EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Heads of Medicines Agencies (HMA) update on Substance, Product, Organisation and Referential (SPOR)

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IDMP/SPOR Task Force – 13 December 2016

Francisco Penaranda
Head of Business Data and Analytics Department

Key messages

- Focus on integration of SPOR with eAF/CESSP
- SPOR has limited benefits alone unless integrated with other systems/processes
- eAF will be the one of the first systems to consume SPOR services (i.e. 2017 RMS and OMS and later PMS and SMS)
- Simplification of variations Type IA requires a joint effort between SPOR and CESSP
- SPOR will require an investment at the beginning but it will give the investments back at the end of the line.
- ROG should facilitate the discussion on legal, fees and resources issues
- Real cases from Austria, Slovakia and Spain were presented on the current use of eAF/CESSP

Discussion (1/2):

- **Question**: Cost savings seems to be small in comparison to this effort
  - **Answer**: Type IA for manufacturers/MAH is a pilot phase and, if successful, it can be extended to other variations. In addition, central SPOR hub and improved data quality may facilitate other business cases (e.g. ePrescription, better PhV, integration of life cycle, shortages, quality defects/recalls, etc)
- **Question**: validation by NCAs will add extra effort and resources
  - **Answer**: Validation will be carried out by NCAs using the current system but IDMP standards. IDMP may facilitate the automatic validation. Training for assessors will be a key deliverable from the SPOR project.

Discussion (2/2):

- **Comment**: A global reliable database is the desired solution
- **Comment (EC):** legislation should not put walls to ongoing projects but firstly it is needed to identify the problems that could stop the regulatory optimisation. Changes in the legislation are possible but slow. Quick wins should be prioritised
- **Comment**: ROG should facilitate the process by prioritising the regulatory optimisation and looking into the procedures and then into the legislation. The concept of the group was adopted by HMA II in Rotterdam in June 2016

Thank you for your attention

European Medicines Agency
30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
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