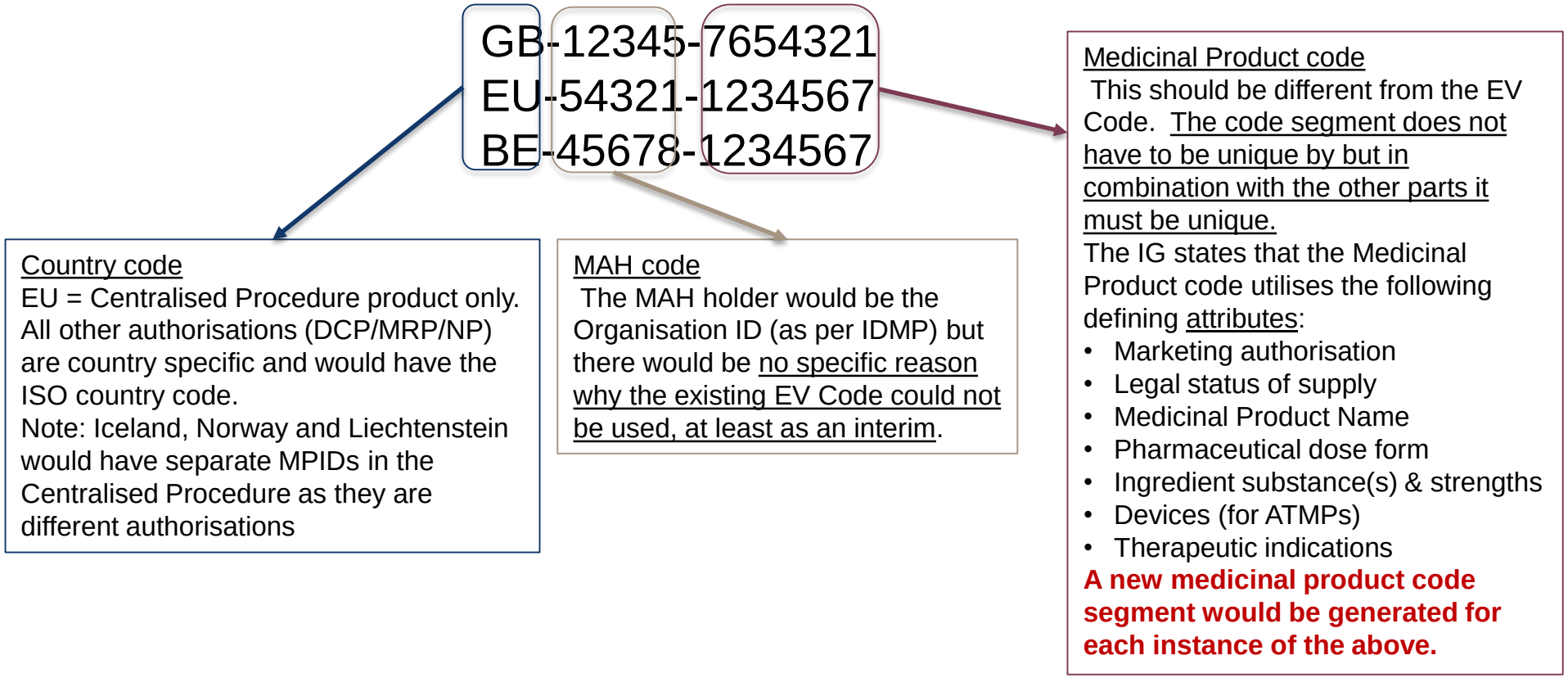
pharmaceutical dose form	PDF-10226000
state of matter	SOM-0097
basic dose form	BDF-0069
release characteristics	RCA-0045
transformation	TRA-0042
intended site	ISI-0031
administration method	AME-0019

Attributes

Same for State of Matter (SOM), Basic Dose Form (BDF) and Transformation (TRA)

„GLOBAL IDENTIFIER“ (MPID)

The assignment of the MPID is to provide a unique identifier to reliably recognize, monitor and trace the use of Medicinal Products. It also states that the MPID shall be allocated supplementary to any existing authorization number as ascribed by a Medicines Regulatory Agency in a jurisdiction.

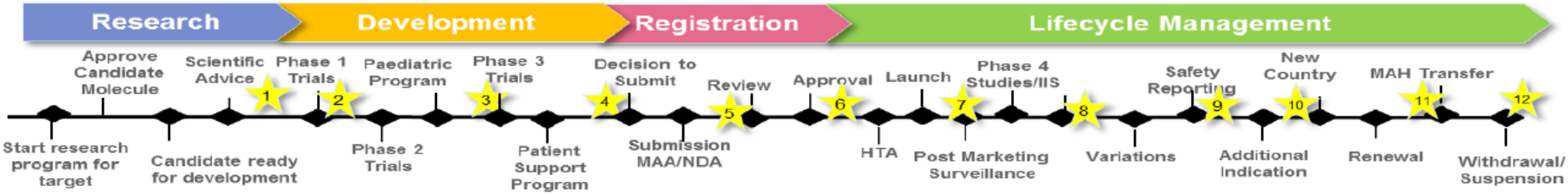


XEVMPD – LESSONS LEARNED

IDMP – FUTURE VISION

Take a broader view without loosing the focus.

Potential IDMP Process Impact

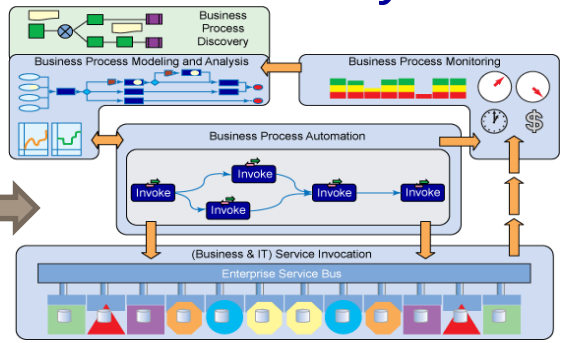


#	Process	Description	IDMP	#	Process	Description	IDMP
1	Pre-Trial	Scientific Advice	?	7	Safety Reporting	Submit ICSRs Maintain PSMF (GVP Inspections) Investigator Initiated Studies/P4	Y
2	CTA/IND	Organization and User Registration New Substance Registration (SID) Submit CTAs and INDs (IMPID) Publish CT Information	Y	8	Manufacturing/CMC	Update BAIDs Update Manufacturing Information GMP Inspections	Y
3	Development	Submit CTA/IND Amendments Submit ATC/INN Requests Provide GCP Information Maintain Trial Master File Submit PIPs/DSURs/PSPs	Y	9	Variations	Submit Variations (Update Clinical Particulars etc) Maintain XEVMPD Information Maintain PACs/FUMs	Y
4	MA Submission	Submit MAA Orphan Drug Designation MAPPs/Breakthrough	Y	10	New Country MAA	Submit MAA in new Country Apply for new MPID, PCID, BAID?	Y
5	MA Review	Maintain current CTD File during Q&A Request MPID and PhPID	Y	11	MAH Transfer	Apply for License transfer (new IDs?)	Y
6	Approval to Launch	Submit XEVMPD Data Request PCID and BAID Linguistic Review/Translate Label	Y	12	Withdrawal	Update Marketing Status of Product (retire IDs?)	Y

THE FUTURE

Data is captured and submitted only once

Structured data for either RA, PcV, clinical, manufacturing information



MAA, variation, Renewal, ICSR, CTA

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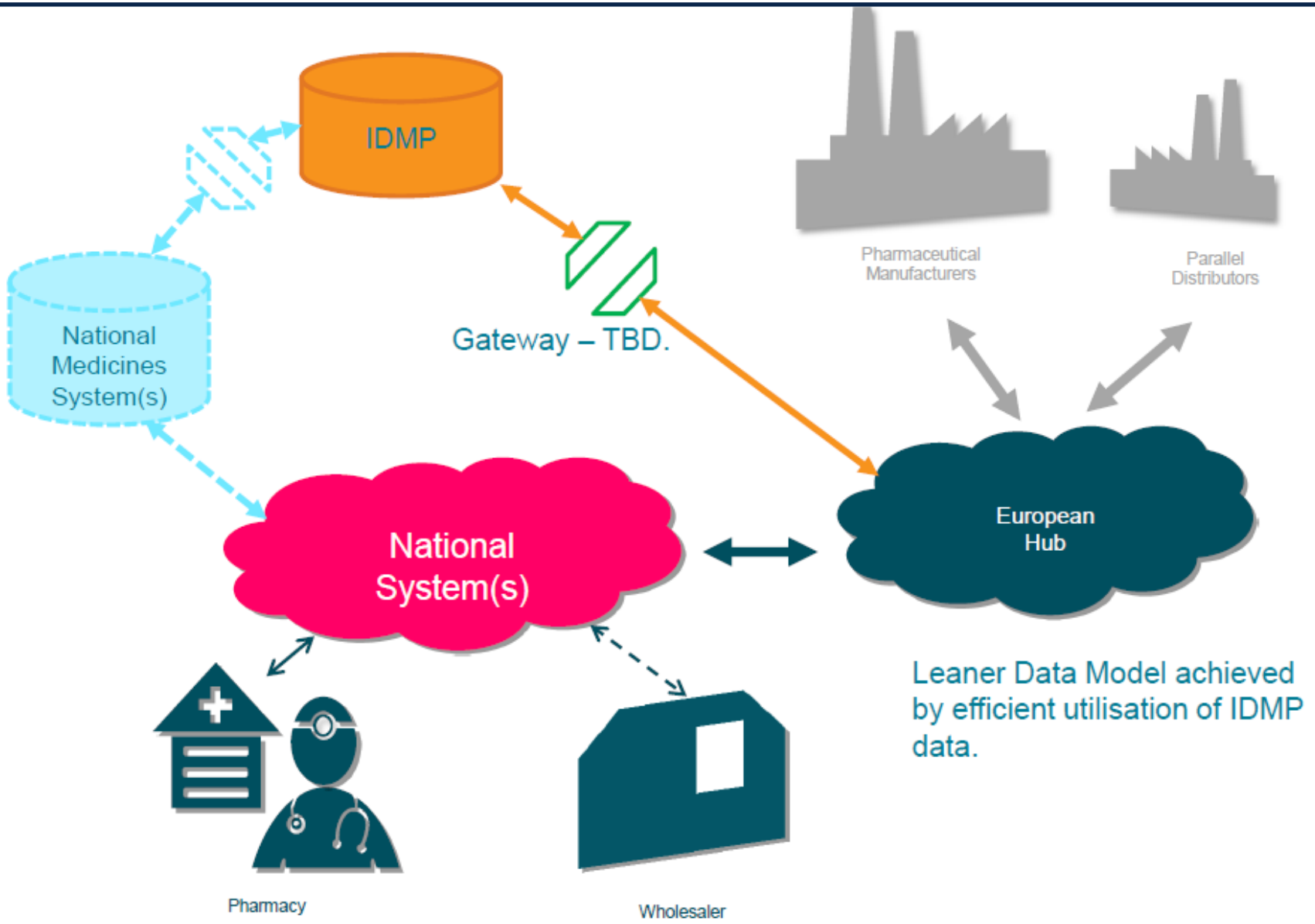
DATA WITHIN PHARMACEUTICAL COMPANIES

- Data in silos used from different functions (RA, PhV, R&D, manufacturing...)
- Data is available, but might not be structured or the same in different places according to very different business needs (e.g. Packs vs. Formulation/Registration)
- Different environment: SAP, Linux, Windows...

FIRST USE CASE

- On 19 October 2015 the Agency launched a new service to national competent authorities, providing them with **continuous access to key Article 57 data**. National competent authorities can access product details based on the latest version of information submitted for medicinal products with a valid marketing authorisation in the European Economic Area, by creating a new report in the EudraVigilance Data Analysis System (EVDAS).
- The EMA Management Board considered the Article 57 database functionality for notifying changes to the QPPV and PSMF at its December 2015 Management Board meeting. The Board agreed that the database is functional for the purpose of notifications of changes to QPPV and PSMF information and that this **takes effect from 1 February 2016**. From that date companies no longer need to notify EMA (for centrally authorised products) or national competent authorities (for nationally authorised products) of changes to the QPPV or PSMF data by submitting a type IA_{IN} variation. No final variation is required to notify an explicit cross reference to Article 57 as the source of QPPV and PSMF information.

EU HUB in the project to fight falsified medicines (FME) (until Feb 2019)



Leaner Data Model achieved by efficient utilisation of IDMP data.

ENDE, END, FIN, EIND, 末端, КОНЕЦ, FINAL

Thank you for your attention

Any questions?

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