Organisations Management Services (OMS)

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

Presented by: Kepa Amutxastegi

Project Manager for OMS

1. Status update

2. Product data comparison in Art. 57

3. OMS next steps

4. OMS data release plan

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

Status update – OMS subgroup work

- **Review of the list of business scenarios and impact on Org_ID and Org_Loc_ID in OMS**

  - ➢ Business rules regarding creation of IDs and versioning of existing IDs

  - ➢ Mergers and splits

  - ➢ Same business rules will be applied for data loads from existing systems and for change requests

- **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)

Status update – OMS subgroup work

- **Proposal for Change Request supporting documentation requirements drafted**

  ➢ A list of preferred documents depending whether or not the organisation is located in the EEA.

  ➢ For manufacturers, possibility to provide references to EudraGMDP documentation instead of supplying the document (i.e. MIA, WDA, API registration or GxP certificate as applicable)

  ➢ If no documents available, self certifying company headed letter to be sent.

  ➢ Although English is preferred, documentation in other EU languages also possible

- **OMS web portal screen mock-up run through**

  ➢ Functionality: OMS dictionary content search, creation of change requests, viewing organisation/location details and past change requests, export functionality, etc.

  ➢ Based on system uses already signed off

  ➢ User registration part not included in the demo.

Status update – OMS subgroup work

- **API specification & messaging format and schema**

  - Introduction to the API specification document

  - Review of specification document under way (deadline for comments **8 July**)

  - Introduction to the justification for the messaging format

- **Preparation work for the UAT**

  - Over 100 testers nominated for each of RMS and OMS UATs

  - All stakeholder groups are now represented by the nominated testers

  - 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

Status update – OMS solutions

All system use cases, Logical data model, detailed requirements and process model signed off

MDM tools configuration and system testing under way

OMS web portal build in progress

OMS web portal user guide drafting in progress

OMS solution training material drafting in progress

Product data comparison in Art. 57

Presented by: Kepa Amutxastegi/Ana Cochino

Building OMS dictionary content

- 5 different systems will provide organisation data for OMS dictionary at go-live (EudraGMDP, xEVMPD – Art. 57 data, and other 3 EMA corporate systems)

- Art.57 data contains the most complete list of MAHs for Human NAPs and CAPs

- MAHs will be the main content of the dictionary at go-live (H+V for CAPs and H for NAPs)

- The scope of data mapping for the initial content of the dictionary is to ensure the completeness regarding MAHs only (xEVMPD also stores Sponsors which will be published in OMS at a later stage)

- EMA propose to use existing Art.57 data maintenance activities to support the data mapping

Art 57 data for OMS implementation

Building & maintaining MAH data:
- Steps to compile data in OMS:
  - One-off data load of organisation data from Art.57 into OMS (via so called *Initial Load*)
  - Any subsequent changes to Organisation data in Art.57 will be reflected in OMS (via so called *Delta Load*)
- For business continuity, the MAH data in the xEVMPD/Art.57 will be kept up to date until PMS is fully implemented, according to the current procedure for submitting Art. 57 data.

Do not map against EV_Codes (MAHs) in xEVMPD/Art. 57:
MAHs data will be subject to considerable changes during the initial load onto OMS (e.g. merging of EV_codes into one OMS ID)
- In order to **avoid mapping twice** (against EV_codes prior to go-live and against OMS IDs after go-live) and having to maintain these mappings
- Wait until EMA communicates about the release of the OMS dictionary content before any mapping against organisation IDs

EMA recommendation
- EMA to undertake mapping of NCA product data against Art.57/xEVMPD via **product data comparison exercise** (see following slides for the process)

Objectives of product data comparison exercise

The comparison of the Art.57 database against national databases aims to:

1. Evaluate and improve compliance of MAHs in submitting medicinal product data (under the Article.57 legal requirements)

2. Ensuring completeness of product data in the Art. 57 database, which will enhance the completeness of the list of MAHs in the OMS dictionary at go-live

Product data comparison approach

Recommended Option:
EMA to perform the product data comparison on behalf of NCAs

- This is based on the existing process ie. compliance check exercise run in 2015 (5 NCAs participated, the exercise took 3 months)

- The methodology used for the exercise was amended to optimize the process and reduce the efforts

- This optimized process is now ready for wider use for product data comparison for other NCAs

- Reference slides: 20-24

Alternative Option:
National Competent Authority to perform the comparison themselves

- Resource intensive exercise for NCAs. Different tools and approaches may be used

- NCAs would need to invest time to become familiar with the Art.57 guidance before taking up the activity

- Also resource intensive for EMA

- This option is not recommended

EMA to perform comparison on behalf of NCAs

4 Steps

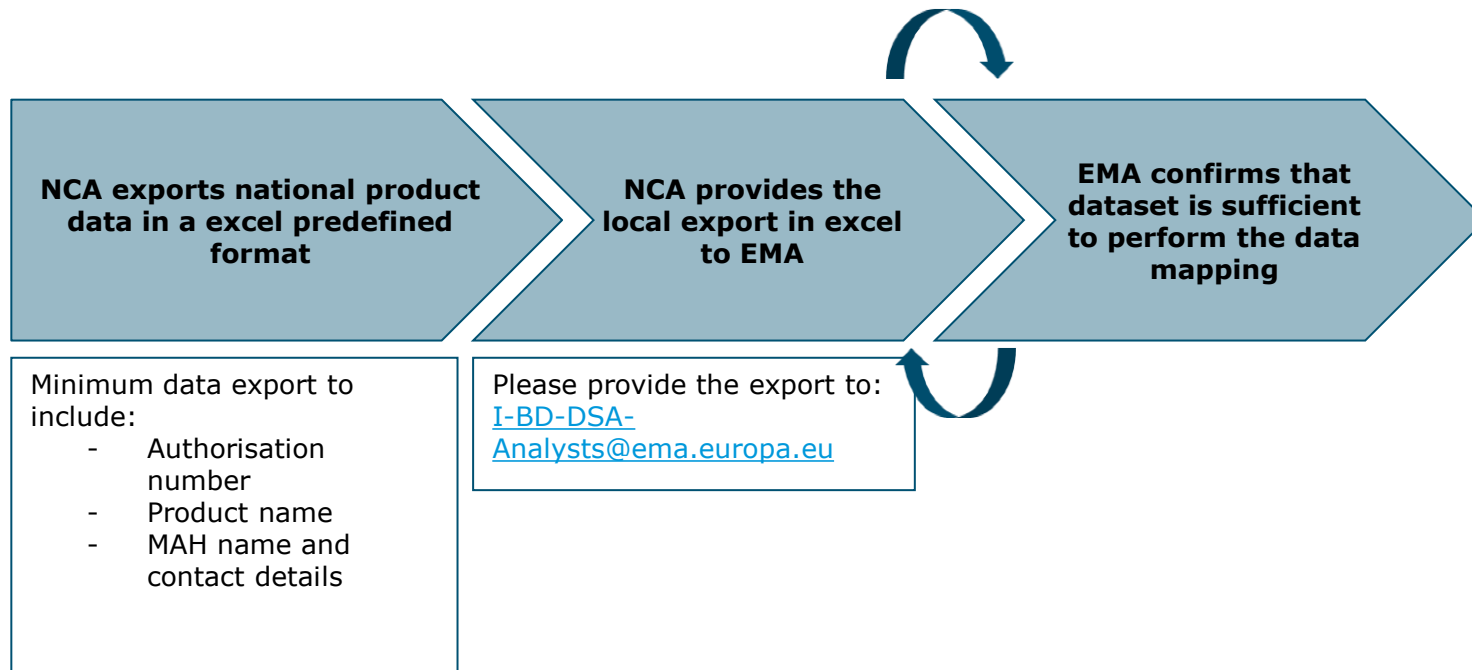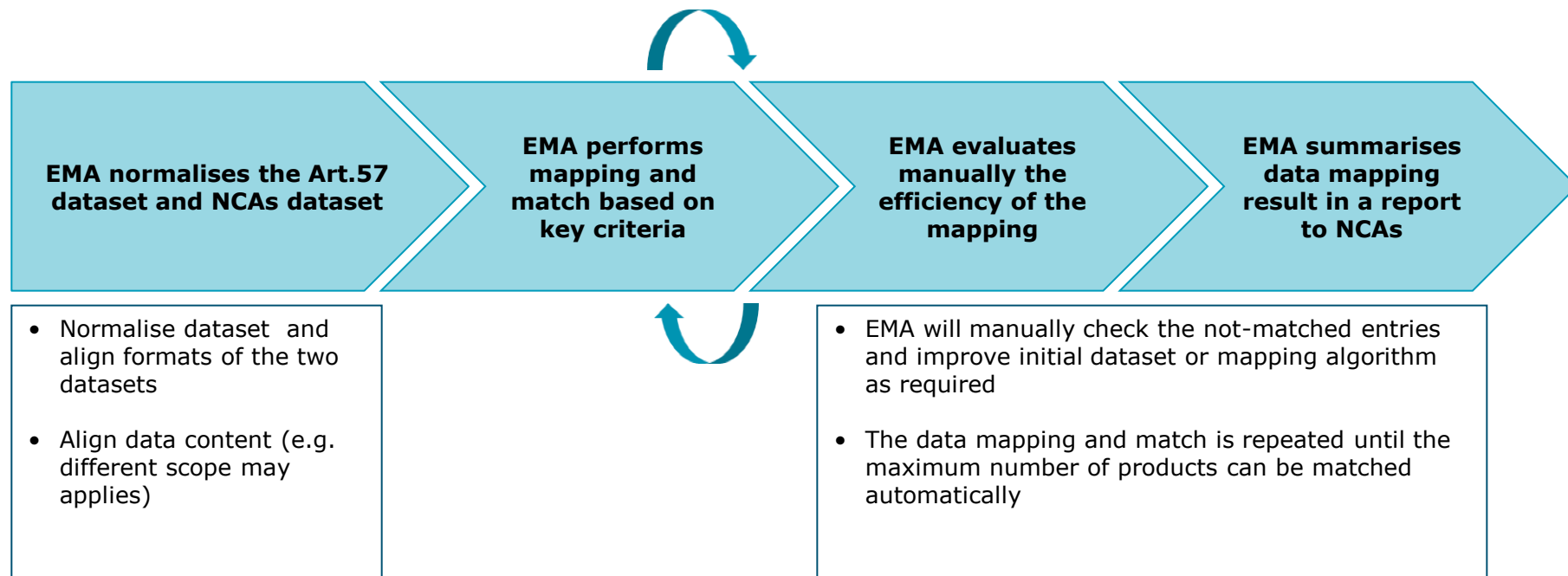| 1. NCA data extraction and provision	2. EMA data Mapping	3. EMA shares results with NCAs	4. EMA contacts industry to submit missing products via Art.57

Estimated that initial outputs can be produced within 2-3 weeks from receiving data export from NCA

Step 1:

1. NCA data extraction and provision

NCA exports national product data in a excel predefined format

NCA provides the local export in excel to EMA

EMA confirms that dataset is sufficient to perform the data mapping

Minimum data export to include:
- Authorisation number
- Product name
- MAH name and contact details

Please provide the export to:
I-BD-DSA-Analysts@ema.europa.eu

Step 2:

2. EMA data Mapping

EMA normalises the Art.57 dataset and NCAs dataset

EMA performs mapping and match based on key criteria

EMA evaluates manually the efficiency of the mapping

EMA summarises data mapping result in a report to NCAs

- Normalise dataset and align formats of the two datasets

- Align data content (e.g. different scope may applies)

- EMA will manually check the not-matched entries and improve initial dataset or mapping algorithm as required

- The data mapping and match is repeated until the maximum number of products can be matched automatically

Step 3:

3. EMA shares results with NCAs

EMA provides the mapping results to the individual NCA in a report

EMA calculates the overall estimation of the Art.57 compliance rate

EMA gathers all information on missing organisation in Art.57 database and in future OMS

Report will include information on:

•Alignment between definition of "product" between the two databases
•Rate/Number of products available in both databases
•Rate/Number of products only available in NCAs database and missing in the Article 57 database
•Individualised feedback on data similarities and differences
•Best practice identified in each particular mapping exercise

EMA includes the individual results into the overall comparison and statistically infers the overall Art.57 compliancy rate taking into consideration the proportion in the entire database

MAHs with missing products will be contacted to increase completeness of database

Step 4:

4. EMA contacts industry to submit missing products via Art. 57

EMA contacts MAHs to submit data

MAHs submit data through Art.57 process

MAH name and contact details are important to be included in data export so that EMA can contact MAHs

Summary of the proposed recommendations

Key:
Industry activity | EMA activity | NCA activity

NCAs

- **Do not map against EV_Codes (MAHs) in xEVMPD/Art. 57**

- EMA will undertake mapping of NCA product data against Art.57/xEVMPD via product data comparison exercise (described earlier)

- Wait until EMA communicates about the release of the OMS dictionary content before any mapping against organisation IDs

Industry (MAHs/Sponsors)

- As part of the data comparison exercise in the art Art.57 database, EMA may contact industry requesting submission of the missing product data

- Meanwhile continue submitting Art.57 data as per current procedures and requirements

- Wait until EMA communicates the release of the OMS dictionary content before any mapping against organisation IDs

OMS next Steps

Presented by: Kepa Amutxastegi

Next Steps – OMS subgroup activities

- **Finalise and sign off:**

  ➢ API specification and messaging format & schema

  ➢ Change request documentation requirements

  ➢ Fine tune the maintenance process for dictionary content until it is integrated with other telematics solutions e.g. CESSP, CT portal, PMS solution, etc.

  ➢ CVs for OMS

  ➢ UAT planning and execution

- **Discussions/further analysis:**

  ➢ Creating the user population for go-live

  ➢ Detailed Telematics multi programme mapping against SPOR

  ➢ Planning data mapping against OMS dictionary content after go-live

  ➢ Feedback from Manufacturers survey

  ➢ …etc.

Next Steps – OMS project activities

- **Release of the MDM EMA internal solution**

  - Data loaded from 5 different systems (includ. xEVMPD and EudraGMDP)

  - Data cleansing, standardisation and consolidation for its publication in the dictionary

- **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**

Organisations data release plan

Organisations data release plan

EMA will issue advance communications to notify all stakeholders that new data is being published on OMS and that Change Requests for that data can be submitted now that it has been published on OMS (not before).
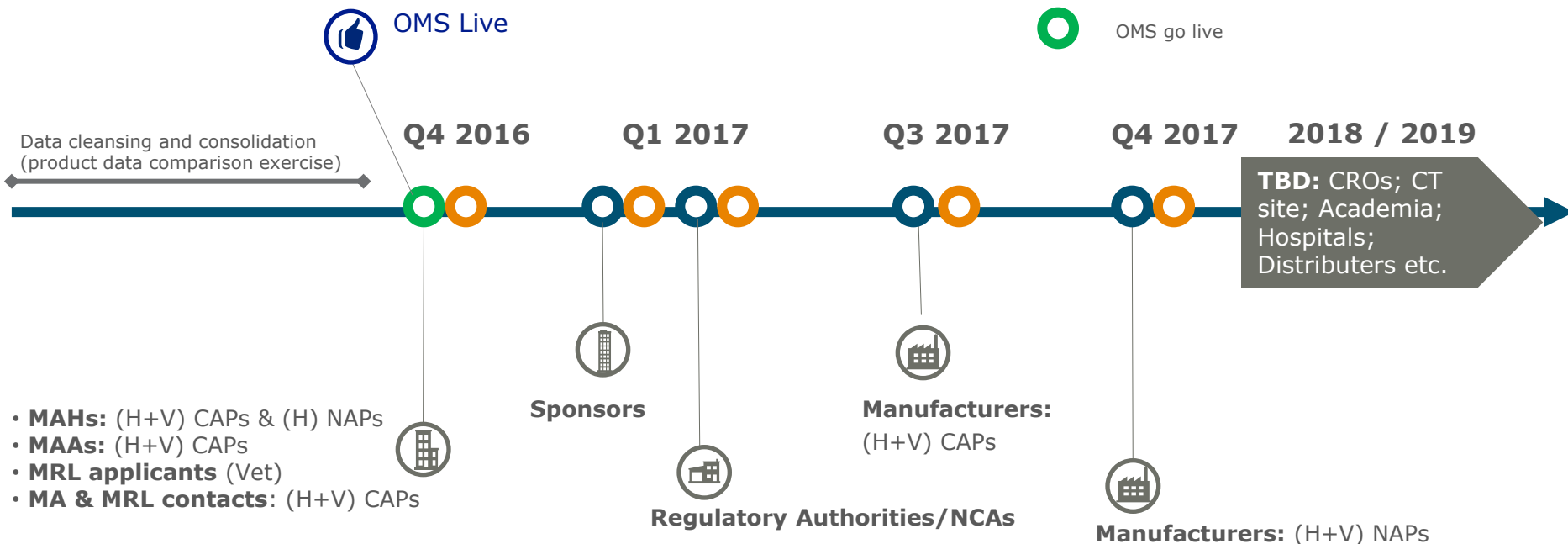
Key

- ○ Points at which new organisation data is published in OMS
- ○ Industry should only start submitting Change Requests for Organisations once the data is published in OMS – not before.
- ○ OMS go live

OMS Live

Data cleansing and consolidation (product data comparison exercise)

Q4 2016   **Q1 2017**   **Q3 2017**   **Q4 2017**   **2018 / 2019**

TBD: CROs; CT site; Academia; Hospitals; Distributers etc.

Sponsors

Manufacturers: (H+V) CAPs

- **MAHs:** (H+V) CAPs & (H) NAPs
- **MAAs:** (H+V) CAPs
- **MRL applicants** (Vet)
- **MA & MRL contacts**: (H+V) CAPs

Regulatory Authorities/NCAs

Manufacturers: (H+V) NAPs

NOTE: In OMS, please note that organisations will not be differentiated in terms of whether they are for Human, Vet or both

Thank you