EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Implementation of the EudraVigilance Access Policy

(Access to EudraVigilance data)

Thursday 20 October 2011

3rd Stakeholders Forum

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Agenda

- Introduction
- EudraVigilance Access Policy overview
- EudraVigilance Access Policy timelines
- EudraVigilance Access Policy implementation
- EudraVigilance Access Policy data quality
- Access to EudraVigilance data - dashboard
- Next Steps

Introduction

Drafting process

Draft agreed by the EudraVigilance Expert Working Group	December 2007
Consultation with the EudraVigilance Steering Committee	February 2008
Consultation with the Heads of Medicines Agencies Human (HMA-h) for public consultation	April 2008
Adopted by EMA Management Board for public consultation	June 2008
Released for public consultation	December 2008
End of public consultation (deadline for comments)	March 2009
Consultation with the EudraVigilance Expert Working Group	September 2010
Consultation with the EudraVigilance Steering Committee	September 2010
Consultation with the CHMP Pharmacovigilance Working Party	September 2010
Consultation with the Committee for Human Medicinal Products (CHMP)	October 2010
Consultation with the Patients' and Consumers' Working Party	October 2010
Consultation with the Health Care Professional Working Group	October 2010
Consultation with the Heads of Medicines Agencies Human (HMA-h)	October 2010
Adopted by the EMA Management Board	December 2010
Coming into force	8 July 2011

EudraVigilance Access Policy Overview (1)

Set goals

- Improve public health by facilitating the safety monitoring of medicinal products (during clinical trials and following their marketing authorisation)
- Support signal detection activities by MAHs in the context of spontaneous reporting for authorised medicines
- Inform healthcare professionals and the general public by publishing collated adverse reaction data related to spontaneous reports for authorised medicines
- Allow for the use of adverse reaction data for research purposes

EudraVigilance Access Policy Overview (2)

EMA assessed all comments made during the public consultation and proposed the following approach in line with the European Ombudsman and Data Protection Supervisor recommendations:

- Allows proactive disclosure of information
  - Maximum data are released proactively
  - Needs of the public are met
  - Requirements of personal data protection are adhered to
- Assessment and categorisation of all ICH E2B ICSR data elements to ensure full compliance with EU data protection legislation
- Definition of Stakeholder Groups and access levels to the safety information – full or defined set of data fields

EudraVigilance Access Policy Overview (3)

The EV Access Policy defines 4 Stakeholder Groups

Stakeholder Group I - European Medicines Regulatory Authorities, European Commission, the Agency

Stakeholder Group II - Healthcare professionals and the general public

Stakeholder Group III - Marketing Authorisation Holders & Sponsors

Stakeholder Group IV - Research Organisations

EudraVigilance Access Policy Overview (4)

	ACCESS TO	ACCESS VIA
NCAs, EC, EMA	all data fields	Data warehouse (EVDAS) ➔ signal detection and data analysis functionalities
MAHs & Sponsors	- all data fields if sender - defined data fields* if not sender	
Research Organisations	defined data fields*	
HCPs & general public	defined data fields*	Dashboards (website) ➔ aggregated reports

* Set of defined data fields available in the EV Access Policy document

EudraVigilance Access Policy Timelines

In conjunction with the implementation of the new pharmacovigilance legislation, the EMA Management Board adopted in March 2011 a stepwise approach:

1 - Healthcare professionals and the general public

Phase 1

- Publication of aggregated data for Centrally Authorised Products (updated on a monthly basis)

-> **by end 2011**

Phase 2

- Publication of aggregated data for all Medicinal Products (updated on a monthly basis)

- Access to defined data elements

-> **by end 2012**

2- Marketing Authorisation Holders & Sponsors and Research Organisations

-> **2014/2015**

EudraVigilance Access Policy Implementation (1)

➔ **Step 1**: **Healthcare professionals and the general public**

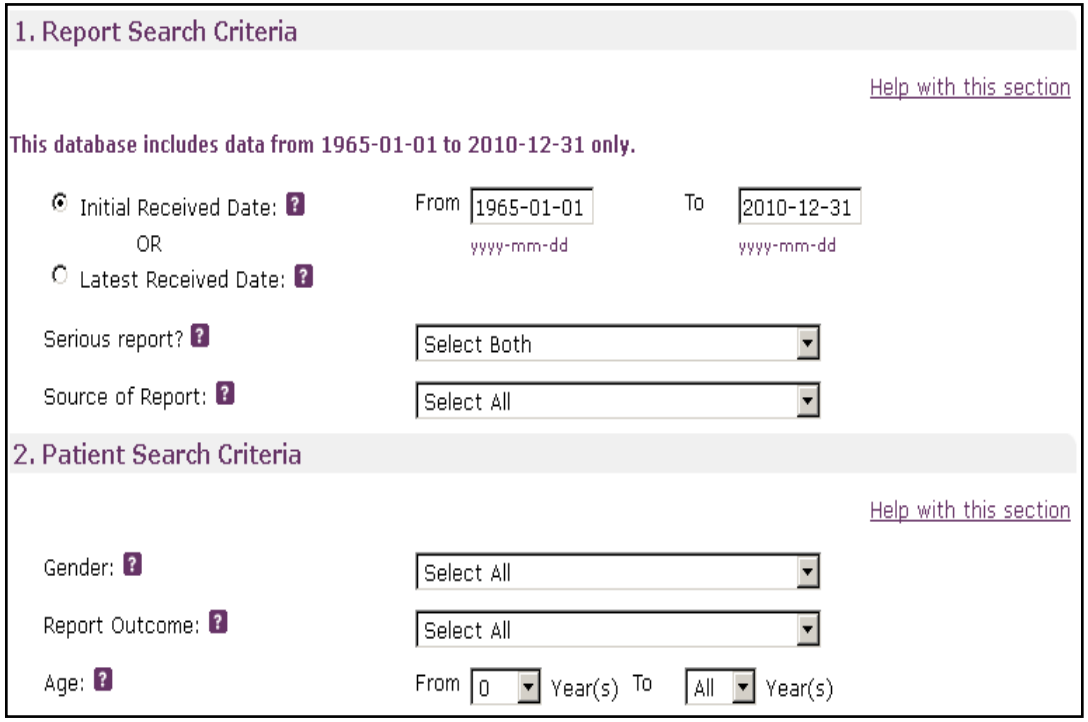
Phase 1: **Publication of aggregated data for Centrally Authorised Products**

- Establishment of 'EV Users Group' with representatives from the Patient and Consumer Working Party (PCWP) and the Healthcare Professionals' Organisations Working Group (HCPWG) to discuss implementation aspects e.g.
  - Format and content of aggregated data reports
  - Development of explanations on pharmacovigilance and EudraVigilance
  - Draft guidance on nature and interpretation of adverse reaction data
  - Develop clear instruction for consumers and patients
- Meeting in October 2010 to discuss how other EU/non EU regulators approach the publication of adverse reaction data

EudraVigilance Access Policy Implementation (2)

How does EMA proposal compare to Health Canada implementation?

HEALTH CANADA



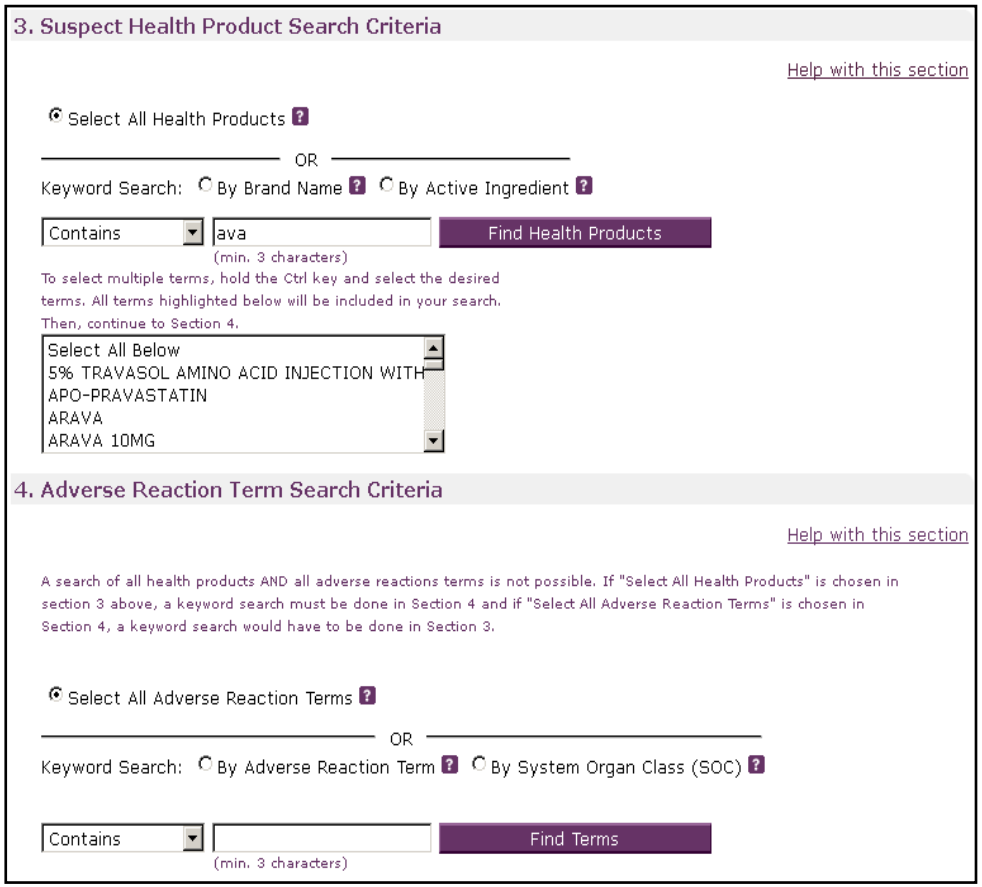
PROPOSAL

No selection for the users -> report contains aggregated data up to the date when the report is run

No selection for the users -> information included in the output

EudraVigilance Access Policy Implementation (3)

HEALTH CANADA



PROPOSAL

Selection for the users -> the user must select

Brand Name

Or

Substance Name

No selection for the users -> information included in the output

EudraVigilance Access Policy Implementation (4)

Publication of data for HCPs & general public

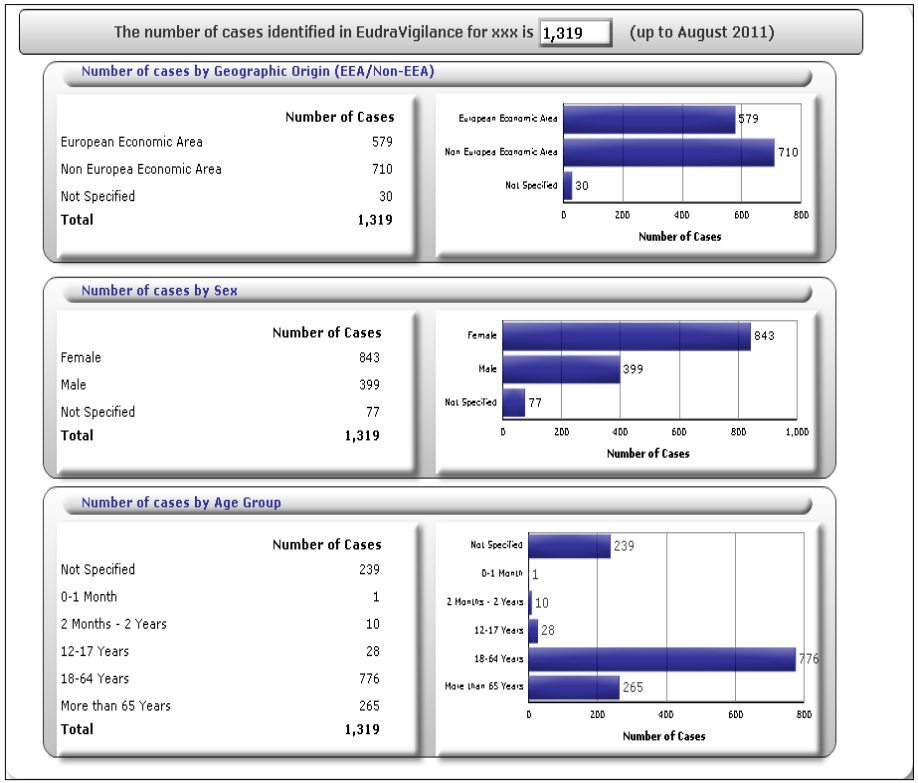
- Best format ? ⇒ dashboard provide functionalities to combine multiple reports, user-friendly for visualisation and navigation, dynamic interface
- Development of draft dashboard for publication of aggregated data
- Questionnaires sent to representatives from the PCWP and the HCPWG ('EV Users Group')

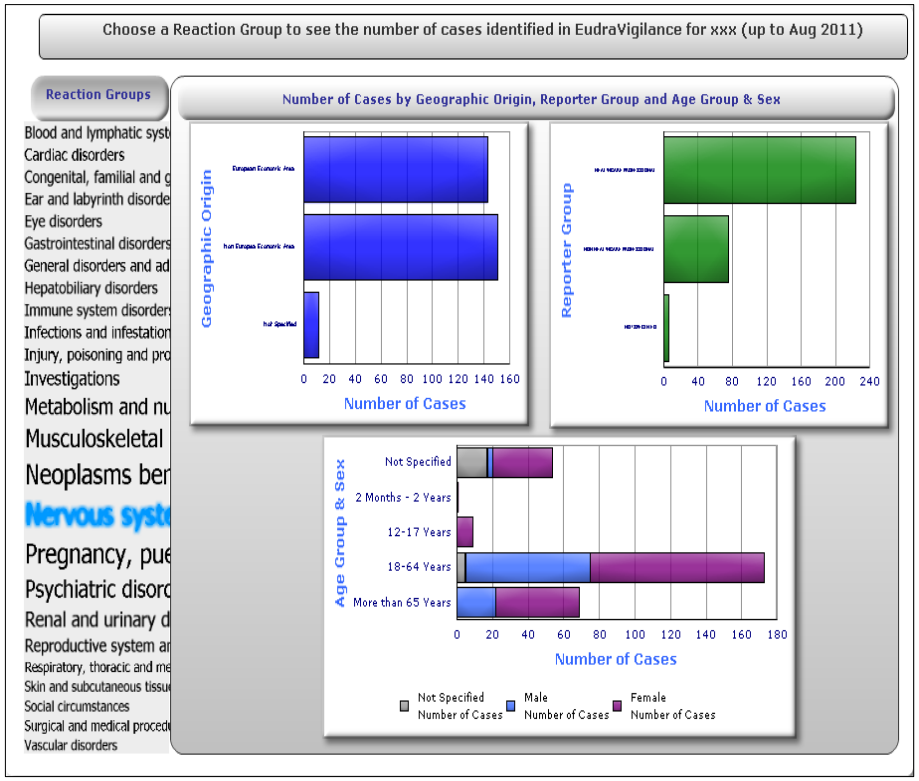
  → questionnaire focused on user-friendliness, layout, level of details, navigation, relevance of available information…

  → feedback received is positive

EudraVigilance Access Policy Implementation (5)

The dashboard provide functionalities for the user to navigate within multiple panels, refining at the same time the level of information provided





EudraVigilance Access Policy Data Quality (1)

In accordance with decisions taken by the Heads of Medicines Agencies in April 2008, the EMA has been undertaking work to clean and code the data in EudraVigilance prior to implementation of the EV Data Access Policy and pre-emptive release of data to the public

Work Package	Objective
WP1 - Detection and management of duplicate ICSRs	'merge' all confirmed duplicated reports
WP2 - Manual recoding of medicinal products reported in ICSRs	'code' all medicinal products to assist signal detection activities
WP3 - Validate and update the medicinal products in the EudraVigilance Medicinal Product Dictionary (EVMPD)	have a reliable coding thesaurus
WP4 - Review the quality of ICSRs reported to EudraVigilance	improve overall quality of the data submitted by providing feedback to the reporting organisations
WP5 - The provision of translation of case narratives and medicinal product information	assist the review of case narratives where an English summary is not provide as defined in Volume 9A, part III

EudraVigilance Access Policy Data Quality (2)

The framework contract with the third-party company runs until mid-2014.

Indicative timelines:

Work Package	Timelines
WP1 - Detection and management of duplicate ICSRs	✓ Started in Dec 2010 ➢ All duplicates should be screened and cleaned by July 2012
WP2 - Manual recoding of medicinal products reported in ICSRs	✓ Started in Dec 2010 ➢ All medicinal product information reported in ICSRs should be recoded by end Q1 2012
WP3 - Validate and update the medicinal products in the EudraVigilance Medicinal Product Dictionary (EVMPD)	❖ To start Q1 2012 according to current forecasts
WP4 - Review the quality of ICSRs reported to EudraVigilance	✓ Started in Jun 2011 ➢ Approx. 100 sender organisations will have been reviewed and contacted by end-2011

Access to EudraVigilance - dashboard demonstration

Reminder

- Dashboard demonstration related to Step 1/Phase 1

Phase 1

- Publication of aggregated data for Centrally Authorised Products (updated on a monthly basis)

Dashboard.mht

Next Steps

- ICT implementation ongoing
- Draft guidance to be circulated to the ‘EV Users Group’ for review and comments
- Website design and development