Referentials Management Services (RMS)

Status update – EU Network Data Board / SPOR Task Force (29, 30 June – 1 July 2016)

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Business Lead for RMS

Status Update

What has been done since last TF

RMS subgroup work

- **RMS SG TCs:**
  - 22 March 2016: **management of standard terms requests**
  - 20 April 2016: RMS implementation + **CVs for OMS** + CVs from the 80 elements for PMS iteration 1 (**Material**) + management of standard terms requests
  - 31 May 2016: ATC-like codes/national classification systems
  - 15 June 2016: **ATC-like codes**/national classification systems

- **Ad hoc Webinars:**
  - 30 November & 16 December 2015: Translations
  - 13 January 2016: Change requests
  - 10 February 2016: Subscriptions, User preferences, Tags, Search and Saved queries
  - 09 March 2016: **RMS API** - intro
  - 15 March 2016: OID
  - 17 March 2016: **UAT**
  - 06 April 2016: RMS API – details

Ad hoc Webinars

- **API specification, messaging format and schema**
  - Introduction to the API specification document (06 April 2016)
  - Review of specification document complete (comments by 20 May)

- **RMS web portal screen mock-up sessions**
  - Sessions since 2015 and into early 2016.
  - Functionality: Browse, Search, downloads, change request, translations, subscriptions, tags, user preferences
  - Based on system use cases already signed off
  - User registration part not covered

Joint RMS & OMS subgroup work

- **CVs for OMS**
  - 5 new lists requested to be created in RMS (Party Category, Party Category Type, Title, OMS Request Reason and OMS Request Rejection Reason)
  - 3 existing EUTCT lists (Country, Language and Source of Information) – already migrated to RMS
  - Definition of each list to be provided in the future (documentation to be generated)
- **Preparation work for the UAT**
  - Over 100 testers nominated for each of RMS and OMS UATs
  - All stakeholder groups are represented
  - UAT delayed to Q4 2016 due to RMS/OMS project replanning
  - On-boarding of UAT Testers webinar booked for **19 July**
  - UAT plan and test cases already drafted pending their review after 19 July webinar

Joint RMS & S/PMS subgroup work

- **Review of CV Q&A**
  - Review of the Q&A for the CVs in the 80 elements required for PMS iteration 1
  - Identified need for 3 new lists: materials, individual roles, organisation roles.
  - Individual roles & Organisation roles: to be defined by regulatory context with PMS implementation
- **Material**
  - simple materials only; no combinations
  - hierarchy of materials catering for both specific and non-specific terms
  - no description needed
  - short names/acronyms needed for searching but will not be preferred name
  - amendments to the list proposed by R Subgroup
  - *on hold, P to clarify the need for materials*

Joint RMS & S/PMS subgroup work

- **ATC like terms**
  - RMS Project is consolidating xEVMPD ATC list with EUTCT WHO ATC Human list
  - xEVMPD codes with status “development” & ”proposed” => provisional in RMS (public!)
  - xEVMPD codes “Not assigned” & “Not applicable” => no CV, will become null flavour
  - WHO ATC Herbal codes => very few may be needed (doubtful business case): option to include required ATC herbal codes in national classification list to be explored.
  - ATC-like codes => 2 options:
    1. separate flat list containing everything ≠ WHO ATC Human codes (if business case justified)
    2. No list maintained (i.e. applicants to choose null flavour “not applicable” or similar)

RMS and EDQM

- **Policy discussion**
  - EDQM and RMS lists serve similar but nonetheless different use cases. Although the lists will be vastly overlapping some differences are accepted:

EDQM	EMA
• **Purpose:** supports regulatory use cases (mostly Marketing application process but possibly also CT and PhVig) • **Pending:** *normally* only publishes terms if/once approved • **Rejected:** does not publish all rejected terms only relevant examples • **Deprecated:** only deprecates terms which were ST, does not consider legacy terms which may have been used in approved products if they were never ST	• **Purpose:** support all use cases, regulatory or other (prescription, data management/application integration) • **Provisional:** publishes all terms while they are still being accessed • **Nullified:** publishes all terms regardless of outcome which includes rejected/nullified terms • **Non-Current:** considers any term that may have ever been used in approved products regardless of being ST (contains EDQM term ID and source of information) or not (does not refer to EDQM term ID)
• **"Clean" list of recommended terms**	• **Comprehensive collection of terms used/required**

RMS and EDQM

- **Use case discussion**
  - The differences across the lists will be dealt as follows:

EMA	EDQM	EMA
Invalidate change request (CR) (no terms created) e.g. incomplete details; **synonyms**	NA	NA
Validate CR & Create Provisional term	Approve CR & Publish ST	Approve CR Update term status to Current Update term details with EDQM file
	Reject CR & Publish rejected ST	Reject CR Update terms status to Nullified Update term details with EDQM file
	Reject CR & Not Publish rejected ST	Reject CR Update term status to Nullified (irrelevant example) OR Update term status to Non-current (legacy term)

RMS and EDQM

- **Use case discussion**

  EMA and EDQM have agreed on:

  - the process to guarantee matching of terms/requests: EDQM will include the RMS term ID in their API
  - dealing with multiple requests for the same/similar term: one change request which is updated to reference subsequent requests and only one outcome
  - how specific EUTCT/EV terms will be included in ST i.e. how to cope with multiple requests at one time and limited product details: working through excel
  - how to process requests when the term is created in one list (e.g. dosage forms) but approved in another (e.g. combined terms): nullify initial term and create a new one in the final list

RMS and Bfarm

- **Interim maintenance by EMA**
  - In July 2015 EUNDB decided that Bfarm is the EU maintenance organisation for the Units of Measurement (UoM)
  - By April 2016 RMS design stage should have been complete and Bfarm was not yet ready to become the list owner

    ➢EMA will go live with our data model and we will be "interim" maintenance organisation for UoM

    ➢We don't replace the decision of July 2015 and BfArM will be the "maintenance organisation" in future.

    ➢BfArM will take the time and necessary actions to "align" with our requirements

    ➢Once they are ready, we need to start a new project to implement the TOM with BfArM in accordance with our requirements.

RMS & WHO

- **Common understanding – ATC H & V**

  Users of RMS can:

  - browse the ATC list in a flat structure but not more than 100 terms are available per page so that the full list is never displayed in its entirety;
  - browse the ATC list in a hierarchical structure. They may be able to expand several nodes of the hierarchy but only one active path at a time i.e. for ATC list maximum of 5 nodes are expanded.
  - perform searches using the ATC hierarchy or using one or more individual ATC terms. ATC terms (the text and code) can be provided as a result of a query and can be viewed on screen, printed, or exported in electronic form.
  - NCA users may be able to export the ATC list from RMS in CSV and XML format (RMS format, common format across all lists) or access it via the API. All of ATC data will be made available.
  - Industry and public users will not be able to export/download the ATC list from RMS

RMS & WHO

- **Common understanding**
  - Managing Change requests: Industry needs to request new/updated terms to WHO and to EMA
    - EMA will receive yearly updates but WHO also publishes temporary codes on their website
    - WHO have no automated mechanism to inform users/EMA of changes apart from yearly update so EMA needs to be prompted upon request

WHO	EMA
Term is NOT in "New ATC codes and alterations"	& the company has only has a proof of submission => Invalidate change request (CR) (no terms created)
	& the company has confirmation in writing from WHO with an ATC code proposal => Validate CR & Create Provisional term
Term is in "New ATC codes and alterations" as temporary	Validate CR & Create Provisional term
Term is in "New ATC codes and alterations" as final	Validate CR & Create Provisional term Then Approve CR & Update term status to Current

RMS & WHO

- **Common understanding**
  - Maintenance process:
    - The term remains as provisional until such point in time where EMA receives the annual WHO ATC excel update. If term is provisional in RMS and
      - is published as final on WHO file => EMA updates it to Current
      - WHO assigns a different term as final=> EMA updates the provisional term to Nullified (and creates the final ATC code as Current if new)
  - Translations:
    - EMA will purchase the ATC Index in English, Spanish (and Norwegian?) from WHO.
    - EMA may collect other translations as provided by the NCAS/Other government bodies and include them in the same list.

RMS Operating Model particularities

	RMS All these lists will be held in RMS				
	RMS/EUTCT	**EDQM**	**Bfarm/ UCUM***	**WHO**	**MSSO**
	- Country/Language - Target species, Vet lists - EudraCT lists, TIGes lists, etc - VedDRA	- Dosage Forms - Routes of Administration - Containers/packaging - Units of Presentation	- Units of measurement * Done by EMA in the first phase	- ATC Human - ATC Vet - INN	- MedDRA
RMS business process	**Lists in RMS to which stakeholders have access**				
NCAs					
Download/access lists via RMS	Yes	Yes	Yes	**Yes**	Yes
Requests changes to lists/terms via RMS	Yes Mostly for legacy Unlikely in other cases, Industry should have done it in advance	Yes Mostly for legacy Unlikely in other cases, Industry should have done it in advance	Yes Mostly for legacy Unlikely in other cases, Industry should have done it in advance	**Request to WHO first and then to EMA**	No, request to MSSO Only available in EMA via updates from MSO
Add/amend translations via RMS	Yes	No, through EDQM only	Yes	**Yes**	No
Industry					
Download/access lists via RMS	Yes	Yes	Yes	No Browse only Access through WHO	No Browse only Access through MSSO
Requests changes to lists/terms via RMS	Yes	Yes	Yes	**Request to WHO first and then to EMA**	No, request to MSSO Only available in EMA via updates from MSO
Add/amend translations via RMS	No	No	No	No	No

RMS project work

- Design work complete: Logical data model, detailed requirements, business process and all system use cases (release 1 and 2)
- **Release 1 go live 15 June!**
  - foundation infrastructure for the delivery of SPOR services: master data, data quality, workflow, services and webportal
  - Data: migrated some of the data from EUTCT; changed some key EUTCT lists significantly to make their structure ISO compliant as per ISO 11239 (Dosage forms, Routes of administration, packaging) and ISO 11240 (units of measurement)
  - Functionality: list publication (& internal data management) - We will start managing future OMS lists in production shortly
  - Web portal (UI) & corresponding API: limited functionality; mostly restricted to browsing lists/terms.
- Release 2 underway
  - MDM tools configuration and system testing under way
  - RMS solution training material drafting in progress

RMS network engagement activities

- **NCAS**
  - NCAs have been requested to start mapping of Dosage Forms, Routes of Administration and Packaging
  - EMA has hosted dedicated mapping webinar to support them
- **Industry**
  - No mapping required at the moment
  - The focus is on establishing Change Liaison network
- **Vets**
  - Engagement recently started and activity plan still to be agreed

Next steps

Presented by: Kepa Amutxastegi/Ana Cochino

RMS subgroup work

- **API specification, messaging format and schema**
  - Approved API specifications expected by June

- **RMS web portal screen mock-up session**
  - Demo of release 1 and run through of system mock-ups for release 2 functionality planned for July

- **Discussions/further analysis:**
  - Creating the user population for go-live
  - UAT planning and execution
  - User guides & training material
  - etc

Joint RMS & S/PMS subgroup work

- **Material**
  - P to clarify the need for materials vs substance list

- **ATC like terms**
  - ATC-like codes => 2 options:
    1. separate flat list containing everything ≠ WHO ATC Human codes (if business case justified)
    2. No list maintained (i.e. applicants to choose null flavour "not applicable" or similar).

RMS & Maintenance Organisations

- **EDQM**
  - Non-EU terms available in EDQM mappings and whether they are needed in RMS
  - How RMS will deal with EDQM mappings
  - When a term is validly constructed but not applicable to the product in question
- **Bfarm**
  - Whether Bfarm can support EMA with change requests in the interim
- **WHO**
  - WHO will discuss and decide if they want to receive/adopt translations provided by NCAs
- **MSSO**
  - Review how MedDRA can be used in the context of RMS
- **Kew Gardens**
  - Initiate possible engagement to support SMS

RMS project

- **Preparation for the UAT**
  - Set up of the SPOR Web portal UAT environment
  - Set up of MDM tools UAT environment (change request management)
  - Preparation of test data for the UAT

- **Provide required support for UAT execution**
  - Ensure testers can perform all test cases
  - Collect all the test results
  - Fix all the blocking, critical or major defects

- **Prepare for go-live release - TBD**

Thank you