Industry Point for Discussion

1. OMS / RMS Industry Implementation Progress & Next Steps
2. Industry Update
3. Key Risks and Mitigations – an industry perspective
4. Proposals for success

NOTE: This material reflects representation from industry and from vendors across the SPOR Task Force and PMS/SMS members

Current Assumptions : Mandating RMS and OMS (MAH)

RMS

- Q3 Use of RMS for requesting new / updated terms will be mandated as of July 2018

OMS

- Q1 2018 – As of Jan 2018 OMS data updated based upon latest changes in xEVMPD
- Q1/Q2 2018 – Add Manufacturing Organisations (H&V) CAPs and Sponsor Orgs (H) CAPS and NAPS
- Q3-Q4 2018 – Plan to mandate the use of OMS (MAH) in eAF (aligned to CESSP MA go-live)

OMS/RMS - Strategic questions for Task Force

- Value in Industry /NCA / EMA Advisory Board to aid adoption and for future requirements?
- With the OMS/RMS Platform in “Business as Usual” we need a means to progress ‘New requirements,’ ‘Bug Fixes’ and ‘Future Road Map’ (e.g. external verification with GS1, D&B)?
- Is it possible to have a full learning review based upon OMS/RMS implementation experience to date prior to mandating data: with view to review current opportunities / challenges.
  - Can Industry /NCA/ EMA review OMS/RMS implementation and provide recommendations for improvement?
  - Agree and approve when OMS MAH data will be mandated.
- With OMS Phase II (Manufacturers Data) being more challenging around ‘Data Ownership’ can Industry recommended approaches to address
  - Based upon the learning from MAH / NCA OMS implementation can improvements be made recommended for Manufacturers Data?
  - Agree and approve when OMS Manufacturers data will be mandated

Industry SPOR Update

- Industry engagement in IDMP is steady
  - More companies desire to fill gaps in sub groups
  - Companies typically focused on IDMP use first and SPOR second
- Risks to adopting the core of IDMP are assessed as high by industry
- Industry desire to engage more in creation of work products
- Key risks perceived as being largely outside of industry control
- Contingency or alternatives to mitigate key risks are unclear to industry

Key SMS/PMS Risks & Mitigations

Risk: A lack of strong sponsorship of EU SRS and the SVG from across the network results in continued duplication of effort and inconsistency in substance identification putting at risk a number of key use cases for IDMP

Mitigations:

- Focus on pharmacovigilance use cases, within and beyond EU
- Position SMS NOT as IDMP Lite but as a stepping stone
- Emphasis significant reuse of technology

Questions: How are NCAs and EMA rating this risk?

What mitigations or contingencies are we missing?

Key SMS/PMS Risks & Mitigations

Risk: A funding gap for ‘CESSP’ would leave the SPOR program without a means of integrating SPOR data in the submission and assessment process, resulting in same behaviours we have with XEVMPD

Mitigation:

- Articulate the risk of not taking action, impact effects trust in data
- Partner across the PMS group to define critical requirements

Questions: How are NCAs and EMA rating this risk?

What mitigations or contingencies are we missing?

Proposal for Success

- Stay intentional about sequencing SPOR, building maturity
  - R -> O -> S -> P
  - Reflect with priorities and resources
  - Be intentional in brining S and P together when needed
- Industry priority to be ‘in’ the data
  - Build out the data pilot (S&P) as a collaborative pilot
  - Address a mix of substance types alongside the ‘P’ data
  - Have industry populate and assessor validate
- Increase access to working materials for direct industry contribution
  - Migration mapping to avoid issues experienced at OMS go-live
  - List of data elements, also grasp what this means and what is expected

Supporting Material Follows

List of topics for continued implementation of OMS

IRIS Survey (30 Jan – 16 Feb 2018 – n =17) Analysis and Conclusions

- There are still some issues encountered with the SPOR website. Mainly by Internet Explorer users.
- Industry foresees the same issues Andrew Marr has raised in his document.
- The majority of the industry has or will request super user rights. The process is experienced as a burden, withholding some organisations from doing so for their (future) organisations in OMS.
    - 40% stated they may not as they do not know if needed: rational maturing process or unclear need.
- Industry has a mixed approach regarding the submission of power of attorney letters. For those who will submit power of attorney letters, most will do this on a periodical basis.
- Industry is holding back from submitting manufacturing organisations in OMS until further notice of the EMA. A large part of the industry will not consider requesting additions of 3rd party organisations
- 18% does not want to rely on the 3rd party organisations and will do it themselves.
- Industry has concerns regarding the use of OMS in the eAF. Data quality in OMS cannot be guaranteed yet as clean up process is still taking place.

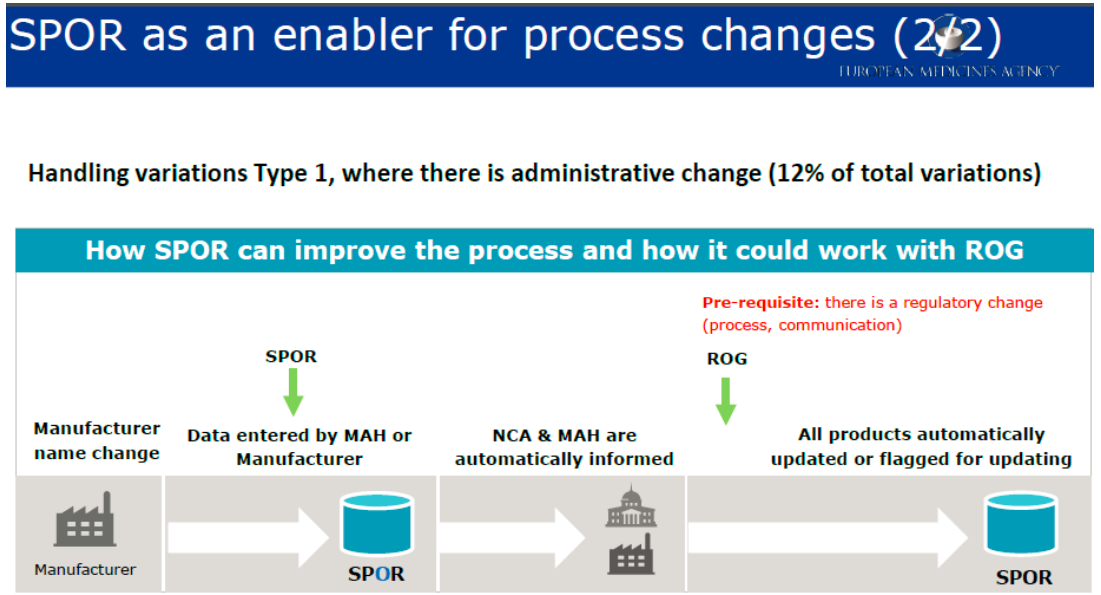
OMS roll-out: findings with MAHs

- Data quality issues
  - Duplicated locations
  - Typos in location addresses
  - Locations to be ‘de-activated’
  - Request to delete the enrichment from Address Doctor (AD)
  - Organisations temporarily disappeared from OMS
- Limitations in functionalities
  - Request status ‘approved’ without changes made in OMS
  - OMS changes made without mail information sent to the requestor
  - History of changes not implemented for Industry
  - Are subscriptions available to be informed about changes?
  - Additional organisations to be entered in OMS (timetable?)
  - Error message with new request: ‘Request could not be processed without giving a reason’ despite correct entries

	Generic (Major)	Pharma (Major)
Total number of MAH (ORG_LOC)	62	49
Major issues (missing LOC, mistake in address, duplicates)	12 (19%)	29 (59%)
Minor issues (typos, etc)	42 (67%)	19 (39%)
Confirmed, correct	18 (29%)	9 (18%)

Discussions Required: How to get Manufacturers update their data in OMS ?

- Manufacturers to register as SPOR Users to proceed with Change requests (CRs)
- This would reduce EMA workload due to similar CRs started by multiple entities (MAHs) although there can be only one CR per Location ID at the same time



OMS roll-out: findings with Medicines Regulatory Agency (MRA)

- It is assumed that OMS data for MRAs are entered in OMS
- Searching by selecting the records where “Category Classification Category Display Name” contains ‘Regulatory Authority’ value will not provide an exhaustive list
- Can EMA indicate which categories are relevant to retrieve MRAs
  - Regulatory Authority
  - EEA National Competent authority
  - Non EU Institution/Body/Agency
  - EU Institution/Body/Agency
  - Non-Pharmaceutical company
  - Health care

OMS impact on the eAF/CESSP

- Contact details for Applicant/MAH not available from OMS therefore to be entered manually on the eAF
- Will contact details for Manufacturers be populated in OMS and generated in CESSP?
- All types of Organisations including Manufacturers to be entered in OMS for CESSP
- A transition period of at least 6 months should be foreseen

OMS Future Plans – Manufacturers (EudraGMPD)

EudraGMPD information (GMPs, MAs) for Manufacturers data in OMS

- Data completeness
  - Information about Manufacturers data completion progress in OMS critical for Industry to start mapping activities
  - Facilitate searches by generating the relevant “Category Classification Category Display Name” (e.g. having ‘Industry¦Pharmaceutical company’ will be difficult)
- Data verification/update
  - Industry to start submitting Change requests before end Q3 2018 to avoid a flow of CRs remaining ‘dormant’ due to EMA relocation
- Lack of robust process for EudraGMDP data
  - Lengthy process, NCA dependent
  - Incomplete database triggering need for MAHs to contact Manufacturers/CMOs directly to get current documents
  - Contain expired and valid documents
  - After release of a new MIA/GMPc, the correspondent database update is often consistently delayed

Appendix

Issues raised by Andrew Marr in his document

- Since there is no Role assigned to an organisation in OMS, they are simply a legal entity with a name and address, EMA may have no way of differentiating between an MAH which needs to be added and a Manufacturer that should not be added at this stage. It is of course possible that the name of the organisation included Manufacturing e.g. Pharmaco Manufacturing Ltd.

- Also, from the explanations given regarding assignment of SuperUsers it will be key that the Organisation ID is provided in the Power of Attorney letter for any organisation to be managed by a specific SuperUser. As currently only MAHs are extensively covered in OMS there may need to be an iterative process of addition of Manufacturers to OMS followed by requests by companies to assign SuperUsers.

- Whilst it is not mandatory to have a SuperUser for each organisation (since any user can submit a Change Request for a new Organisation or change to existing details), I do anticipate companies to do so, for completeness, and to cover all eventualities in future. I believe that companies will want to be able to submit a single of Power of Attorney letter covering all of their organisations rather than to submit multiple letters over time.

- Hence I suspect that a number of companies may choose to submit Manufacturers (and potentially Sponsors) at an early stage so that they are ‘in the system’ and can be covered by a single SuperUser request. This could still inundate EMA with requests to add Manufacturers at a time when they are processing the migration of such organisations as a bulk activity and they may not be able to filter out Manufacturer requests from MAH requests.