HMA
Heads of Medicines Agencies

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Terminologies and Coding Systems SPOR

Final Expert Council meeting

SPOR – Referential's

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

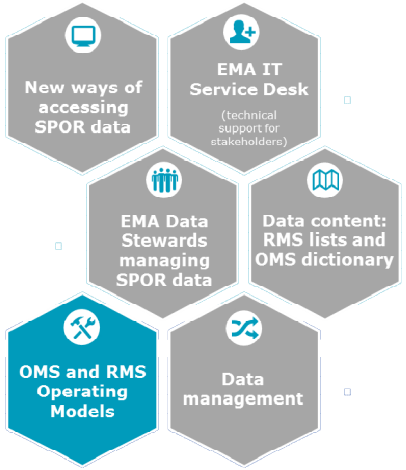
Terminologies and coding

- 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

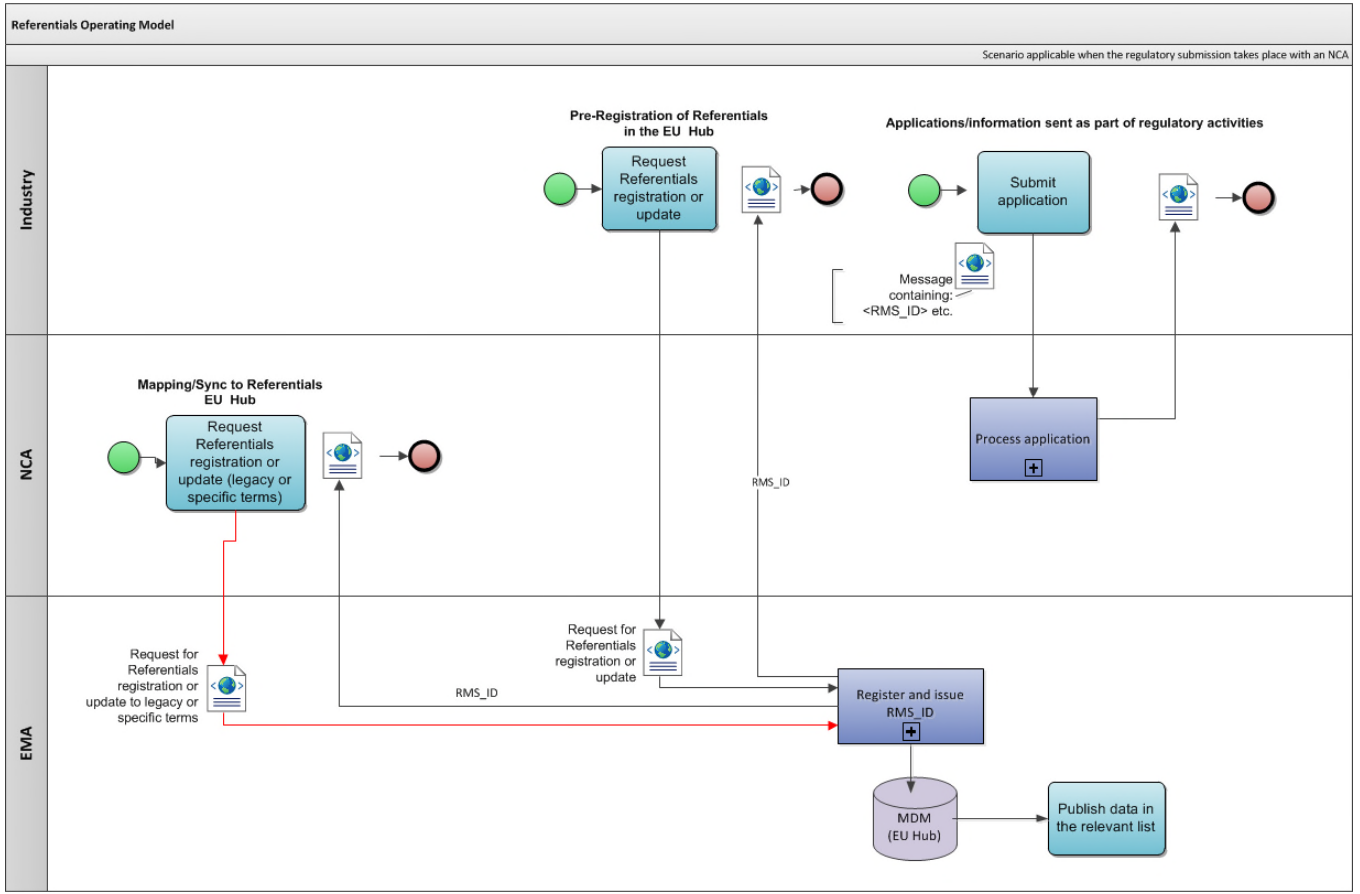
Operating Model



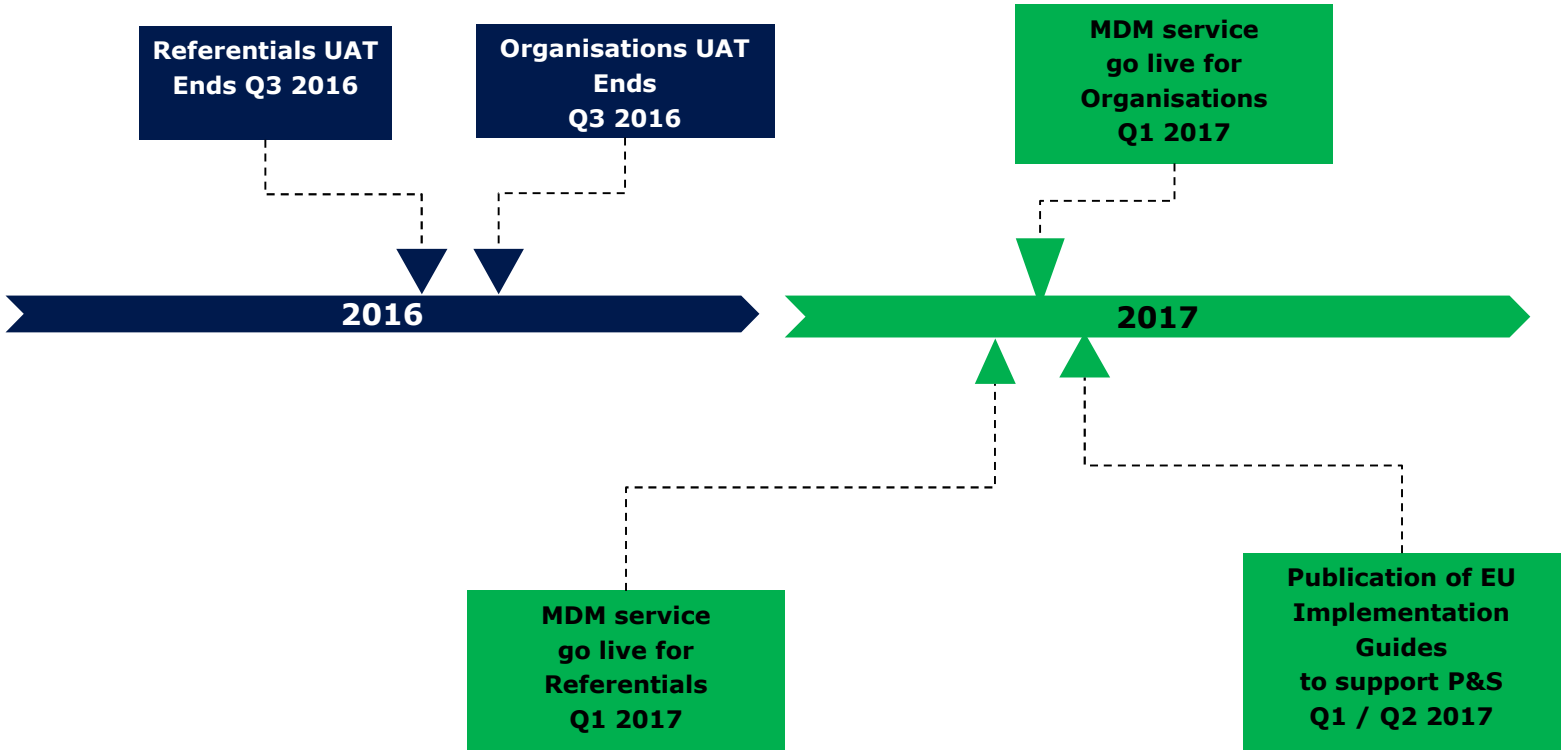
RMS Operating Model

- 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

Terminology Process



Referential Implementation



Thank you for your attention

Further information

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