EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Current status and update of the Article 57(2) implementation

5th Stakeholders forum

25 May 2012

Presented by: Ilaria Del Seppia

Summary

- Background
- Achievements
- Article 57 Figures on:
  - Registration and Helpdesk Support
  - Test (XCOMP)
  - Production
- Next Steps

Background

- Implementation of the electronic submission of information on medicines - first deliverable of new PV legislation
- Article 57(2), second subparagraph of Regulation (EC) No. 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 as of 2 July 2012, using this format

Background

This information will help the Agency to:

- Create a list of all medicinal products authorised in the EU including medicines authorised centrally via the Agency and medicines authorised by regulatory authorities in EU Member States
- Coordinate the regulation safety-monitoring and pharmacovigilance activities of medicines across the EU

This information will help stakeholders and the Agency to:

- Identify medicines accurately, especially medicines included in reports of suspected adverse reactions
- Facilitate the international harmonisation activities (ICH E2B and ICH M5)

Background

The Agency delivered on 1 July/1 September 2011:

- Legal Notice
- Detailed Guidance
- XML Schema Definition (XSD) for the individual data elements
- Structured Substance Information (SSI) Controlled Vocabularies
- XSD schema files and naming conventions for substances

The Agency received concerns by EU Pharmaceutical Industry Associations related to:

- Short timeline to comply with e-submission requirements
- High workload
- Content

Background

- Agency held a workshop with European pharmaceutical industry associations in January 2012 to address Industry's concerns and agree on a way forward to meet 2nd July legal deadline
- Stakeholders were supportive of the Agency's proposal to considerably reduce the mandatory data fields initially required in the format published on 2 July 2011
- Key objectives to maintain public-health goals of the legislation and patient safety were not compromised
- Significantly reduces the administrative burden and helps marketing authorisation holders to meet their legal deadline of 2 July 2012

Achievements

The following documents were published on EMA website since 5th March:

- Background info: Press release, Article 57 webpage, summary of EMA workshop with EU Pharmaceutical Industry Associations, training and registration information (New)
- Revised Legal Notice
- Revised Detailed Guidance
  - Including chapter 3.I: Revised technical specs
  - Including chapter 3.II: Business guidance (New)
  - Including chapter 3.III: XEVPRM examples (New)
- Questions & Answers (New)
- XEVPRM Terminologies and Controlled Vocabularies (New)
- Revised XEVPRM schema
- Release of the new XEVMPD e-learning modules (New)

The XEVMPD web application (new EVWEB) deployed in production on 5th March

Article 57

Figures & Numbers

XEVMPD registration and helpdesk

Number of organisations registered to the XEVMPD Community as of 23rd May

Registration Statistics	
Head Quarter	512
Affiliates	183

Helpdesk enquiry figures (art57@ema.europa.eu) since March 2012

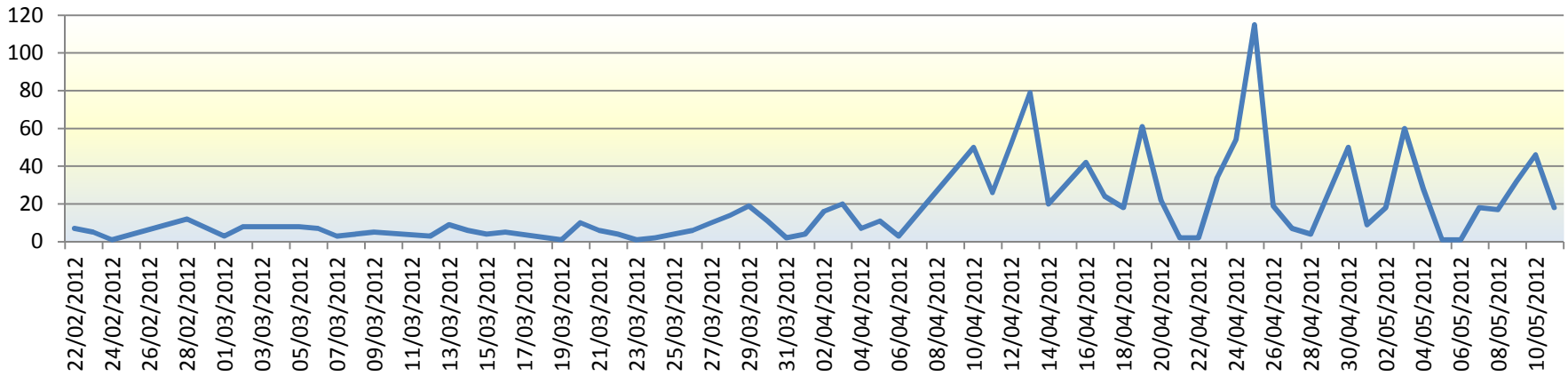
	March	April	May	Total
Tot query logged	264	256	371	891
Tot query closed	247	167	62	476
Tot query still open	17	89	309	415

XEVPRM received in Test (XCOMP)

Figures as of 23rd May

XCOMP Statistics	
No. companies testing	78
No. XEVPRM Received	1417
No. XEVPRM Loaded	693

XEVPRM received in Test (Trend) as of 10th March

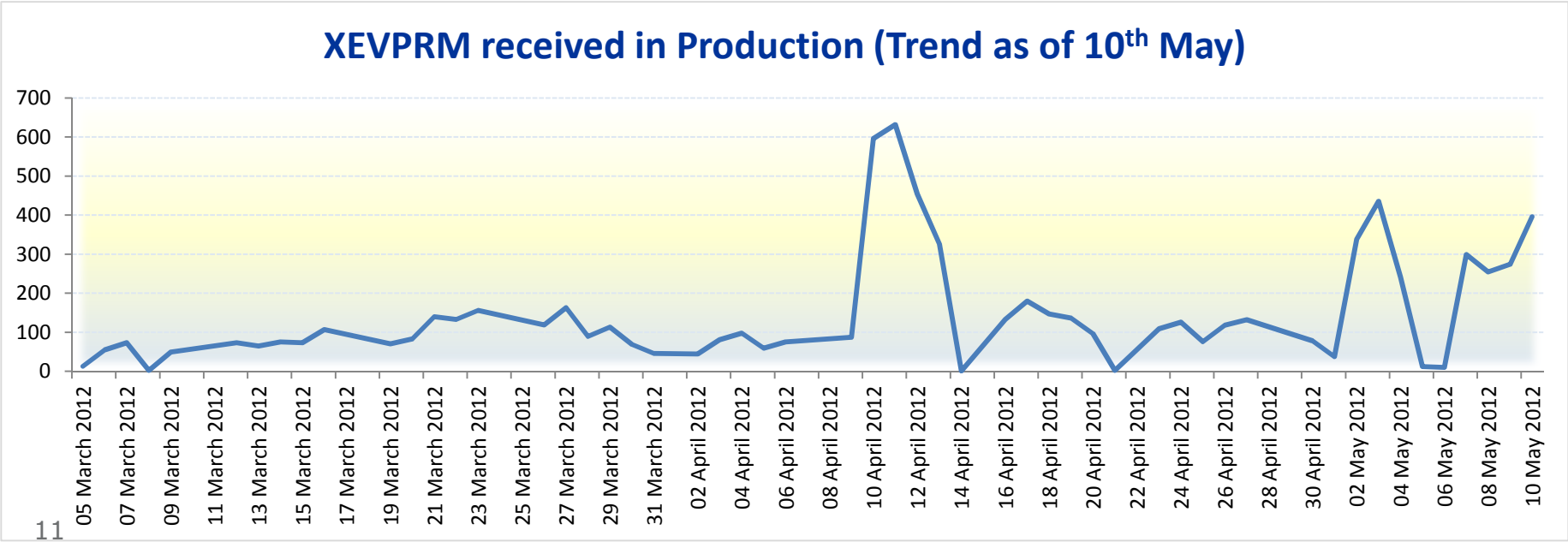


XEVPRM received in Production

Figures as of 23rd May

Product Presentations Statistic	
New product presentation	9684
Product updates (wrong submission)	77

Substance Statistics	
New substance English	810
New Synonyms	63
New translations	2972



Next Steps

The Agency will work with stakeholders throughout 2012 on:

- Further defining requirements for data maintenance (e.g. handling of variations)
- Submission of structured substance information (SSI)
- Implementation of ISO IDMP standards and a set of internationally harmonised specifications for the unique identification of medicines

Next Steps

Implementation of ISO IDMP standards and a set of internationally harmonised specifications for the unique identification of medicines

- Taking into account the international harmonisation work and the technical and scientific progress, the XEVPRM format will subsequently be replaced by a new format following the finalisation of the ISO IDMP and HL7 messaging standards
- A roadmap towards the implementation of the ISO IDMP standards will be developed in consultation with the EU regulatory network and the European pharmaceutical industry associations focusing on the
  - Extension of data set to meet the Agency's/EU Regulatory Network needs
  - EU input on Step 2 ICH Implementation Guide (November 2012)
  - Mapping of XEVMPD/ISO IDMP standards and HL7 messaging
  - Migration of legacy data (EUTCT)
  - Preparation for the EudraVigilance Audit (milestone)

Thank you

art57@ema.europa.eu

Telephone: +44 (0)20 7523 7010