Terminologies and Coding Systems SPOR
Final Expert Council meeting
In the case of the regulated EU pharmaceutical industry, there are four domains of master data:

**Master data is any non-transactional information that is considered to play a key role in the core operation of a business and re-used for multiple purposes**

1. **Substances:** Harmonised data and definitions to uniquely identify the ingredients and materials that constitute medicinal product.

2. **Products:** Harmonised data and definitions to uniquely identify medicinal product based on regulated information (e.g. marketing authorisation, packaging and medicinal information).

3. **Organisations:** Data that comprises of organisation name and location address data for organisations such as MAH, sponsors, regulatory authority, manufacturers.

4. **Referentials:** Lists of terms (controlled vocabularies) used to describe attributes of products e.g. lists of dosage forms, units of measurement, routes of administration.
Terminologies and coding

• 100 terminologies currently available within the Reference management System

• RMS will be the single point of reference for all terminologies utilised within the regulatory process by both internal and external stakeholders.

• Regulatory agencies in member states are reviewing national lists and mapping to the RMS terminologies.

• Number of terminologies in use within Art 57
Terminology Providers

- MSSO - MedDRA
- WHO - ATC H; ATC V; INN
- ISO - languages, countries
- EDQM - RoAdm, Pharmaceutical Dose Forms, Packaging, Units of presentation, release characteristic, intended site, transformation, etc
- EMA - Material, Authorisation status, Application legal basis, Legal status for supply, Ingredient role, Manufacturing activity, MRL classification, Target species, Shelf life type, Storage conditions, Variation classification, VedDRA, etc
Key changes as a result of SPOR

• EMA will act as the broker and it will provide Referentials data services to the EU network
  • Referentials data maintained by EMA Data Stewards and available in structured format
• EMA will host reference lists from different maintenance organisations (WHO, EDQM, MSSO, BfArM, etc)
  • EDQM: maintenance organisation for ISO IDMP 11239 (ph. forms, units of presentation, routes of administration, packaging)
  • BfArM: maintenance organisation for ISO IDMP 11240 (units of measurement)
• EMA will be a maintenance organisation for new lists where no maintenance organisation exists
• Common process which requires industry and other parties to request registration of Terms before regulatory submission
  • Translations done by NCAs
• All organisations need to register legacy & specific terms with EMA
Referential Implementation

- Referentials UAT Ends Q3 2016
- Organisations UAT Ends Q3 2016
- MDM service go live for Organisations Q1 2017
- MDM service go live for Referentials Q1 2017
- Publication of EU Implementation Guides to support P&S Q1 / Q2 2017
Thank you for your attention

Further information

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