EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

The EMA current activities towards ISO IDMP implementation

An overview

Ginas meeting – 11 June 2014

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An agency of the European Union

Outlines

- EMA Vision:
  - Objectives and priorities on data
  - The EU data boards
  - The Master Data Management System
- Status Quo: the EMA Medicinal Product and Substance Dictionary
- Next steps: moving towards ISO IDMP implementation

The EMA vision: objectives and priorities

New EMA organisation structure: drivers

- Better support the scientific work of the EMA committees
- Better share the knowledge and information the Agency holds throughout the European Union (EU) medicines regulatory network
- Better meet the needs of our stakeholders and partners

New EMA organisation structure: Objectives & Priorities

Top priorities for the Agency are to:

- Improve management of data
- Coordinate the development and implementation of international standards
- The following fora has been established:
  - ✓EMA Business data & Support department
  - ✓Internal EMA Data Board
  - ✓European Network Data Board

European Network Data Board

- EU Network Data Board (EU NDB) kick off meeting → *6th March 2014*
  - VISION (aspiration) is that the EU NDB will work with the regulatory network (i.e. EU National Competent Authorities) to establish appropriate data standards and supporting terminologies, necessary to support the sharing and analysis of data/information as an important asset for the network through its life cycle.
  - MISSION (to support the vision) of the EUNDB is to inform and support the regulatory networks implementation of data standards in a coordinated manner to optimise the value of its investment in data/information assets, support effective and efficient operations, mitigate legal and regulatory risk and improve the delivery of services and of proactive & reactive data analysis to its stakeholders and customers.

European Network Data Board

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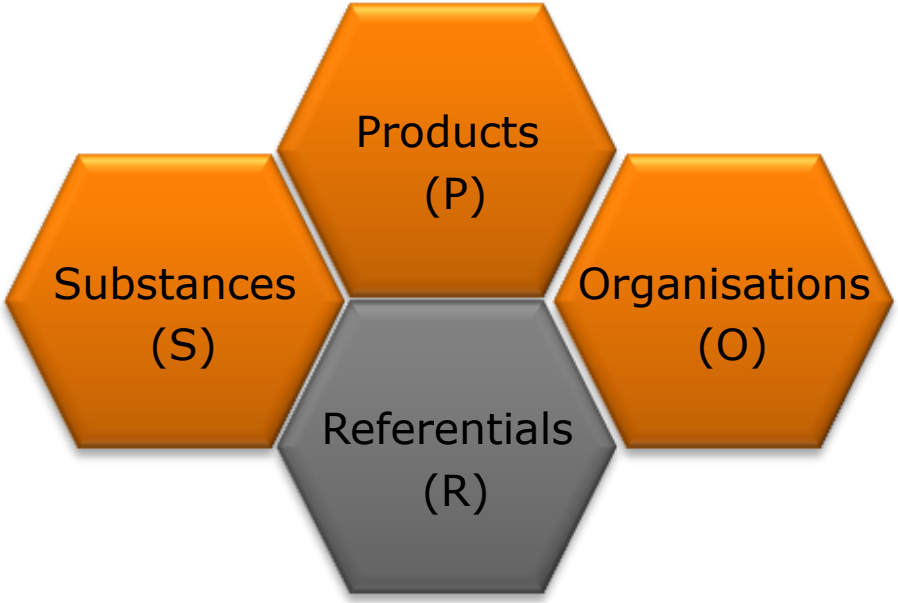
- The EU NDB objectives are focused on:
  - Ensure that data and information assets are known, usable, reusable, and can be accessed and integrated when and where needed.
  - Propose common policies, procedures, architecture and standards to maximise the sharing and investment in data and information.
  - Identify opportunities to coordinate and leverage existing EU investments in data and information.
  - Provide metrics and dashboards on the state of the EU data management performance.
  - Provide advice to the network on appropriate security and privacy policies to protect data assets.
  - Establish collaborative and cooperative relationships with stakeholders and consumers (i.e. industry and patients) to invest strategically in data and information assets and promote reusability.
  - Define European business requirements for business intelligence solutions/reports and for both proactive and reactive data analysis outputs.

The EMA vision:

Master Data Management System

Master Data Management Concepts



Master Data:

•Basic business data used across multiple systems, applications, and/or processes. Represents key business entities such as customers and products in all the necessary detail (e.g., for customers: number, name, address, and date of account creation).

•Can in itself contain reference data.

•Typical examples of Master data are: Products; Substances; organisations; people.

Reference Data:

•Set of permissible values to be used by other (master or transaction) data fields.

•Typical examples of reference data are: Units of measure; Country codes; Dosage Form.

Establishment of a Master Data Management Service (MDMS)

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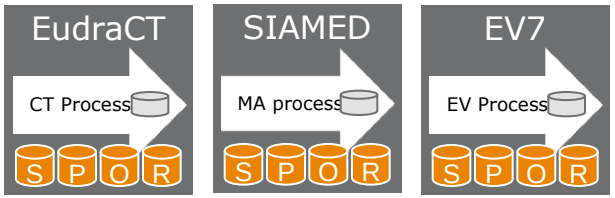
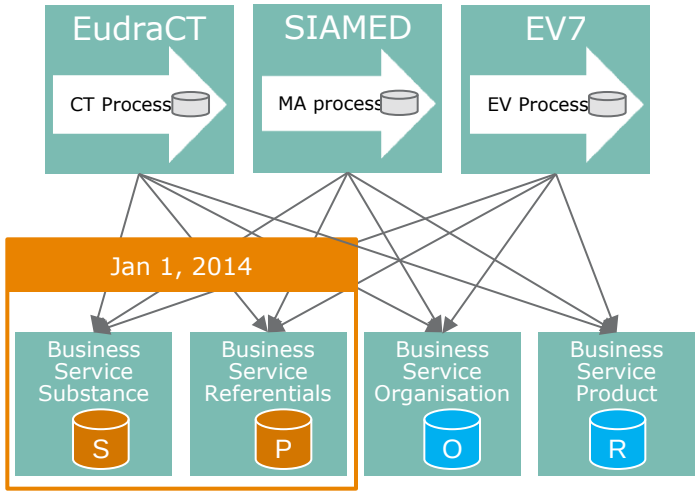
As-Is

- Multiple systems and databases containing substance data across the Agency
- Time-consuming and complex for users to ascertain which version of data is the truth or guarantee that data is the master copy
- No data governance, with data architecture driven by IT
- Organic systems evolved as point solutions, driven by technology rather than business



To-Be

- A single department responsible for data governance and information assets
- Mandate to own data architecture and governance
- Single, trusted, identifiable master copy of substance data available as a service



Status Quo:
The EMA Medicinal Product and Substance Dictionary

EMA Substance and Product management: Article 57(2)of Regulation 726/2004

- Implementation of the electronic submission of information on medicines was the first deliverable of new PV legislation
- Article 57(2), second subparagraph of Regulation (EC) No. 726/2004 requires:
  - The Agency to make public a format for the electronic submission of information on medicinal products for human use by 2 July 2011
  - Marketing authorisation holders (MAHs) to submit information to the Agency electronically on all medicinal products for human use authorised in the European Union by 2 July 2012, using this format
  - MAHs to inform the Agency of any new or varied marketing authorisations granted in the EU as of 2 July 2012, using this format

Article 57(2): Data Content

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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

Business Service Product

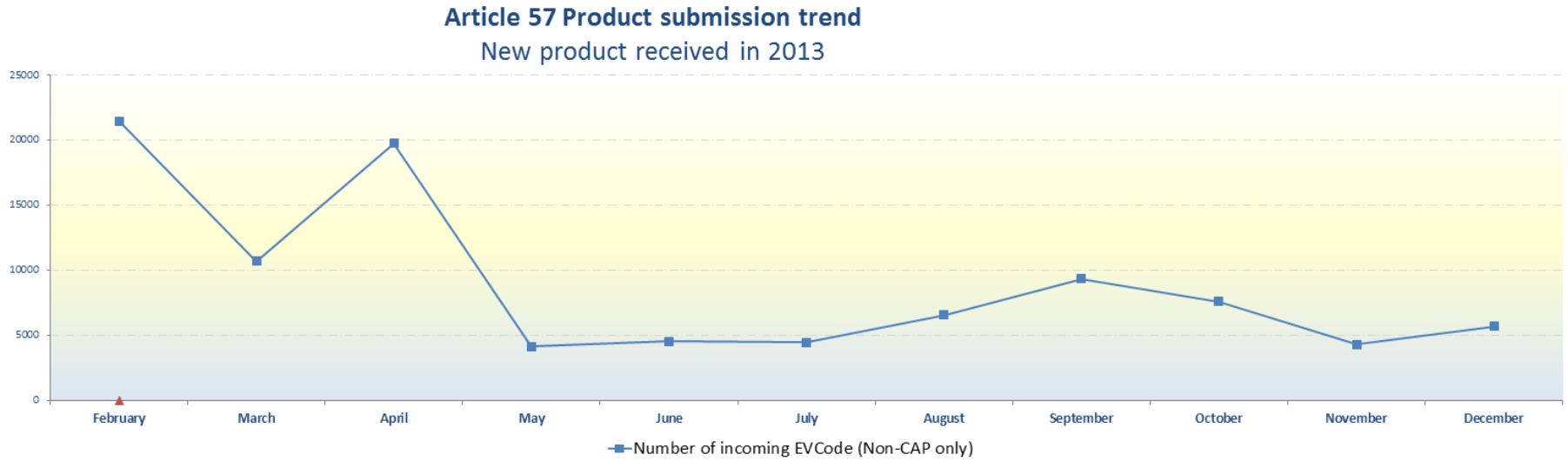
P

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

Article 57(2): Initial submission

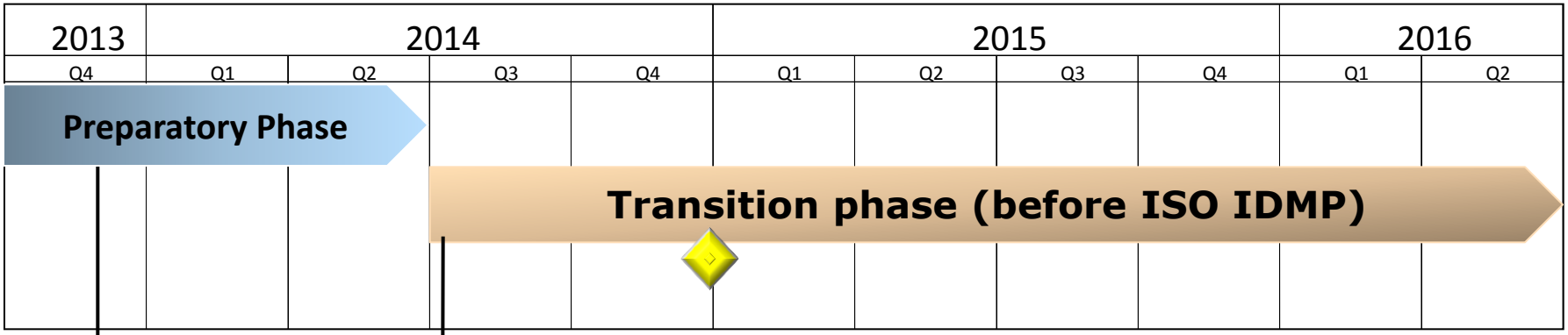
(since 2nd July 2012)

Total number of medicinal product submissions by MAHs up to 3 Feb 2014	
Total number of medicinal products (based on EudraVigilance codes)	459.290
Total number of marketing authorisation holders (legal entities) established in the EU (corresponding to EudraVigilance codes)	3.996



Article 57(2) Submission plan 2014-2016

The Article 57 data maintenance submission plan has been endorsed at the EMA Art.57 Implementation Working Group meeting with representatives from industry association in January 2014



December 2013 – June 2014

The aim is:

- For the Agency to upgrade the Agency's data entry tool and provide necessary guidance to support the maintenance submission
- For industry to start upgrading in-house IT systems

June 2014 – December 2014

The objective is to enable the MAHs to update, complete, improve the quality and submit the Article 57 data via the transition process **before the end of 2014**.

From January 2015

MAHs to continue notifying any changes affecting the Article 57 data by means of the transition processes within **30 calendar days** from the date of which the changes have been authorised.

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Business cases to cover 2014-2016

Data analysis

- EudraVigilance (EV) data analysis and Signal management
- Reporting and coding of medicinal product and substance information in ICH ICSRs
- Data analytics and business intelligence

Regulatory actions and legal obligation

- Regulatory action to safeguard public health (e.g. Referrals, PSUR repository, Literature monitoring)
- Support calculation of Pharmacovigilance fee

Communication with stakeholders

- European medicines web portal
- Granting access to EudraVigilance data (proactive and reactive)
- EU/ International data exchange
- Support to PRAC for communication with MAHs

EMA Preparatory phase:

Substance Quality Control

Substance Quality Control (QC) - Phased plan:

1. De-duplication of substance names
   - Identification and merging of duplicate substance names in the XEVMPD
2. Completion and integration phase:
   - Validation of other referential substance data (e.g. CAS number)
   - Integration with international substance terminologies (e.g. FDA-SRS)

Objectives:

- Development of a **comprehensive** and **consistent** reference terminology of unique substance names and identifiers (EVCODEs) in the Article 57(2) database
- Best practice guidance on how to handle Substance information

Substance QC: current status

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- **Volumes of substance names de-duplicated:**
  - Total number of substance ~33.000 (Based on EVCodes)
  - Referring to ~115000 Names (e.g. synonyms and translations)
  - Deployment of the new XEVMPD substance name CV in XEVMPD completed at the end of April
  - **The list is publicly available at the EMA article 57 website:**

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000336.jsp&mid=WC0b01ac058079126c

Article 57(2) Substance Information:
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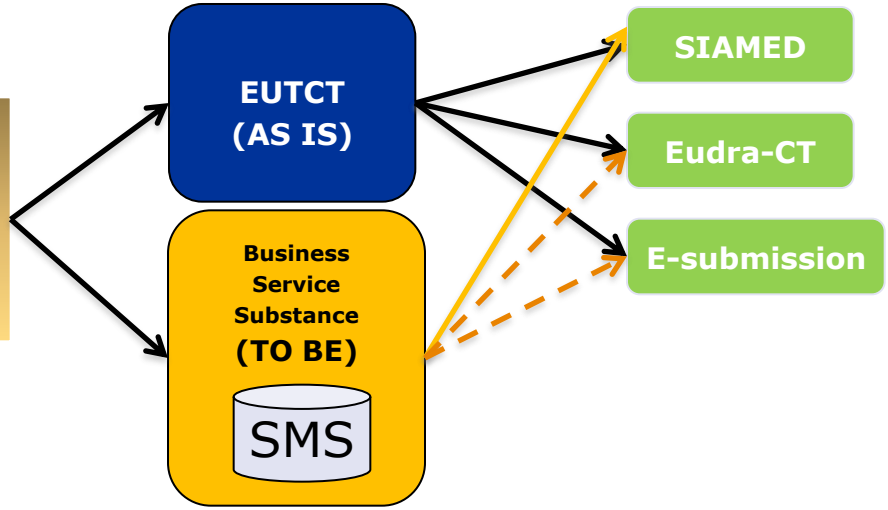

Next steps:
Moving towards ISO IDMP implementation

EU Legal framework

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Commission Implementing Regulation (EU) No 520/2012

- Articles 25 and 26 define the use of internationally agreed terminology formats and standards across the EU network as of **July 2016**
- In EU, the network and stakeholders will exchange medicinal product and substance information based on the ISO IDMP format and implementation guides defined in EU with the aim of:
  - Improving interoperability of systems used for the performance of regulatory activities (included and not limited to pharmacovigilance)
  - Eliminating duplication of encoding activities concerning the same information
  - Speeding up the activities of medicines regulatory agencies worldwide for a variety of regulatory activities including the life cycle management of medicinal products information
  - Reducing the operational risk due to the exchange of medicinal product information among EU network and with regulatory authorities

EU Modus operandi

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EMA to coordinate inputs for the ISO IGs development

EU Network to provide business data requirements and liaise with SDOs

EMA to feed into MDMS and EU Data Integration

EU Network Submit comments into ISO ballots and Implementation Guides

- EU Network data Board
- Art. 57 IWG with industry associations
  - Define the ISO IDMP Implementation Roadmap
  - EMA Product Management System

Next steps

- EMA has set up the '*EU ISO IDMP task force*' recruiting scientific and regulatory experts from EMA Committees and the EU Network Data Board
- EU task force is providing the business requirements for the ISO IDMP EU implementation and specifically is defining:
  - Mandatory and optional ISO 11615 and 11238 data elements
  - Business rules for optional data elements
  - Data types
- Following finalisation of the mature draft of the ISO IDMP TSs, EMA and the EU Network will define the EU ISO IDMP implementation Roadmap and the EU data governance
- EMA is coordinating the EU inputs and will ensure international alignment with non-EU regulators

Any questions?