EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Electronic submission of information on medicinal products in accordance to Article 57(2) requirements: Maintenance submission

SME workshop: Focus on quality for medicines containing chemical entities

4th April 2014

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Outlines

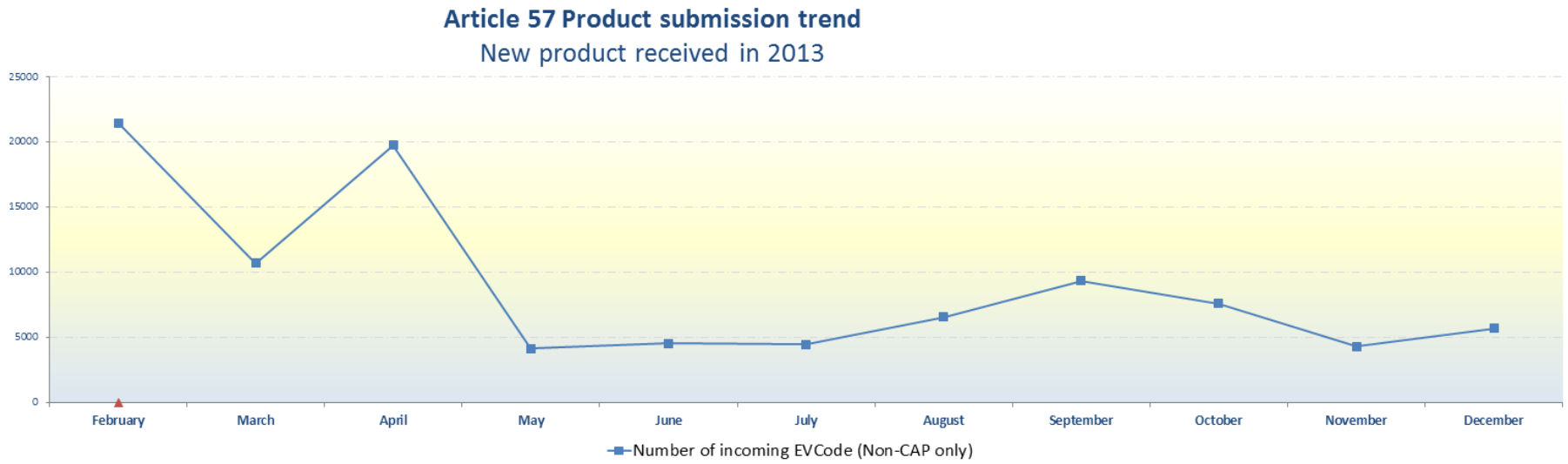
- Article 57 initial submission: status update
- Article 57 Maintenance submission: status update
  - Key objectives
  - Business cases
  - 2014 – 2016 Submission plan
  - Article 57 schema amendments outlines
  - Maintenance submission processes
- Next steps

Article 57(2) of Regulation 726/2004

- Implementation of the electronic submission of information on medicines was the first deliverable of new PV legislation
- Article 57(2) of EC Regulation 726/2004 requires:
  - The Agency to make public a format for the electronic submission of information on medicinal products for human use by 2 July 2011
  - Marketing authorisation holders (MAHs) to submit information to the Agency electronically on all medicinal products for human use authorised in the European Union by 2 July 2012, using this format
  - MAHs to inform the Agency of any new or varied marketing authorisations granted in the EU, using this format

Article 57(2): Initial submission

Total number of medicinal product submissions by MAHs up to 3 Feb 2014	
Total number of medicinal products (based on EudraVigilance codes)	459.290
Total number of marketing authorisation holders (legal entities) established in the EU (corresponding to EudraVigilance codes)	3.996



Article 57(2): Deliverables and next steps

- 4 EMA Art.57 IWG meetings with representatives from industry association since October 2013
- 15th January 2014 EMA and IWG endorsed the:
  - Maintenance submission plan
  - Maintenance business processes
  - Amended Art.57 Schema (XEVPRM format)
- Since 31st January 2014 EMA published the maintenance submission requirements in the form of:
  - Revised Art.57 legal notice and detailed guidance
  - Outlines of the Art.57 Schema changes
  - Revised Art.57 FAQs

Data maintenance submission 2014 - 2016

Key objectives

- Key objectives focused on the collection of **up-to-date, complete** and **improved quality** of Article 57 medicinal product data by end of the 2014
- Thereafter, to maintain information on medicinal product up-to-date in accordance with the regulatory processes (e.g. variations transfer of marketing authorisation)

Article 57 Business Cases 2014 - 2016

Data analysis

- EudraVigilance (EV) data analysis, signal management
- ICSRs reporting and coding of medicinal product and substance information
- Data analytics and business intelligence

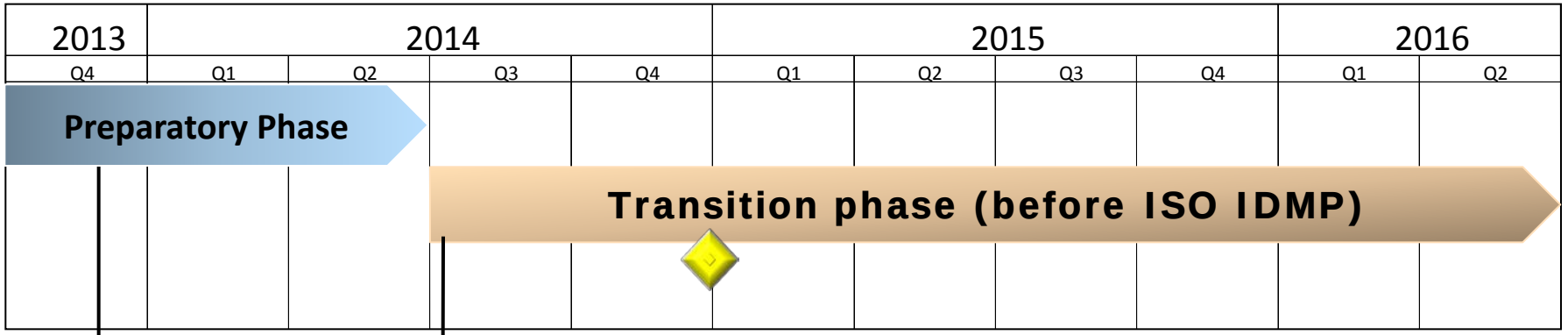
Regulatory actions and legal obligation

- Regulatory action to safeguard public health (e.g. Referrals, PSUR repository, Literature monitoring)
- Support calculation of PhV fee

Communication with stakeholders

- European medicines web portal
- Granting access to EudraVigilance data (proactive and reactive)
- EU/ International data exchange
- Support to PRAC for communication with MAHs

Article 57(2) Submission plan 2014-2016



December 2013 – June 2014

The aim is:

- For the Agency to upgrade the Agency's data entry tool and provide necessary guidance to support the maintenance submission
- For industry to start upgrading in-house IT systems

June 2014 – December 2014

The objective is to enable the MAHs to update, complete, improve the quality and submit the Article 57 data via the simplified process **before the end of 2014**.

From January 2015

MAHs to continue notifying any changes affecting the Article 57 data by means of the simplified process within **30 calendar days** from the date of which the changes have been authorised.

Key principles for preparatory phase

- **Amendments to the XEVPRM format** were necessary to support new legal obligations, nevertheless, the information required for submission has been limited to the following key elements:
  - The details of the legal basis of the marketing authorisation
  - A description of the medicinal product type based on selected criteria
  - Information on the authorised pharmaceutical form and, where applicable, before reconstitution into the 'administered' pharmaceutical form
  - A description of the size of organisation (MAH)
  - Pack size information – deferred until ISO IDMP implementation
- To improve **data consistency and completeness**:
  - New business rules will be implemented
  - The scope and intended use of key Article 57 data will be provided to industry

*Outlines of the schema amendments are available Outlines of amendments to the Extended EudraVigilance Medicinal Product Report Message (XEVPRM) schema and EVWEB Labels

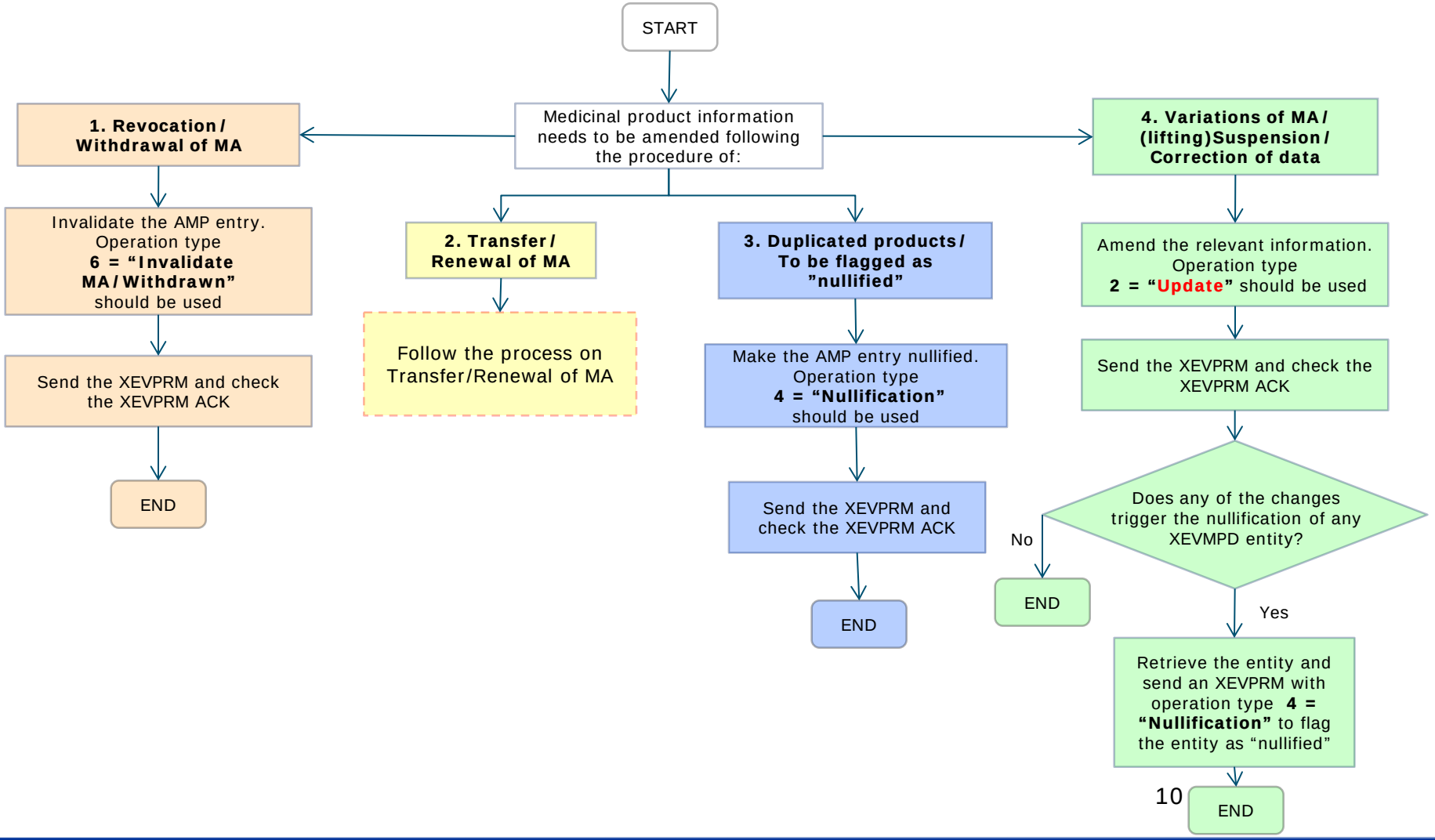
Transition phase business process

(Until ISO IDMP implementation)

1. Change of Qualified Person for Pharmacovigilance information (QPPV)
2. Change of details in the controlled vocabulary maintained by MAH
    a. Pharmacovigilance system master file location (PSMFL)
    b. Organisations (MAHs)
3. Amendments of medicinal product information
4. Transfer/Renewal of Marketing Authorisation
5. Withdrawal, suspension and revocation of Marketing Authorisation

Details of the maintenance business processes are available in the Detailed Guidance Chapter 3.II

Amendments of medicinal product information business process



Next steps (1)

- EMA is performing a **de-duplication of the Substance names** in the Article 57/XEVMPD database
  - A first *sample* of de-duplicated substance names list is available in the Controlled vocabularies: quality control section
  - Expected deployment in production end of April (TBC)
- New document on *Article 57 Quality Control Methodology* for MAH to improve data quality during maintenance submission will be published mid April
- Revised XEVMPD training material and XEVMPD e-learning covering the submission plan and the maintenance business processes will be made available in Q2 2014
- IT functionality to support MAHs in maintenance submission and data quality improvement in April
  - E.g. XEVMPD data export functionality

Next steps (2)

- Monthly Teleconferences and IWG meetings are scheduled to support industry in the implementation of the maintenance submission
- EMA will continue liaise with EU regulatory Network and Industry representatives to initiate the development of an ISO IDMP implementation plan and the roadmap for ISO IDMP implementation covering:
  - *Article 57/ ISO IDMP Gap analysis*
  - *Migration Plan*
  - *ISO IDMP Implementation plan*

All documents are available at the Article 57 webpage:

Home ▸ Human regulatory ▸ Data submission on authorised medicines ▸ Guidance documents

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000336.jsp&mid=WC0b01ac05804d8b2b#section5

Any questions?