HMA
Heads of Medicines Agencies

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Substance and Product (S&P) project(s) and sub-group

Status update for 2016

Presented by: Paolo Alcini

Head of Data Standardisation and Analytics

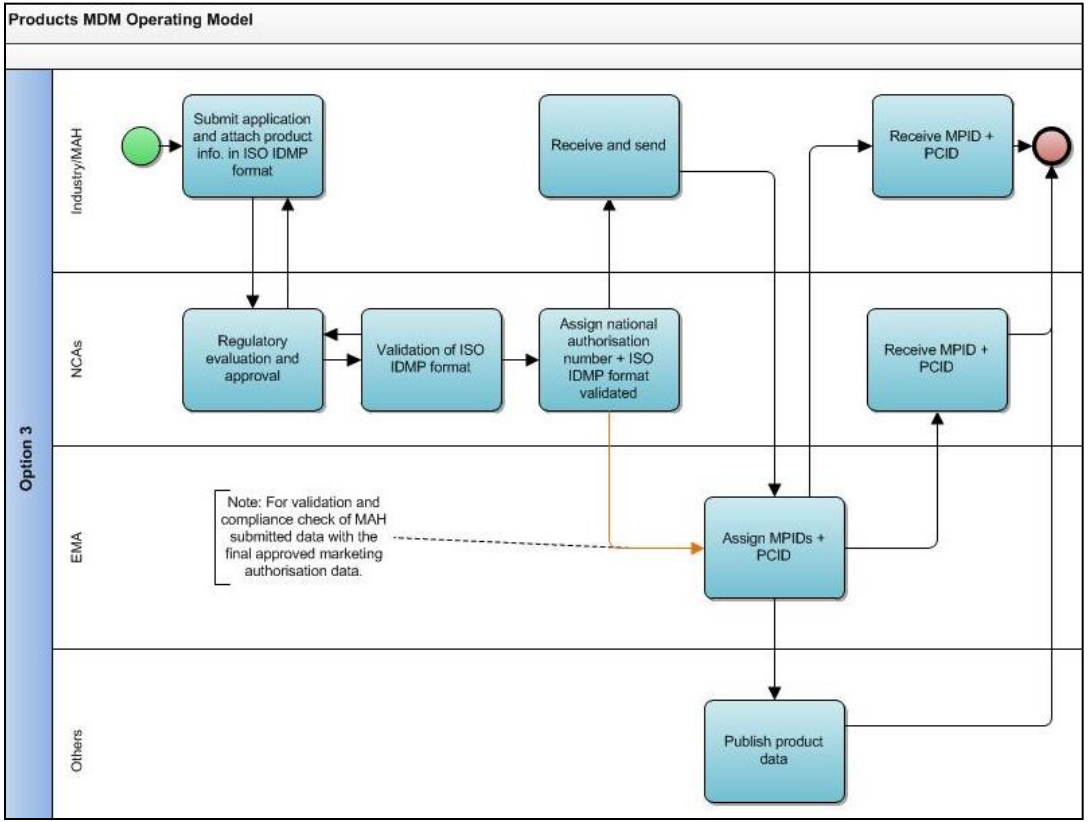
Deliverables

- Review and provide comments on:
  - the target operating model (TOM) for the final ‘TO BE’ solution;
  - the mandatory elements for the implementation of each iteration;
  - the business cases to be supported in each iteration of the S&P implementation and the impacted stakeholders;
- Contribute to the drafting of the EU Implementation Guide (EU IG) for each iteration;
- Contribute to the drafting of the change management process, e.g. transition from XEVPRM submissions to HL7 SPL format.

Achievements to date

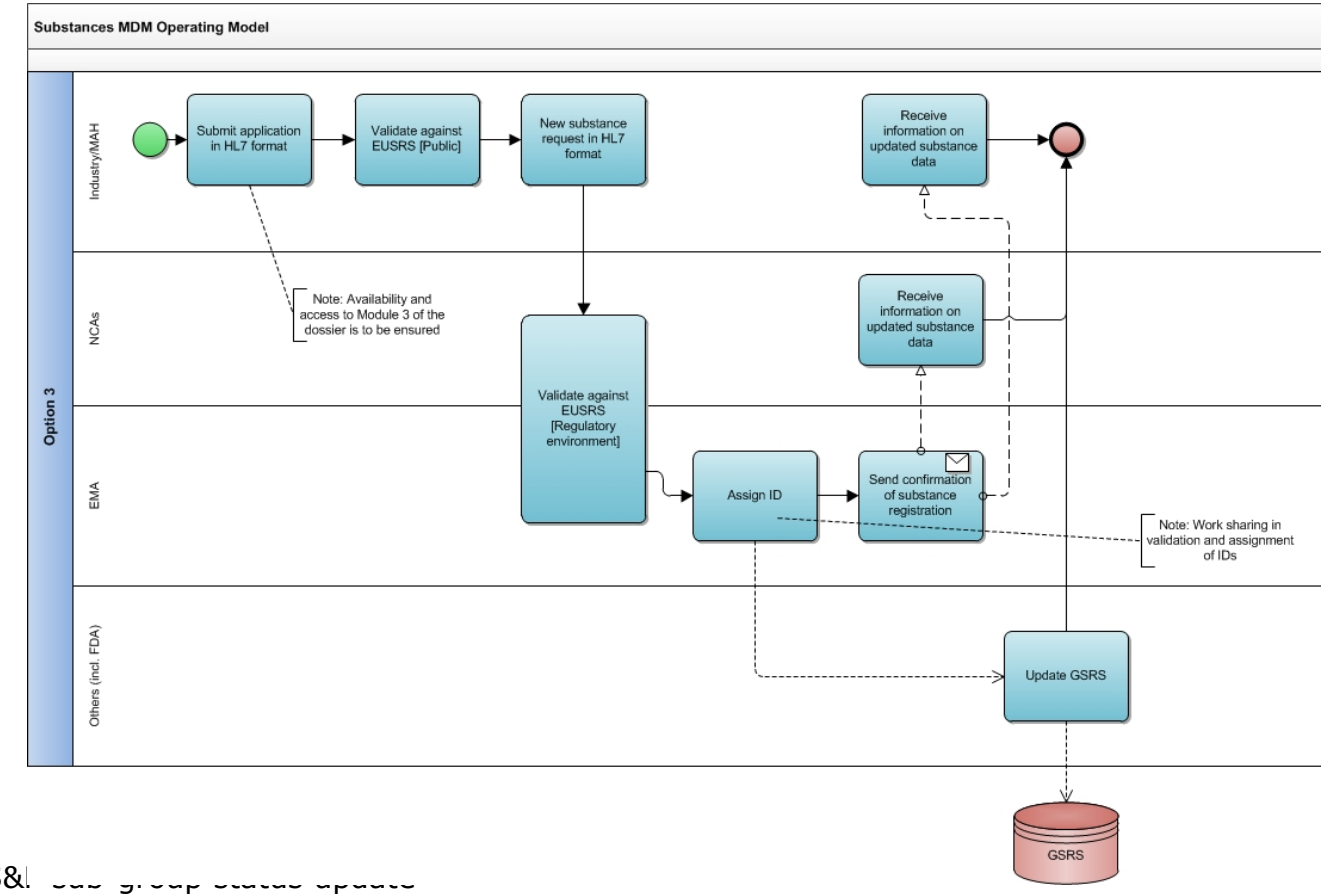
- TOMs for P&S were endorsed by SPOR Task Force two years ago but undergoing review;
- Data elements (80) for Iteration 1 were identified and endorsed by the SPOR Task Force;
- Modular table of content for the EU IG was prepared;
- IDMP workshop was organised in August 2016 to identify business cases to be supported in each iteration of the S&P implementation.

TOM: Product



Under discussion

TOM: Substance



To be reviewed next

TOMs: S&P

- In the context of the product application (i.e. initial MA or post-authorisation activities), the evaluation and validation of the (updated) substance information will be performed by the Substance Advisory Board established by the EU Network and EMA
- The Product Management System will be integrated within the regulatory submission processes as defined in each iteration business cases to enable reduction of codification of product and substance information and re-usability of data across various domains (e.g. from pre to post-authorisation)
- Infrastructures will be made available to NCAs and industry for the exchange and management of medicinal product and substance information

Data elements for Iteration 1

Medicinal Product
MPID
Combined Pharmaceutical Dose Form
IMPID Corss-Reference
Additional monitoring indicator
Orphan Designation Status
Name (Med.Product)
Invented Name Part
Scientific Name Part
Strength Name Part
Pharmaceutical Dose Form Part
Formulation Part
Intended Use Part
Target Population Part
Container or Pack Part
Device Name Part
Trademark or Company Name Part
Time/Period Part
Flavour Part
Classification System
Classification System Value
Version Date
Version Identifier
Document Type
Document Identifier
Regulated Document
Document Effective Date
Country
Language

Marketing Authorisation
Marketing Authorisation Number
Country
Legal Status of Supply
Authorisation Status
Authorisation Status Date
Date of First Authorisation
Procedure Identifier/Number (e.g. MRP number)
Procedure Type (e.g. MRP/DCP)
Country (national authorisation)
Marketing Authorization Number (national authorisation)

Organisation (e.g. MAH, QPPV, PSMFL)
Identifier
Role
Location Address
Location Role
Entity Identifier (according to Role e.g. PSMF ID)

Marketing information
Country
Marketing Status
Marketing Strat Date
Marketing Stop Date
Risk of shortage supply
Risk of shortage supply comment

Indication
Indication Text
Indication as "Disease/ Symptom/ Procedure"
Co-Morbidity
Intended Effect

Pharmaceutical Products
Administrable Dose Form
Unit of Presentation
Route of Administration
PhPID Identifier Sets
Device Type (combined medical device ATMP)
Device Trade Name (combined medical device ATMP)

Ingredient
Ingredient Role
Substance
Specified Substance
Confidentiality Indicator
Strength Range (Presentation)
Strength Range (Concentration)
Reference Strength Substance
Reference Strength Specified Substance
Reference Strength Range

Package description
PCID
Package Description
Package Item (Container) Type
Package Item (Container) Quantity
Material
Component Type
Component Material
Manufactured Dose Form
Unit of Presentation
Manufactured Item Quantity
Device Type
Device Trade Name

EU Implementation Guide

- The EU IG will contain:
  - Process-oriented content for business (to be drafted by industry),
  - Technical and business specifications, including data elements descriptions and business rules (to be drafted by the EMA on the basis of the SPL message);
- The content will be restricted to the data elements defined for Iteration 1 only;
- Examples and diagrams will be included.

S&P group
Revision of membership(1/2)

- Must have experience, background and time to actively contribute to the S&P subgroup
- Preference should be given to Task Force members
- Industry & Interested Parties – Human
  - Task Force members can be nominated up to max 20 participants
    - EU Pharmaceutical Associations can nominate for the S&P group also experts that are not members of the TF
  - Industry/interested parties nominations collected by John K.
  - List agreed and reviewed by Industry TF co-chair & Industry Associations
- Industry & Interested Parties – Vet
  - Ideally composed of volunteers from Veterinary Coordination Group (VCG)
  - Up to max 20 participants
  - *List agreed and reviewed by VCG*
- EMA & NCAs (H&V)
  - Any volunteer
  - No maximum limit of participants
  - *List agreed and reviewed by EUNDB*

Expected commitments & level of engagement

- 2 x 1.5h TC /month; 2d/month effort
- If a member of the S&P subgroup does not participate in the TCs (or face to face meetings) for 3 consecutive times this will be escalated to either Industry TF co-chair & Industry Associations , VCG or EUNDB to discuss the replacement.

S&P group
Revision of membership(2/2)

- All parties are kindly requested to review S&P membership and provide an amended list by end December

Next steps

- S&P project was re-started in November 2016;
- The EU IG framework to be reviewed and finalised; drafting of the individual sections to be allocated the responsible S&P members (i.e. industry/EMA);
- TOMs for P&S is currently under discussion on the SG, it will be reviewed and amended if necessary;
- Technical and business specifications, including data elements descriptions and business rules (to be drafted by the EMA on the basis of the SPL message);
- High-level business processes to be reviewed and amended if necessary; e.g.
  - Change requests by industry -> validation -> approval
  - Degree of structured data provided by industry
  - Handling of translations
  - Match/consolidate sources
  - Synchronisation of data between EMA/NCAs/FDA