Though many points remain open, we have at least some indications about how the European Agency intends to proceed:

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EMA Article 57 Planned Evolution

- Article 25 and 26 of Commission Implementing Regulation (EU) No 520/2012 requires the use of common standards, formats and terminologies in the EU for the identification and exchange of information on medicines. Specific reference is made to the ISO Identification of Medicinal Product (IDMP) standards that were finalized in 2012 and implementation guides are currently under development at international level.

- **EMA will replace** the current Art57/XEVPRM format with the formats, terminologies and standards as defined by the ISO IDMP standards and as agreed within the EU Regulatory Network. The **implementation of the ISO IDMP** terminology in the EU is expected to take place in **July 2016**.

- The Agency is currently developing an **EMA roadmap** to implement Substance, Products, Organizations and Referentials (SPOR) **Master Data Management** (MDM) services, which will also support the implementation of the ISO IDMP standards in consultation with the EU regulatory network and EFPIA. The roadmap will cover aspects related to the implementation of a SPOR MDM and a suite of services around it. The SPOR MDM implementation will include activities around business processes, data and governance aspects around these processes as well as the technology to be used as the enabler for the desired MDM services. The roadmap will provide a high level strategy of integrating non ISO IDMP compliant data from the existing core EMA systems into an ISO IDMP compliant MDM system and related processes considering the legal deadlines set in the implementing regulation.

- The following general activities will have to be performed regarding Article 57 database: A full **gap analysis** to compare the **current XEVPRM** and the **ISO IDMP format**, data migration from the current Article 57 database into the future MDM system, optimization of current processes to capture and manage the SPOR master data and implementation of a new data governance to mention some.

- The legal obligations as described in the Article 57 will continue to apply, however EMA is discussing with the EUNDB an operating model for the exchange of medicinal product information within the EU Network based on the ISO IDMP format, where information may be obtained from different sources (i.e. industry and NCAs) instead of only MAHs and is cleaned, consolidated and stored in a single repository. The **EU data operating model** will be defined cooperatively, taking into account international initiatives such as **GInAS for the identification of Substance** in compliance with the ISO IDMP 11238 standard.

- The **EMA roadmap** is planned to be consolidated **by end of Q1 2015** in consultation with the EU regulatory network partners. Starting from Q1 2015, the industry will be involved in the discussion of the roadmap and in the aspects related to the ISO IDMP implementation.

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NOTE:

The scope of the ISO IDMP standards covers human medicines only, however there is an ongoing discussion assessing the possibility to adopt/adapt the standards for the identification of veterinary medicines. A summary of the realizations planned for the Article 57 project is summarized in Annex 1 - Article 57 summary of next deliverables.

EMA states that it will foster the creation of a dedicated ISO IDMP Implementation Task Force with NCAs and MAHs.

The application of *ISO IDMP Standards* will bring you to an important level of

Regulated, Actionable Quality Information

for you *internally* and with your key Stakeholders - *globally*

Introduction

Since the Vioxx scandal and the product recall in 2004 the urgent need for patient safety reached the highest levels of awareness and the requirement to harmonize data globally to take effective and timely actions.

ICH to ISO: Standards defined and published
HAs and many others have elaborated on what they are, so we do not want to repeat it here.
Besides the need to become compliant with these new requirements, we want to look at the various benefits that will justify its implementation, based on your level of ambition and what you want to get out of it!

ISO IDMP (& Information Management) **Benefit Landscape**

The driver is not “just” for Drug Safety (DS) & PV, but to ***leverage Enterprise Information Assets***

In the IDMP context – an assessment, depending on your starting point – to be updated as Implementation Guidelines (IG) are released:

Compliance

- Consistency across functions and in HA communication
- Harmonized safety data and reporting e.g. ISO ICSRs (R3)
- Given granularity of content facilitates more rapid information exchange with stakeholders (depending on the level of risk a corporation is will to take/control/mitigate over time)

Business

- Controlled Vocabularies (CVs) applied, avoiding misinterpretations, in the decision-making process and translations
- Harmonization of internal CVs with Regulator's CVs
- Reducing or even eliminating redundancies (Single Source Principle)
- Optimization content re-use
- Gain agility while moving out of silos and making regulated content components accessible by architecting an Enterprise Content Repository

In a more holistic Information Management context implementation of IDMP could be used to drive further changes and lead to additional benefits (Depending on Corporate Information - and Change Management ambition)**, such as:**

- MAH – HA labeling consensus reached more rapidly
- Transparent Drug Safety (DS) processes for labeling changes
- Considerable risk reduction – more reliable data in decision processes, e.g. clinical phases
- Agility for action and reaction
- Interpretable, validated data = Actionable information
- Much more quality data available for pricing debates (PROs)
- Early signals in PV at any stage of DD & PI process
- Accelerating joint development/marketing or any other Partnerships
- Access to PI at a later date to current content, including translations

Perceived current Status

*Date for implementation according to **EU** legislation still unchanged:* ***July 1, 2016****!* There may be variations as to the depth of the implementation requirements and the full process is likely to be in steps.

No mandatory date in the **US** yet as FDA will proceed based on the already mandatory SPL. Other HAs to be expected as "rapid followers"

Cautionary comments that have been made include:

"It is again a regulatory effort that will satisfy the Authorities' needs not ours"

"We will start thinking when we have the final guidance from the regulators"

More positive statements that take a more holistic view:

"What is it really? We want to engage in an Awareness Process"

"As we learned, the IDMP Standards will - with full implementation – impact ALL functions within an Enterprise: Planning ahead is vital"

And even more "positive"
"Let's identify potential business benefits, test them in Use Cases (UC) within a Proof-of-Concept (PoC) with tangible outcomes that will allow us to develop a solid Business Case (BC) as a base for the needed investment"

IDMP – from an Information Management perspective

The driver is not "just" for Drug Safety (DS) but to *leverage Enterprise Information Assets*

Reflections – just some key points

- In the future, more information will be used for many different purposes and audiences.
- The behavior of Patients and Providers in the capture, comparison and use of information of interest and context has changed considerably.
- The exchange of information does not take place in traditional channels alone – Social Media become more and more important, with multiple opportunities, but also consequences (e.g. company reputation)
- All these environments have become much more dynamic it emphasizes the importance of companies getting organized in its use of Information Assets.

Suggestions

Starting from today's standpoint, what will be the best way forward?

An excellent starting initiative is to launch an ***Awareness Program*** with multi-functional participants:

The **LSCP** recommendation is to **start any activities by creating a *Holistic Enterprise View* and approach** (including a review of the Business Model [BM]), as the broad impact of the Standards need to be understood across the organization. You may well have already started some of the steps below.

Reflections for review/discussion:

- Identification of IDMP-relevant Data:
  - Where do they reside
  - What is the quality of the data
  - Where will they be used/re-used
  - What harmonization opportunities can be identified (e.g. Metadata, MedDRA applied, "old coding")
  - Data validation/migration path
  - Paper/Digital (ePaper?)
  - …

Please note that there might be some parallel work streams

So here are *examples* for discussion and reasoning:

- Define the horizon
  - Plan step-by-step to leverage the learning from one step to the other
  - With the knowledge gained above, the scope of the program/project:
    In the context of an Enterprise Information Architecture (EIA) the depth of your ambition needs to be defined
  - Priorities for a pragmatic way forward will be identified and agreed with the sponsor
  - Program plan and roadmap
  - Include a Change (Culture change) Management (CM) plan and project to complement your program. This will also include the Program communication strategy and media to be used.

And a suggestion:

- For capturing new business requirements **users must have a good idea/visual representation of what is possible today**
- Such an approach will increase buy-in and ***acceptance***

A pragmatic approach model is also available on request

For more information and/or a first, non-committing dialogue please contact: info@lsconsultingpartners.com

Author:
Ruedi F. Blattmann with Jim McKiernan acting as a reviewer