EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Monitoring of medical literature and the entry of relevant information into the EudraVigilance database by the European Medicines Agency

Current activities and next steps

3rd PhV industry platform meeting - 13 March 2015

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Overview

I. Legal background

II. Expected benefits

III. Detailed guide

IV. EudraVigilance functionalities – how will it work

V. Change management

I. Legal background (1)

Article 27 of Regulation (EC) 726/2004:

1.The Agency shall **monitor selected medical literature** for **reports of suspected adverse reactions** to medicinal products containing certain active substances. It shall **publish the list of active substances being monitored** and the medical literature subject to this monitoring.

2.The Agency shall enter into the **Eudravigilance** database relevant information from the selected medical literature.

3.The Agency shall, in consultation with the Commission, Member States and interested parties, draw up a **detailed guide** regarding the monitoring of medical literature and the entry of relevant information into the Eudravigilance database.

I. Legal background (2)

Article 107(3) of Directive 2001/83/EC:

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For medicinal products containing the active substances referred to in the list of publications monitored by the Agency pursuant to Article 27 of Regulation (EC) No 726/2004, **marketing authorisation holders** shall not be required to report to the Eudravigilance database the suspected adverse reactions recorded in the listed medical literature, but they **shall monitor all other medical literature and report any suspected adverse reactions**.

II. Expected benefits (1)

- Enhance the **efficiency** of adverse reactions reporting
- Provide a **simplification** for pharmaceutical industry
- **Improve data quality** by reducing the number of duplicates
- Contribute to **resource savings**
- **Support signal detection** activities by NCAs and MAHs

III. Detailed Guide

Consolidated list of comments
EMA/716877/2014

- *Released for public consultation from 5 June – 27 July 2014*

2015

- Consolidated comments circulated to PMG 1 at their TC on 16 January
- EV-EWG review of key comments at their meeting on 4-5 February
- Draft MLM guide updated and circulated to PMG 1 on 6 February
- Draft MLM guide finalised with PMG 1 at their TC on 13 February
- Draft MLM guide circulated for comments to PRAC on 13 February
- Draft MLM guide circulated to the EC for comments on 13 February
- Draft MLM guide presented to the IG at their TC on 18 February
- Draft MLM guide discussed at PRAC ORGAM TC 26 February
- Draft MLM guide adopted by PRAC by written procedure on 3 March
- Draft MLM guide endorsed by ERMS-FG on 6 March

III. Detailed Guide - Scope

Definition of active substances

- Selection based on Article 57(2) submissions by MAHs
- Centred around high number of marketing authorisations in EEA

Definition of scientific and medical Literature

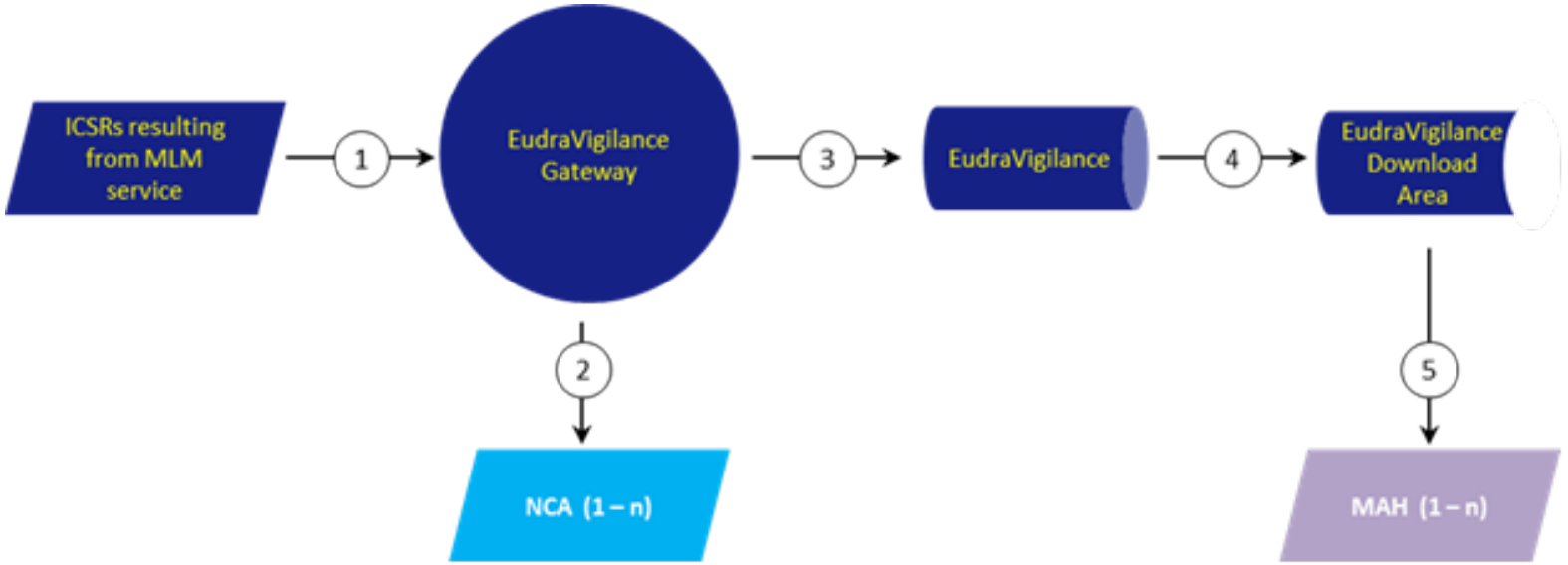
- Journal coverage based on three literature reference databases
  - Large, comprehensive and widely used, daily updated and indexed biomedical reference database covering literature from EEA and non-EEA countries
  - A monthly updated database with specialised literature coverage including pharmaceuticals, medical and health related literature and herbals
  - A monthly updated database on complementary medicine and alternative treatments with mainly European coverage

III. Detailed Guide – Business process description

Process definition

- Definition of search strategy
- Performance of scientific and medical literature search
- Screening, review and assessment of scientific and medical literature
- Processing of ICSRs (potential and confirmed ICSRs)
- Follow-up
- Recording of activities
- Quality management
- Interaction with stakeholders – service desk

IV. EudraVigilance functionalities - How will it work?



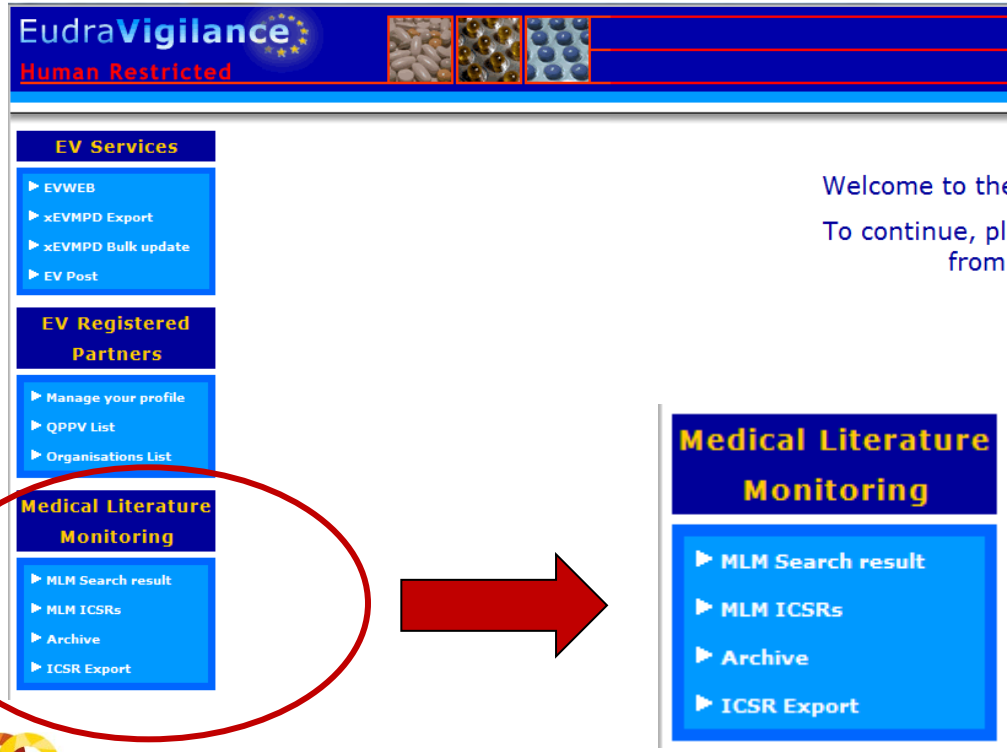
IV. EudraVigilance functionalities - How will it work?

1. ICSRs resulting from the MLM service refer to the selected medical literature subject to the monitoring by the Agency and the identified reports of suspected adverse reactions to medicinal products containing active substances identified as part of the scope of the Agency's activities
2. ICSRs resulting from the MLM service are transmitted electronically via the EudraVigilance Gateway to NCAs in EEA Member States in accordance with the reporting requirements of ICSRs applicable during the interim period
3. ICSRs resulting from the MLM service are transmitted electronically to EudraVigilance

IV. EudraVigilance functionalities - How will it work?

4. ICSRs resulting from the MLM service are made available for download by the MAHs concerned (EudraVigilance download area or EVWEB). This refers to ICSRs of suspected serious adverse reactions occurring within and outside the EEA and non-serious adverse reactions from within the EEA
5. Concerned MAHs can download the ICSRs resulting from the MLM service in XML format in compliance with the “Note for guidance: EudraVigilance Human – Processing of safety messages and individual case safety reports (ICSRs)” (EMA/H/20665/04/Final Rev. 2)

IV. EudraVigilance functionalities - How will it work?



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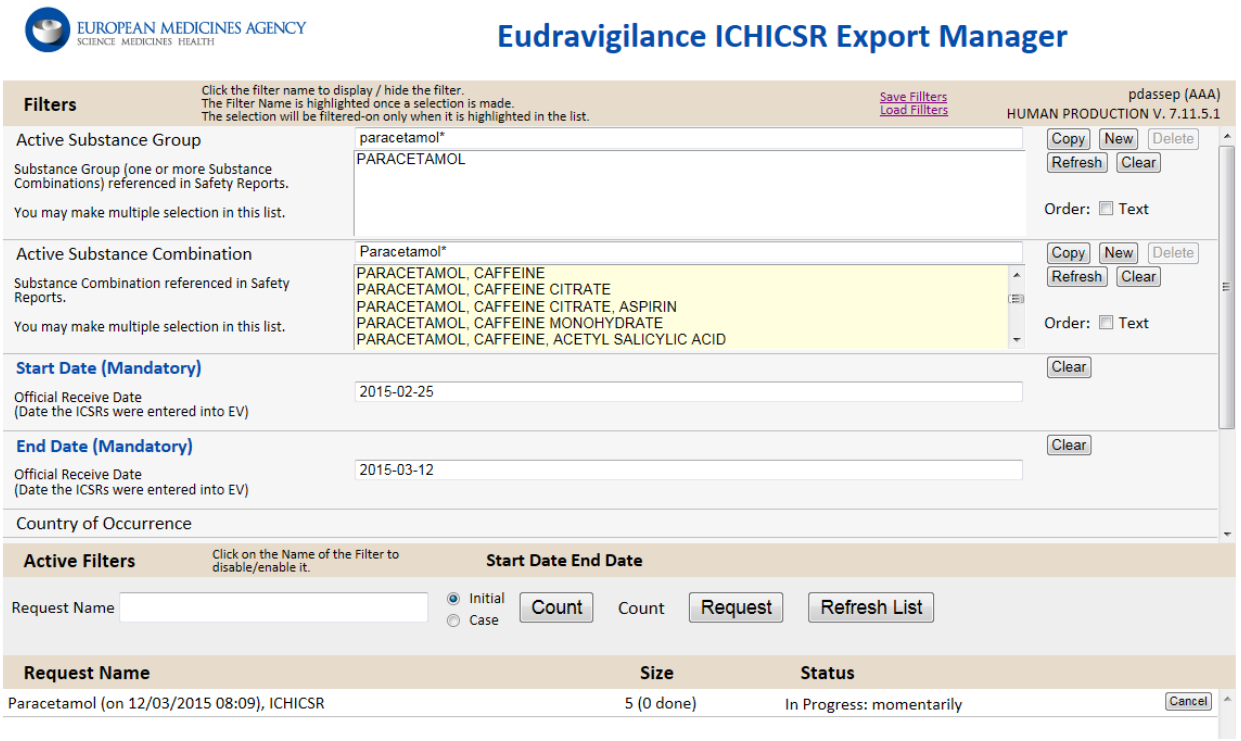

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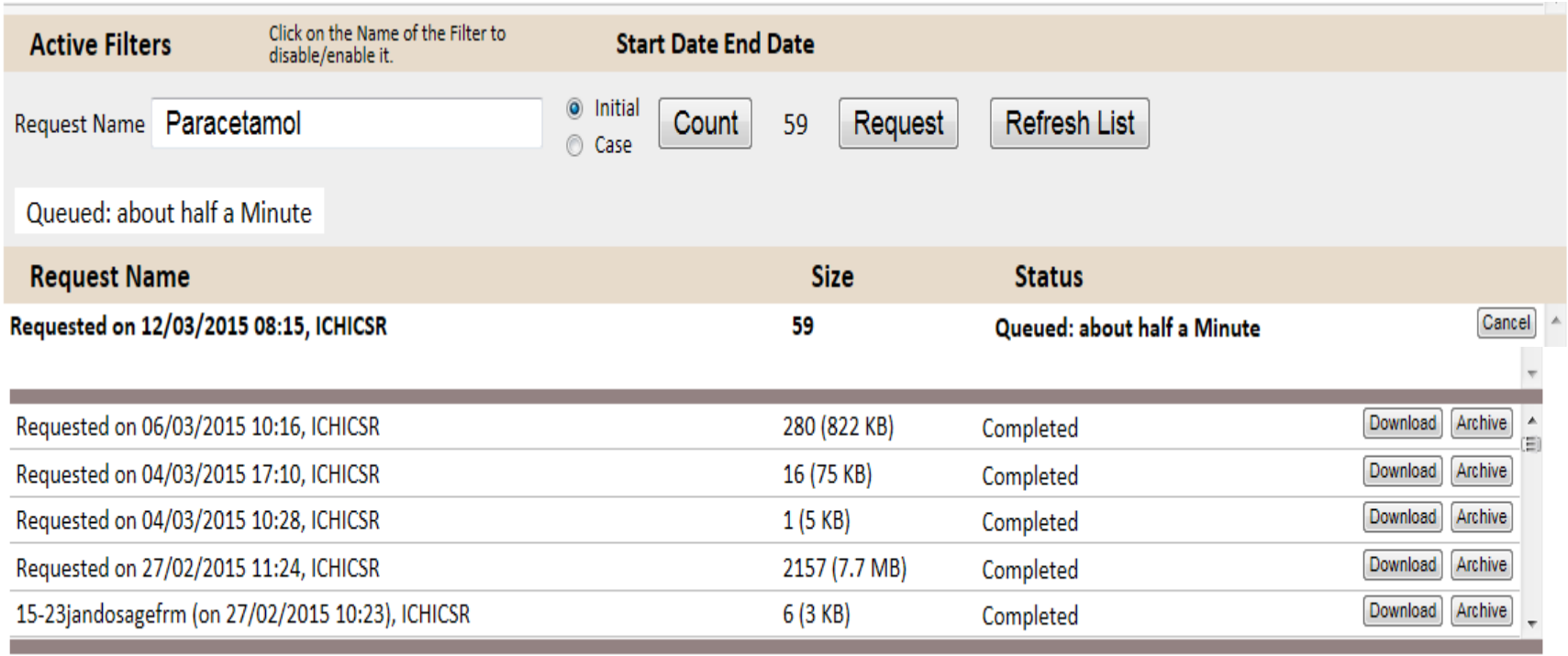
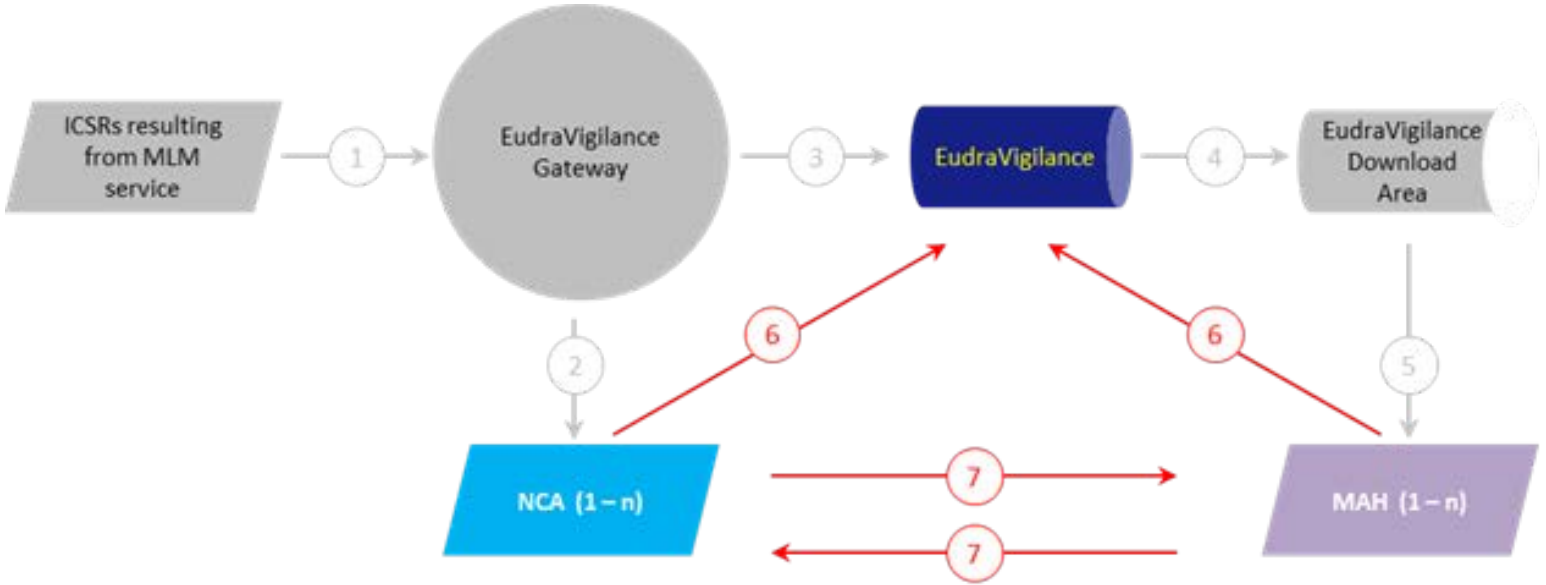


V. Change Management - Technical Preparations

- **MAH WEB Trader user**
  - Access to EVWEB environment: no changes for users registered in the EVWEB environment
  - The existent requirements and browser restrictions for EVWEB apply (preferable IE 8)

- **EudraVigilance download area for MAHs**
  - Test and production environment :
    - ✓ System configured to accept ICSRs with the **Sender identifier "MLMSERVICE"**

V. Change Management – Processes to be discontinued



V. Change Management – Processes to be discontinued

6. Member States should not re-submit the ICSRs resulting from the MLM service to EudraVigilance.

6. Member States should no longer forward/provide the ICSRs resulting from the MLM service to the concerned MAHs, since MAHs can download those ICSRs from the EudraVigilance Download Area

7. Concerned MAHs should not re-submit the ICSRs resulting from the MLM service to EudraVigilance (suspected serious adverse reactions from outside the EEA)

7. Concerned MAHs should no longer forward/provide the ICSRs resulting from the MLM service to the concerned NCA(s) in the EEA

III. Change Management – Next steps

- Launch of MLM dedicated webpage at Agency's corporate website
  - Publication of Detailed guide, substances and literature included in the service
- Training on MLM processes and related EudraVigilance functionalities (webinar)
- Testing of new EudraVigilance related functionalities with identified testers (NCAs/MAHs)
  - Agency will contact associations to identify testers from industry (in addition to testers from EV-EWG) and inform about timelines for testing
- Execution of pre-production pilot (two months)
  - Start of operation with a subset of substances
- Full operation of MLM service

Thank you for your attention

Further information

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