EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Implementation strategy for ISO IDMP in EU

Paolo Alcini
Head of Data Standardisation and Analytics
Business Data & Analytics
Information Management
EMA

An agency of the European Union

The EU ISO IDMP Task Force

- The Agency established the EU ISO IDMP Task Force with representatives from EU Network, Industry Associations and other interested parties
- The **VISION** of the ISO IDMP Task Force is to develop the common EU strategy for the ISO IDMP standards implementation in response to a worldwide demand for internationally harmonised specifications for medicinal products
- The **MISSION** of the ISO IDMP Task Force is to have an on-going dialogue between the main EU stakeholders which plan to develop and implement the ISO IDMP standards

EU ISO IDMP Task Force: Mandate (1/2)

1. Recommendation on the best practice on the EU operating model and EU data governance for the registration and maintenance of substance and medicinal product information in the EU

2. Contribution to the development and endorsement of the EU ISO IDMP Road Map including the implementation plan and strategy

3. The implementation and migration plan from current Article 57 database into the Master Data Management (MDM) system as defined by the EMA Roadmap, that includes:

   3.1.Contribution to and endorsement of the **gap analysis of Article 57 format** (i.e. xEVPRM) vs ISO IDMP

   3.2.Contribution to and endorsement of the **data submission and maintenance business processes based on the agreed EU operating model and data governance**

   3.3.Contribution to and endorsement of the **business processes to enrich the additionally required data**

   3.4.Contribution in establishing an ISO IDMP **data quality control methodology**

EU ISO IDMP Task Force: Mandate (2/2)

4. Contribution to the necessary documentation as regards the EU ISO IDMP implementation aspects such as EU ISO IDMP Implementation Guide/technical specifications and any other relevant guidance
5. Contribution to the **Organisation** master data management and **Referential data** in line with the EMA Roadmap
6. Communication channel towards all external stakeholders affected by the implementation of the ISO IDMP standards in the EU
7. In addition, this forum may provide recommendations and views on initiatives impacted by the ISO IDMP such as: Horizon 2020, Falsified Medicines Directive, Regulatory Submissions and Clinical Trials

ISO IDMP Standards: what it is

- The ISO IDMP standards establish definitions and concepts and describe data elements and their structural relationships that are required for the unique identification of:
  - Medicinal product information (MPID/PCID) - ISO 11615
  - Pharmaceutical product information (PHPID) - ISO 11616
  - Substances (Substance ID) - ISO 11238
  - Pharmaceutical dose forms, units of presentation, routes of administration and packaging - ISO 11239
  - Units of measurement (UCUM) - ISO 11240

- ISO IDMP standards apply to both authorised and developmental medicinal products for Human use

EU ISO IDMP Ultimate Goal

To build a **comprehensive list of medicines and substance in EU** with a **harmonised definition**, supported by a **standardised data exchange** model, available in an **easily accessible format** aimed to power business and *regulatory processes* in EU and at global level.

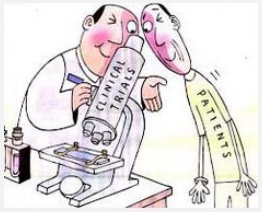
As adopted by EU ISO IDMP Task Force

12 June 2015

Overall Regulatory Benefits

- Facilitate the identification and exchange of product and substance information in EU and globally
- Improvement of Data Integrity enabling:
  - Reliability of data
  - Re-usability of data within the Agency and across the network
  - Avoidance of duplication of data and services
- Optimisation and simplification of data operating model and data management practices reducing silos and improving interoperability across EU systems
- Streamline, optimise and simplify regulatory processes to fulfil regulatory requirements more efficiently
- Speed up decision-making and improve communication with our stakeholders through easily accessible and highly reliable data

Overall Regulatory Business cases



Clinical Trial

GMP/Inspections

PharmacoVigilance

Regulatory Submission

Product lifecycle management

Use of ISO IDMP in Pharmacovigilance

- Improve accuracy of codification of Medicinal Products and Substance information reported in ICSRs
  - Enhance data analysis
  - Support signal management
- Speed up decision-making and regulatory actions as necessary
  - Referral, PSURs, Medical Literature Monitoring
- Communication with stakeholders in relation to aspects on safety of medicines
- Fulfil pharmacovigilance regulatory requirements

Use of ISO IDMP in Clinical Trial

- Support the assessment of a human medicine and its scientific evaluation by providing access to medicines data
  - Development of services with integration of the data from the EU CT database, EV SUSAR, Annual safety report repository
- Improve accuracy of codification of Medicinal Products and Substance information reported in SUSARs
- Fulfils regulatory requirements
  - ➢ Enable the exchange of SUSARs within EU
- To allow proactive and reactive access to CT data improving communication and transparency on CT data (i.e. EU Clinical Trials Register)

Use of ISO IDMP in GMP/inspections

- Providing easy access to manufacturing information
- To facilitate retrieval of medicines information for the rapid and efficient handling of urgent situations involving medicinal product defects (e.g. recall)
- Support and streamline inspections on manufacturing sites based on accessible information
- Sharing information with international partners about alternative sources of supply when shortage of medicines occur
- Support in the context of the anti-falsified medicines

Use of ISO IDMP in Regulatory Submission

- Gateway, Single submission portal
- eCTD
- e-Application Form
- EU CT portal
- Eudravigilance
- Referrals
- PSUR repository
- Eudra GMDP

Other regulatory submissions to support:

- Scientific Advice/Orphan/Paediatrics applications

Measures to facilitate ISO IDMP implementation

- EMA is closely participating in and following the activities performed at International level to ensure timely delivery
- EMA has established a bilateral partnership with FDA to foster harmonised implementation between EU and US and create unique substance IDs for EU and US.
- The EU ISO IDMP Task Force was established to engage with additional stakeholders
- Analysis on options are ongoing to allow resources to be forecasted appropriately
- As part of the implementation strategy, definition of a solid configuration management strategy including change management will be delivered to ensure business continuity

Problem Statement for S&P

Ultimate Goal: to build a **comprehensive list of medicines and substance in EU** with a **harmonised definition**, supported by an **standardised data exchange** model, available in an **easily accessible format** aimed to power business and regulatory processes in EU and at global level

Problem	Solution
A single implementation of the ISO IDMP standards on the July 2016 **legal deadline is unrealistic** due to dependencies on the availability of the ISO Implementation Guides, required technology changes and other external factors such as controlled vocabularies and interfaces with databases	• A **phased implementation** of ISO IDMP would mean more effective change management • It is expected a phased approach would result in **better adoption of the new operating model** and therefore achieve a sustained **higher quality of data** while also allowing for the **resources to be forecasted** appropriately

Product Operating Model – Preferred option

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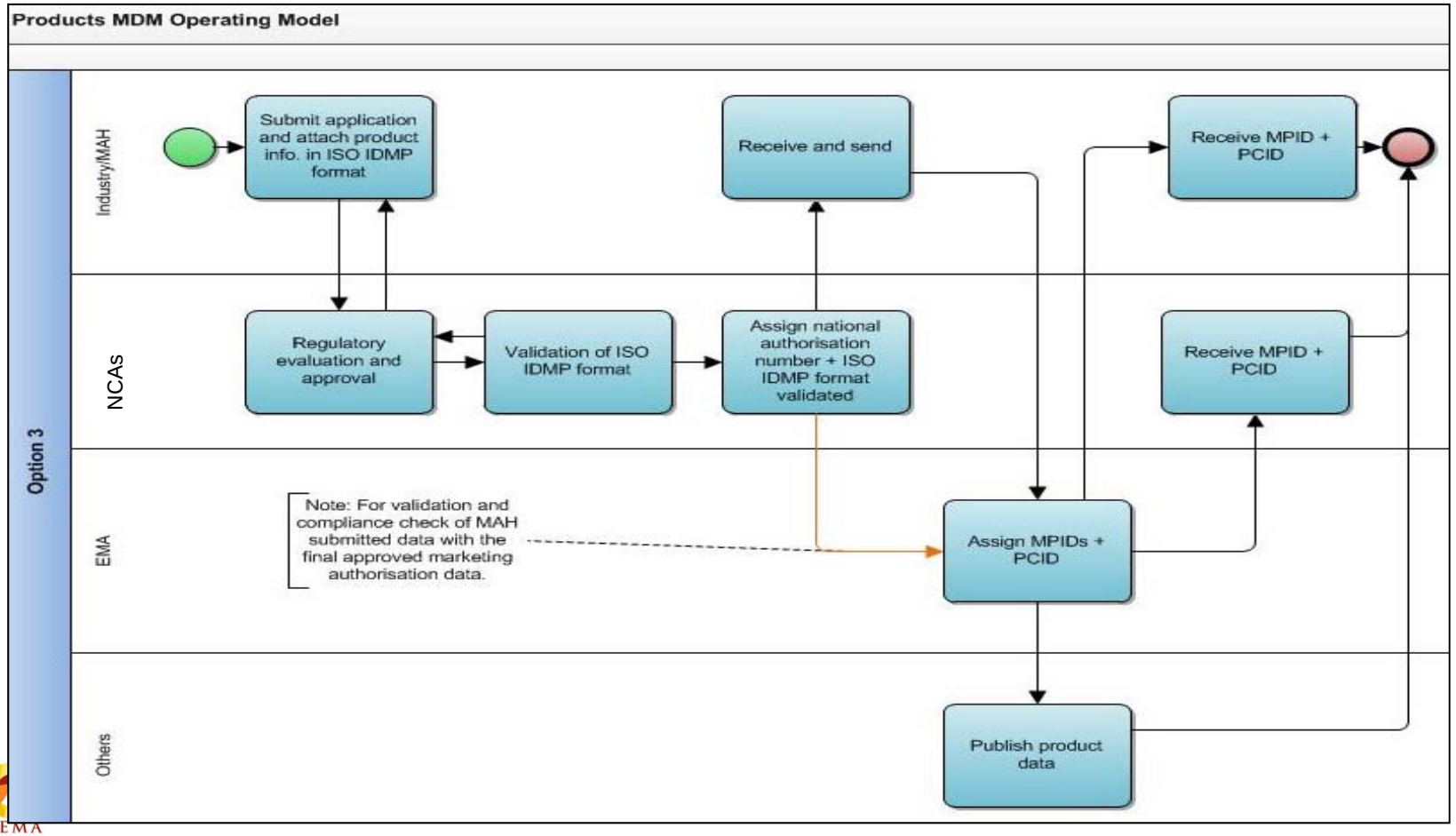

Product Operating model – Considerations

- In the **context of the product application** (i.e. initial MA or post-authorisation activities), the evaluation and validation of the (updated) substance information will be performed by the *Substance Advisory Board* established by the EU Network and EMA
  - The next phase of the project will be focused on defining technical implementation of the HL7/SPL message within relevant existing solutions (e.g. eCTD)

- The Product Management System will be **connected** and **integrated** to support the regulatory submission processes as defined in each iteration business cases to ensure **reduction of duplication of codification of product information** and **re-usability of data** across various domain (e.g. from pre to post-authorisation)

- Infrastructures will be made available to NCAs and Industry for the exchange and management of medicinal product information

Iterations

It. #	Scope	Business case
1	Content currently available in the **Article57** format and minimum required elements **to assign and maintain identifiers** for authorised medicinal products and support product **life cycle management** (MPIDs, PCIDs and PhPIDs)	• **Pharmacovigilance iteration 1** (i.e. to power the activities currently supported by Article 57) • **Regulatory submission Iteration 1** • GMP/Inspections Iteration 1 (current processes as supported by Article 57 database e.g. PhV inspections) • e-Prescription Iteration 1
2	ISO IDMP 11615 content to support the assignment and maintenance of the **Investigational Medicinal Product** IDs	• **Clinical Trial** • Regulatory submission support Iteration 2 (e.g. include the Clinical Trial application)
3	Remaining EU requirements for the **Clinical Particulars** section	• **Pharmacovigilance iteration 2** • e-Prescription iteration 2
4	**Batch Identifiers** and remaining EU ISO 11615 and ISO TS 20443 compliant	• **GMP/Inspections** Iteration 2 (e.g. full traceability of medicinal products) • Scientific advice orphan/ paediatrics application • e-Prescription Iteration 2 • **Anti-falsified medicines**
5	Additional standards (TBC) to support **Veterinary** medicinal product	• **Veterinary products**

Substance Operating Model – Preferred option

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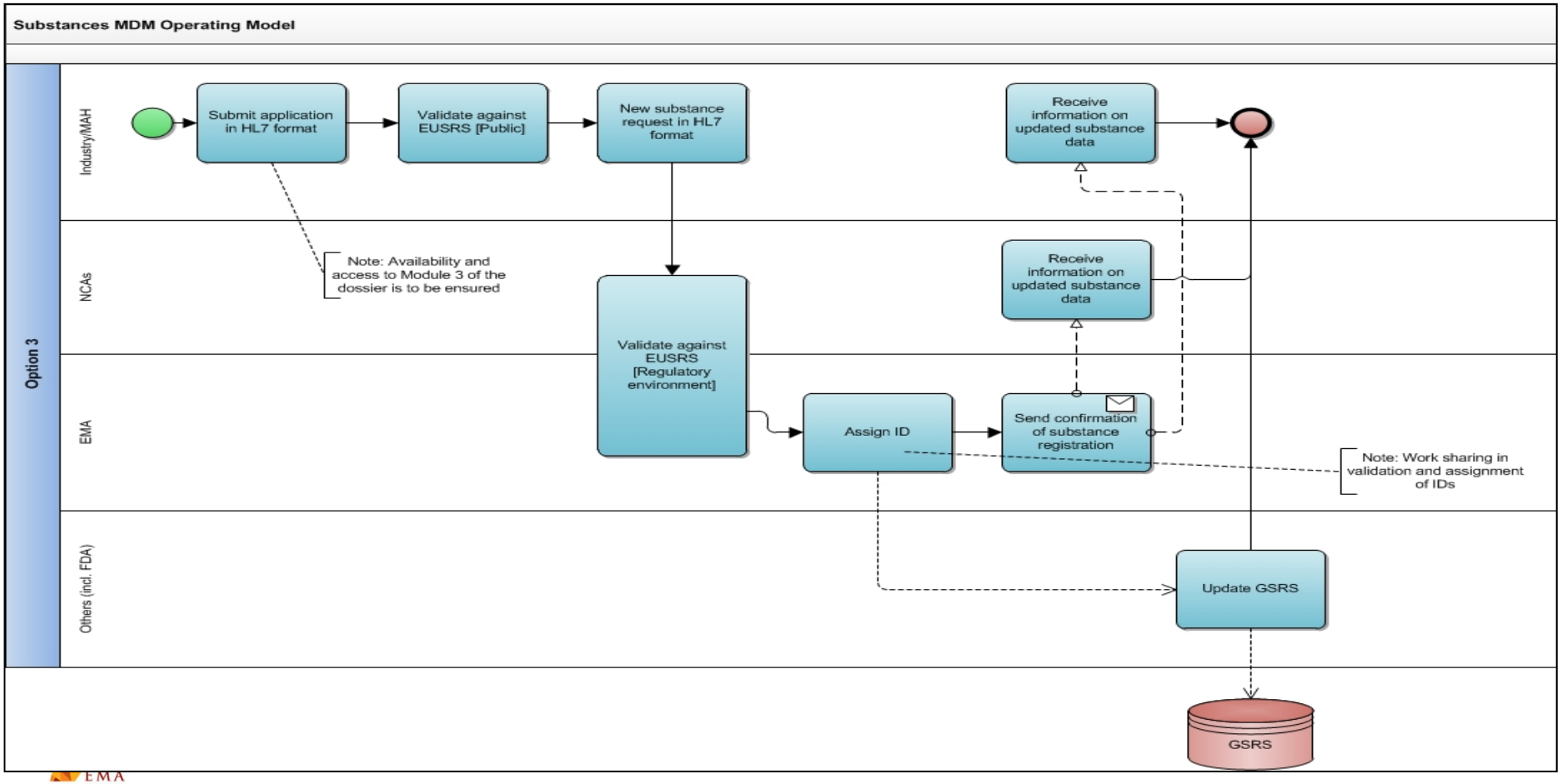

Iterations

It.#	Scope	Business case
1	Implementation of the minimum required mandatory elements as defined in **ISO Technical Specification 19844** •EU mandatory elements based on the EU requirements (TBC if any differences apply based on the further development of the ISO 19844 TS – differences will be minimised)	• **Pharmacovigilance** activities currently supported by Article 57 (e.g. Signal management, PhV fee) • **GMP / Inspections / Falsified medicines** • **Clinical Trials** • **Regulatory submission** support (e.g. marketing authorization application, CT application, e-Application Form)
2	Additional phase(s) to implement additional requirements outlined in the ISO TS 19844 in **alignment with US**	Better **global oversight** of medicines Global efficiencies
3	Additional standards (TBC) to support **Veterinary** medicinal product	Identification of **veterinary substance**

Key messages

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Operating Models:

•Proposed operating models integrated with the regulatory process for the assessment and evaluation of the substance and product information delivering an agile and high quality content solution with greater efficiency

Implementation strategy:

•A phased implementation of ISO IDMP would mean more effective change management and would result in better adoption of the new operating models allowing for appropriate resource allocation and training in a realistic timeframe

Identified dependencies:

•Dependencies on international and other (MDM) project deliverables will be closely monitored and current plan will be adapted as necessary

Key outcome & actions

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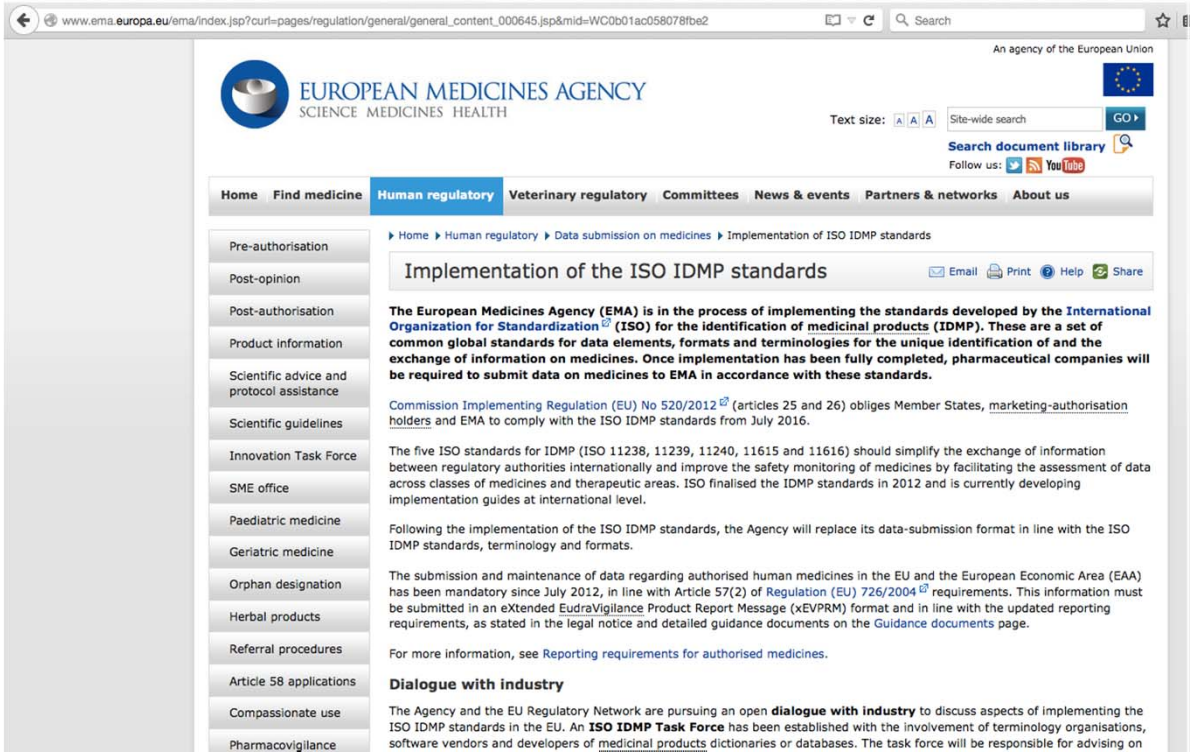
- Operating model for S, O and R were adopted by the Task force (TF)
  - Operating model for P was adopted by EU Network Data Board as a post-meeting action
- All iterations content and timelines of the SPOR components were adopted by the TF
- Proposed phased implementation has been endorsed at the HMA July meeting
- Sub-groups to progress with their activities and outstanding actions (i.e. defining content and change management)
- The Agency will continue communicating on the ISO IDMP implementation activities via the new webpage (e.g. minutes and presentation will be published once adopted)
- Next meeting 25th September 2015

Implementation of the ISO IDMP standards



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Implementation of the ISO IDMP standards

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The European Medicines Agency (EMA) is in the process of implementing the standards developed by the International Organization for Standardization (ISO) for the identification of medicinal products (IDMP). These are a set of common global standards for data elements, formats and terminologies for the unique identification of and the exchange of information on medicines. Once implementation has been fully completed, pharmaceutical companies will be required to submit data on medicines to EMA in accordance with these standards.

Commission Implementing Regulation (EU) No 520/2012 (articles 25 and 26) obliges Member States, marketing-authorisation holders and EMA to comply with the ISO IDMP standards from July 2016.

The five ISO standards for IDMP (ISO 11238, 11239, 11240, 11615 and 11616) should simplify the exchange of information between regulatory authorities internationally and improve the safety monitoring of medicines by facilitating the assessment of data across classes of medicines and therapeutic areas. ISO finalised the IDMP standards in 2012 and is currently developing implementation guides at international level.

Following the implementation of the ISO IDMP standards, the Agency will replace its data-submission format in line with the ISO IDMP standards, terminology and formats.

The submission and maintenance of data regarding authorised human medicines in the EU and the European Economic Area (EAA) has been mandatory since July 2012, in line with Article 57(2) of Regulation (EU) 726/2004 requirements. This information must be submitted in an eXtended EudraVigilance Product Report Message (xEVPRM) format and in line with the updated reporting requirements, as stated in the legal notice and detailed guidance documents on the Guidance documents page.

For more information, see Reporting requirements for authorised medicines.

Dialogue with industry

The Agency and the EU Regulatory Network are pursuing an open **dialogue with industry** to discuss aspects of implementing the ISO IDMP standards in the EU. An **ISO IDMP Task Force** has been established with the involvement of terminology organisations, software vendors and developers of medicinal products dictionaries or databases. The task force will be responsible for advising on

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Thank you for your attention

Further information

Contact me at: paolo.alcini@ema.europa.eu

European Medicines Agency
30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

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