European Medicines Agency

EMEA/MB/45112/2009
5 March 2009

Status Report on the EudraVigilance-Human Project

I Introduction

This status report provides an update on the current status of implementation of EudraVigilance-Human at the EMEA and on the EMEA initiatives to progress with the population of EudraVigilance in the field of human medicines.

II Current Status of Implementation of EudraVigilance-Human Covering the Period 1 November 2008 – 31 January 2009[1]

Activities focused on:

- The continuation of the EVDAS roll-out to the NCAs. The EudraVigilance Support Programme has been initiated for interested NCAs and a training session was delivered to pharmacovigilance experts in the frame of the CHMP Pharmacovigilance Working Party on 19 November 2008. This allows for wider access to EudraVigilance data by proactive distribution of Reaction Monitoring Reports of selected medicinal products and will aid signal detection within NCAs.
- The practical implementation of Volume 9A part III and the monitoring of the implementation of mandatory electronic reporting of ICSRs in the EU by NCAs and MAHs for Centrally Authorised Products (CAPs).
  - All Member States are now in production with EudraVigilance for the electronic reporting of ICSRs in the post-authorisation phase.
  - Three MAHs for CAPs are not yet in production with EudraVigilance and the EMEA continues its efforts to ensure that those companies meet their obligations within the shortest possible timeframe.
  - Retrospective population of EudraVigilance continued to increase; 55,771 backlog ICSRs and SUSARs were submitted during the period 1 November 2008 – 31 January 2009 and 570,576 backlog ICSRs and SUSARs have been transmitted in total.

Three EudraVigilance Expert Working Groups and one EudraVigilance Steering Committee meeting were held. See Section III.1 for further details.

The three-day user training courses for the EVWEB application, the one-day training course for the EVMPD (EudraVigilance Medicinal Product Dictionary) and the three-day EVDAS training course for NCAs continued during the reporting period.

[1] The previous report to the Management Board referred to the period 1 September 2008 – 31 October 2008.

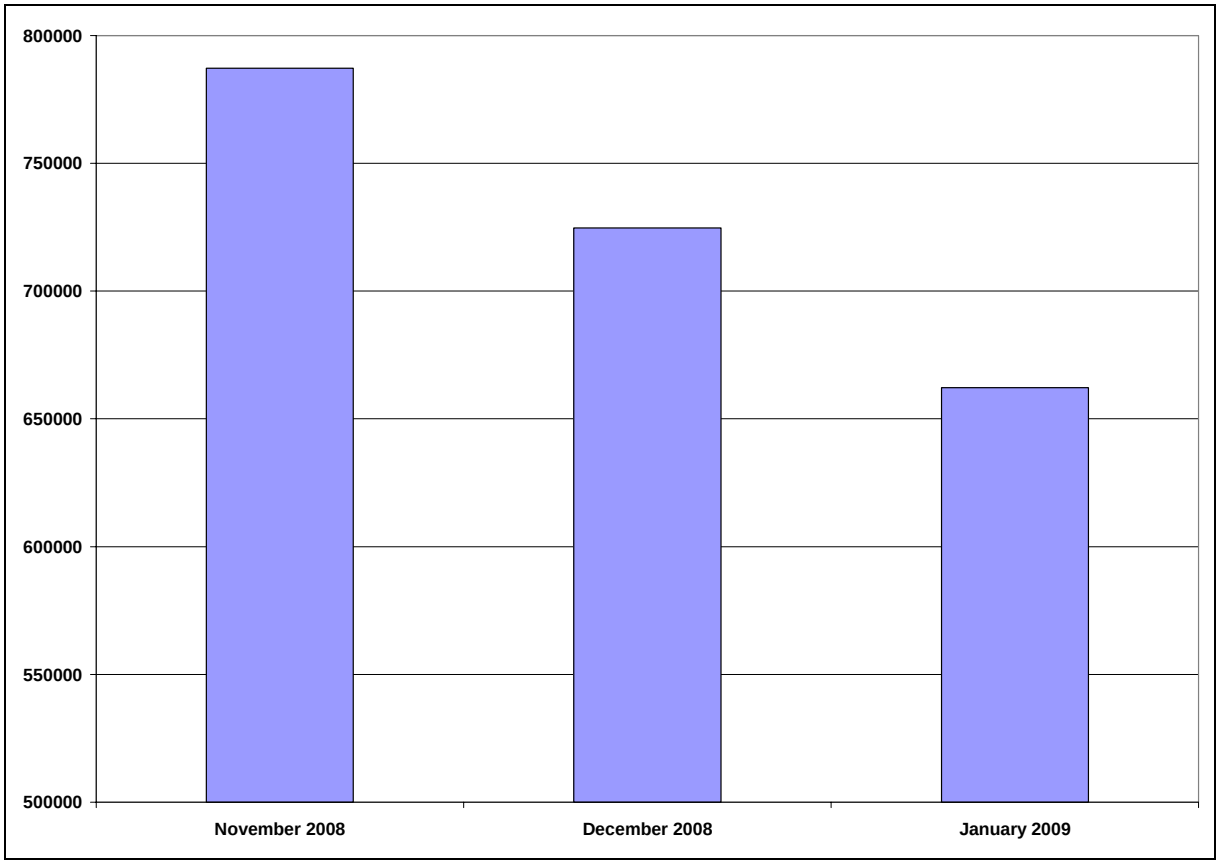
7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 09
E-mail: mail@emea.europa.eu www.emea.europa.eu

II.1 EudraVigilance Gateway

With regard to the reporting period from 1 November 2008 – 31 January 2009 a total of 2,174,221 transactions (including message disposition notifications) were performed by the EudraVigilance Gateway (production) (EVPM and EVCTM). These transactions included messages exchanged between the EMEA, pharmaceutical companies, sponsors of clinical trials and NCAs and rerouted messages to and from NCAs, sponsors of clinical trials and pharmaceutical companies.

Overall, since the establishment of the EudraVigilance Gateway in November 2001, a total of 18,521,453 transactions have been performed.

Graph 1 gives an overview of the number of transactions for the EudraVigilance Gateway (Production) from 1 November 2008 – 31 January 2009.



Graph 1: Total number of transactions performed at the level of the EudraVigilance Gateway from 1 November 2008 – 31 January 2009.

II.2 EudraVigilance Database Management System (EVDBMS)

II.2.1. E-reporting status for MAHs and Sponsors of Clinical Trials

- A total of 370 MAHs (at headquarter level) have sent reports to EVPM in the period between 1 December 2001 and 31 January 2009.
- In the period from 1 November 2008 – 31 January 2009 these MAHs reported 108,851 ICSRs to EVPM referring to 92,338 individual cases.

- In the period from 1 November 2008 – 31 January 2009 the MAHs reported a total of 54,762 backlog cases to EVPM.
- A total of 385 sponsors of clinical trials have sent reports to EVCTM in the period between 1 May 2004 and 31 January 2009.
- In the period from 1 November 2008 – 31 January 2009 these sponsors reported 17,020 ICSRs to EVCTM referring to 9,929 individual cases.
- In the period from 1 November 2008 – 31 January 2009, the Sponsors reported a total of 198 backlog cases to EVCTM.
- 16 pharmaceutical companies are currently testing with the EMEA.
- 16 pharmaceutical companies have completed testing in the period from 1 November 2008 – 31 January 2009 and are either ready to move into production or have already done so.

II.2.2. E-reporting status for NCAs

- All 31 NCAs have been authorised to enter into production with EudraVigilance.

The status as of 31 January 2009 is:

– 29 NCAs have reported ICSRs to EVPM (in alphabetical order of country name):

Agentur für Gesundheit und Ernährungssicherheit	Austria
Federal Agency for Medicines and Health Products	Belgium
Bulgarian Drug Agency	Bulgaria
Pharmaceutical Services	Cyprus
State Institute for Drug Control	Czech Republic
Federal Institute for Drugs and Medical Devices	Germany
Paul-Ehrlich-Institut	Germany
Danish Medicines Agency	Denmark
State Agency Of Medicines	Estonia
National Agency for Medicines	Finland
AFSSAPS	France
National Organisation for Medicines	Greece
National Institute of Pharmacy	Hungary
Lyfjastofnun (Icelandic Medicines Control Agency)	Iceland
Irish Medicines Board	Ireland
AIFA	Italy
State Agency of Medicines of the Republic of Latvia	Latvia
State Medicines Control Agency	Lithuania
Medicines Authority	Malta
College ter beoordeling van geneesmiddelen PRO	Netherlands
Norwegian Medicines Agency	Norway
The Office For Registration of Medicinal Products	Poland
Infarmed	Portugal
ANM	Romania
State Institute for Drug Control	Slovakia
ARSZMP	Slovenia
AGEMED	Spain
Medical Products Agency	Sweden

Medicines and Healthcare Products Regulatory Agency	United Kingdom

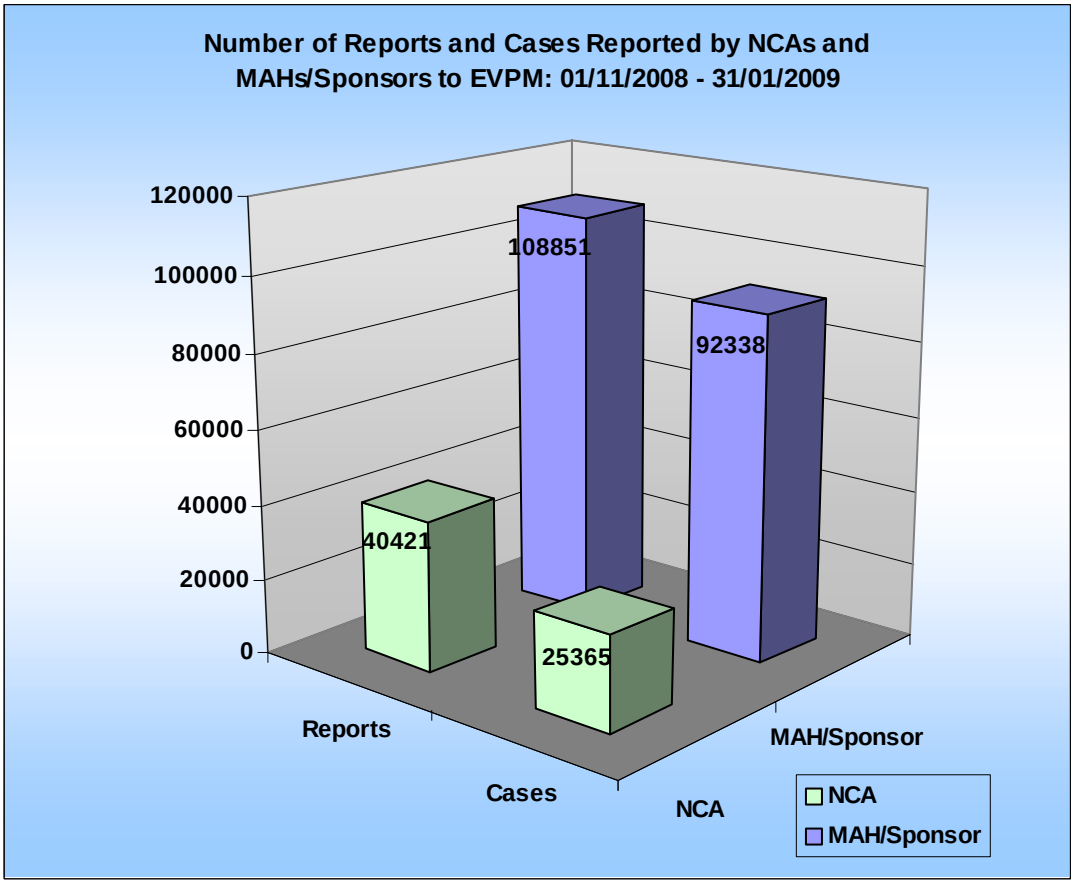
- Two NCAs have special arrangements:
  - The NCA for Lichtenstein (AFLUV) has a special agreement with the EMEA regarding EudraVigilance.
  - The NCA for Luxembourg, the Division de la Pharmacie et des Médicaments, has their reports transmitted by AFSSAPS.
- **EVPM:** In the period from 1 November 2008 – 31 January 2009, the NCAs reported 40,421 ICSRs to EVPM referring to 25,365 individual cases.
- **EVCTM:** In the period 1 November 2008 – 31 January 2009, the following 10 NCAs transmitted a collective total of 4,460 ICSRs referring to 2,488 individual cases to EVCTM:

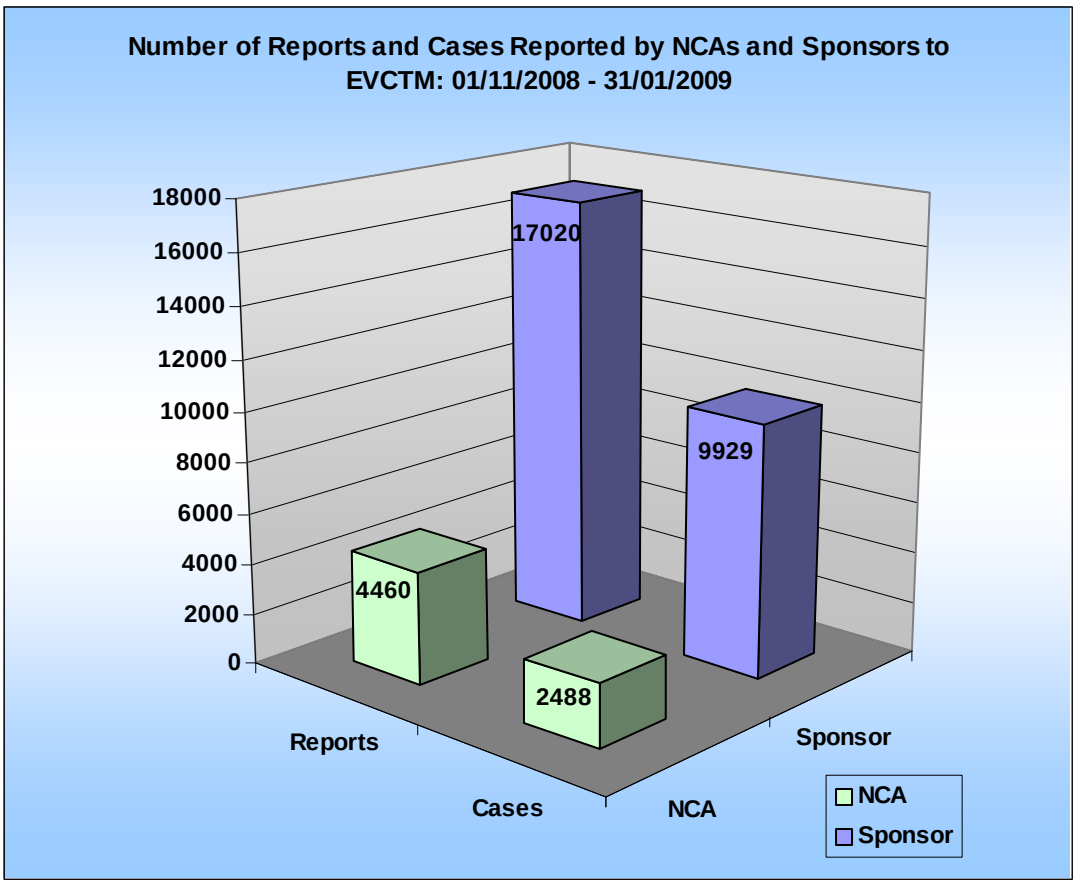
Federal Agency for Medicines and Health Products	Belgium
Danish Medicines Agency	Denmark
Federal Institute for Drugs and Medical Devices	Germany
Paul-Ehrlich-Institut	Germany
National Organisation for Medicines	Greece
College ter beoordeling van geneesmiddelen PRO	Netherlands
Norwegian Medicines Agency	Norway
Infarmed	Portugal
ANM	Romania
Medicines and Healthcare Products Regulatory Agency	United Kingdom

- **Backlog:** A total of 17 NCAs have transmitted a collective total of 79,332 backlog ICSRs referring to 73,002 individual backlog cases to EudraVigilance:

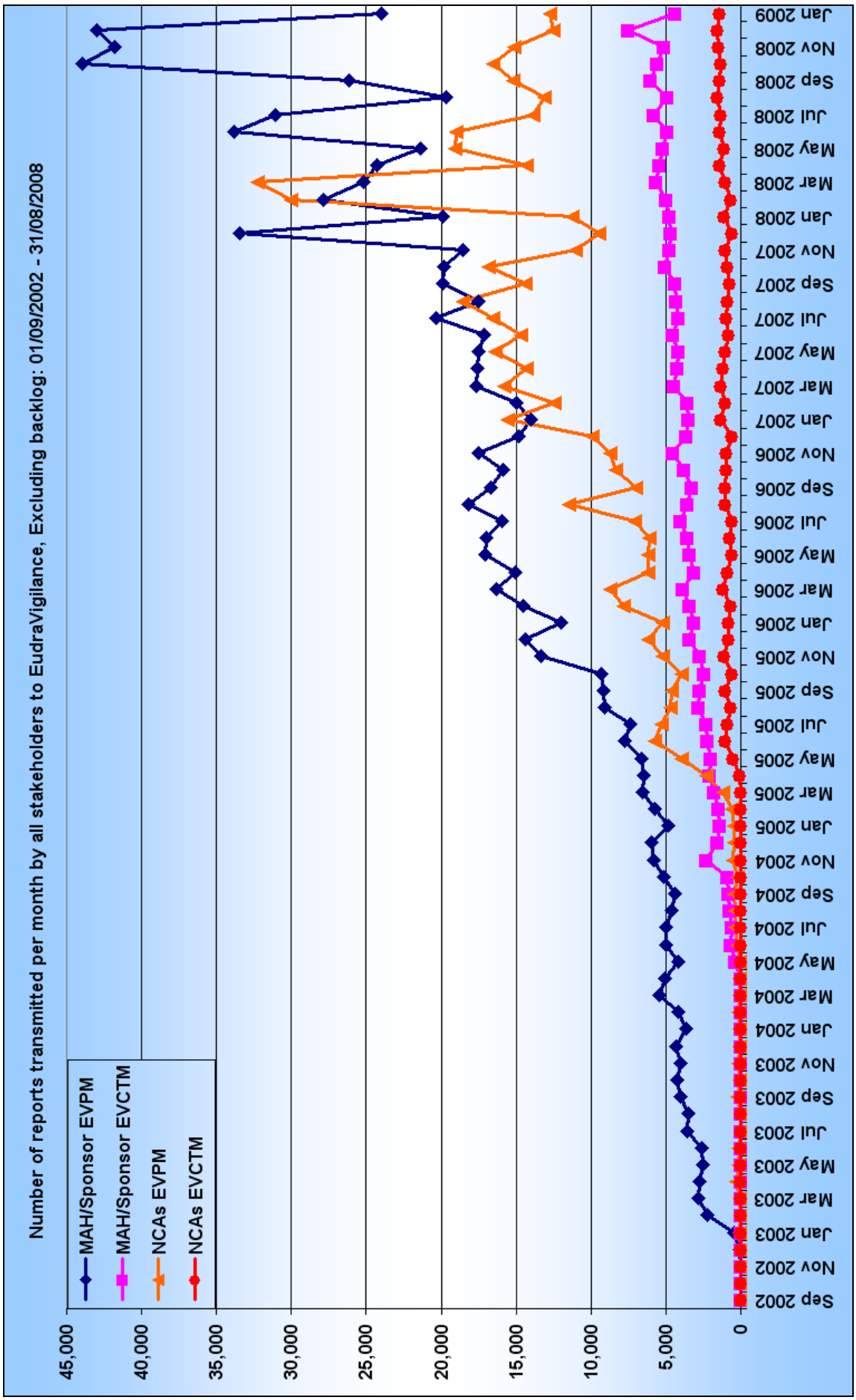
Agentur für Gesundheit und Ernährungssicherheit	Austria
Federal Agency for Medicines and Health Products	Belgium
Bulgarian Drug Agency	Bulgaria
State Institute for Drug Control	Czech Republic
Danish Medicines Agency	Denmark
Paul-Ehrlich-Institut	Germany
National Organisation for Medicines	Greece
National Institute of Pharmacy	Hungary
AIFA	Italy
State Agency of Medicines of the Republic of Latvia	Latvia
State Medicines Control Agency	Lithuania
College ter beoordeling van geneesmiddelen PRO	Netherlands
The Office For Registration of Medicinal Products	Poland
Infarmed	Portugal
State Institute for Drug Control	Slovakia
AGEMED	Spain
Medical Products Agency	Sweden

Number of reports and cases reported to EudraVigilance during the reporting period, excluding backlog





Number of reports submitted per month to EudraVigilance, excluding backlog


Number of reports transmitted per month by all stakeholders to EudraVigilance, Excluding backlog: 01/09/2002 - 31/08/2008
MAH/Sponsor EVPM
MAH/Sponsor EVCTM
NCAs EVPM
NCAs EVCTM
45,000
40,000
35,000
30,000
25,000
20,000
15,000
10,000
5,000
0
Sep 2002
Nov 2002
Jan 2003
Mar 2003
May 2003
Jul 2003
Sep 2003
Nov 2003
Jan 2004
Mar 2004
May 2004
Jul 2004
Sep 2004
Nov 2004
Jan 2005
Mar 2005
May 2005
Jul 2005
Sep 2005
Nov 2005
Jan 2006
Mar 2006
May 2006
Jul 2006
Sep 2006
Nov 2006
Jan 2007
Mar 2007
May 2007
Jul 2007
Sep 2007
Nov 2007
Jan 2008
Mar 2008
May 2008
Jul 2008
Sep 2008
Nov 2008
Jan 2009

II.2.3. Summary of e-reporting status by all Stakeholders (NCAs, MAHs and Sponsors of Clinical Trials), excluding backlog

In the period from 1 January 2002 to 31 January 2009 a total of

- 1,543,140 ICSRs were reported to EVPM referring to 968,632 individual cases.
- 247,133 ICSRs were reported to EVCTM referring to 104,468 individual cases.[2]

II.2.4. Summary of e-reporting status by all Stakeholders (NCAs, MAHs and sponsors of Clinical Trials) to EVPM split by EEA and Non-EEA, excluding backlog

In the period from 1 January 2002 to 31 January 2009 a total of

- 625,136 EEA ICSRs were reported to EVPM referring to 387,007 EEA individual cases.
- 918,004 non-EEA ICSRs were reported to EVPM referring to 581,625 non-EEA individual cases.

II.2.5. Summary of e-reporting status by all Stakeholders (NCAs and Sponsors of Clinical Trials) to EVCTM split by EEA and Non-EEA, excluding backlog

In the period from 1 May 2004 to 31 January 2009 a total of

- 127,992 EEA ICSRs were reported to EVCTM referring to 53,351 EEA individual cases[3].
- 119,141 non-EEA ICSRs were reported to EVCTM referring to 51,117 non-EEA individual cases[3].

II.3 EudraVigilance Medicinal Product Dictionary (EVMPD)

During the period 1 November 2008 – 31 January 2009:

315 presentations for Authorised Medicinal Products were entered or updated in the EVMPD via EVWEB or gateway.

II.4 EudraVigilance Help Desk Support Provided by the PhV-RM Sector

During the period 1 November 2008 – 31 January 2009, the EMEA PhV-RM Sector handled 1,056 written help desk requests and 171 telephone requests.

[2] Corrigendum to the previous Management Board report of 11 December 2008 (Doc. Ref. EMEA/MB/596416/2008): the correct number of ICSRs that were reported to EVCTM by 31 October 2008 was: 225,616, referring to 92,288 individual cases; this breaks down as:
116,409 EEA ICSRs were reported to EVCTM referring to 47,015 EEA individual cases; and
109,207 non-EEA ICSRs were reported to EVCTM referring to 45,273 non-EEA individual cases.

III EMEA Initiatives to Progress with the implementation of EudraVigilance in the Field of Human Medicines

III.1 Activities at EudraVigilance Steering Committee and EudraVigilance Expert Working Group Level

The EudraVigilance Expert Working Group (EV-EWG) met on 6-7 November 2008, 16-17 December 2008 and 22-23 January 2009 and the EudraVigilance Steering Committee (EV-SC) met once on the 8th December 2008.

A summary of the most important topics discussed during these meetings is provided below:

– EudraVigilance Phase IIb Project

The EudraVigilance phase IIb project plan, which outlines the project deliverables for 2009, was finalised and adopted by the EudraVigilance Steering Committee on 8 December 2008. HMA-Human was provided with a project summary report on 22 December 2008.

– Important Medical Events list

The Important Medical Events list was published on 16 January 2009.

– Implementation Questions related to Volume 10

Implementation questions related to the SUSAR reporting in clinical trials were finalised and published by the European Commission in chapter V of Volume 10 "Questions & Answers" Document - Version 2 on 16 December 2008.

III.2 EVDAS Training for NCAs

The EVDAS training for NCAs has been initiated with a professional trainer. The first training courses were organised on 19 to 21 January 2009.

III.3 Activities related to the International Standardisation Work in the frame of ICH

In the context of the ISO TC 215 'Health Informatics' WG 6 'Pharmacy and Medicines Business' the Committee Drafts for the following topic have been finalised with major input from the Scientific Committees of the EMEA:

- **ISO Identification of Medicinal Products (IDMP)** which comprises the following working packages:
    - **prEN ISO 11615:** Data Elements and Structures for the Exchange of Regulated Product Information for Drug Dictionaries (MPID)
    - **prEN ISO 11616:** Structures and Controlled Vocabularies for Pharmaceutical Product Identifiers (PhPIDs)
    - **prEN ISO 11238:** Structures and Controlled Vocabularies for Ingredients (substances)
    - **prEN ISO 11239:** Structures and Controlled Vocabularies for Pharmaceutical Dose Forms, Units of Presentation and Routes of Administration
    - **prEN ISO 11240:** Structures and Controlled Vocabularies for Units of Measurement

- **prEN ISO 11595:** Structures and Controlled Vocabularies for Laboratory Test Units for the Reporting of Laboratory Results

A report on the status of the ongoing activities was sent to HMA-Human on 22 December 2008. Feedback from the ISO Secretariat on the initiation of the 'Enquiry Stage' is awaited.