EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Working Party with Patients' and Consumers' organisations

EudraVigilance Access Policy
&
Access to EudraVigilance data (medicines for human use)

Tuesday 13 September 2011

Pharmacovigilance and Risk Management Sector, EMA

Agenda

- Introduction
- EudraVigilance Access Policy overview
- Access Policy for healthcare professionals and the general public
- EV Access Policy implementation strategy
- Access to EudraVigilance - dashboard demonstration
- Dashboard feedback from EudraVigilance Users Group
- Conclusion

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 by EU regulators of medicines during clinical trials and following their marketing authorisation
- Support signal detection activities by MAHs in the context of spontaneous reporting for authorised medicines
- Publish collated adverse reaction data related to spontaneous reports for authorised medicines to inform healthcare professionals and the general public
- 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 recommendation:

- 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 definition for the 4 Stakeholder Groups

I - European Medicines Regulatory Authorities

→ access to the signal detection and data analysis tools in the EudraVigilance Data Warehouse and Analysis System (EVDAS)

II - Healthcare professionals and the general public

→ access to aggregated adverse reaction data published on the EMA website

EudraVigilance Access Policy Overview (5)

III - Marketing Authorisation Holders & Sponsors

→ access to the signal detection and data analysis tools in the EudraVigilance Data Warehouse and Analysis System (EVDAS)

→ sender-based access to safety information

IV - Research Organisations

→ access to the signal detection and data analysis tools in the EudraVigilance Data Warehouse and Analysis System (EVDAS)

EudraVigilance Access Policy Overview (6)

- Healthcare professionals and the general public, Marketing Authorisation Holders & Sponsors and Research Organisations, have access to the same data fields as defined in the Annex 1 of the EV Access policy

- Examples of defined data elements: reaction, country, age group, sex, duration of reaction/event, time interval between administration of drug and start of reaction, duration of drug administration, action taken with drug, did reaction recur on readministration, outcome of reaction, drug characterisation, dose and unit, dosage form, route of administration…….

Access Policy for HCPs and the general public (1)

What does it mean for healthcare professionals and the general public?

In conjunction with the implementation planning of the new pharmacovigilance legislation, the EMA Management Board adopted in March 2011 the following stepwise approach for the EV Access Policy:

1 - Healthcare professionals and the general public -> *timelines next slide*

2- Marketing Authorisation Holders & Sponsors and Research Organisations -> *2014/2015*

Access Policy for HCPs and the general public (2)

For healthcare professionals and the general public, the proposed timeline for implementation is:

Phase 1

- Publication of aggregated data for Centrally Authorised Products (monthly basis) -> by end 2011

Phase 2

- Publication of aggregated data for all Medicinal Products (monthly basis) -> by end 2012

- Access to defined data elements

EV Access Policy implementation strategy (1)

- Establishment of 'EV Users Group' with representatives from the PCWP and the 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

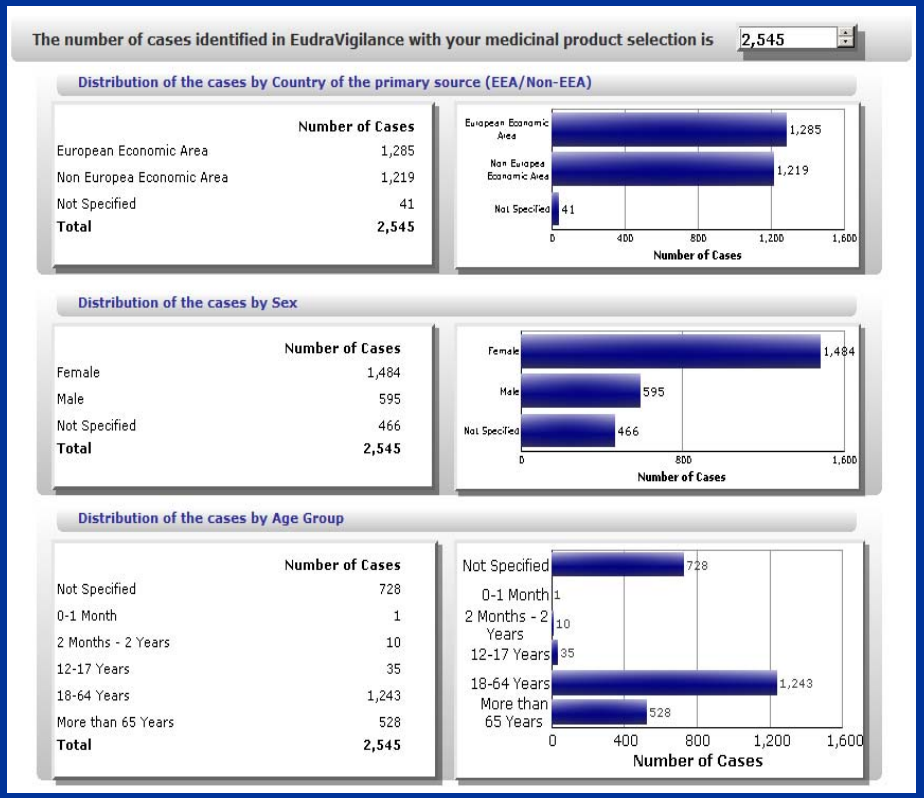
EV Access Policy implementation strategy (2)

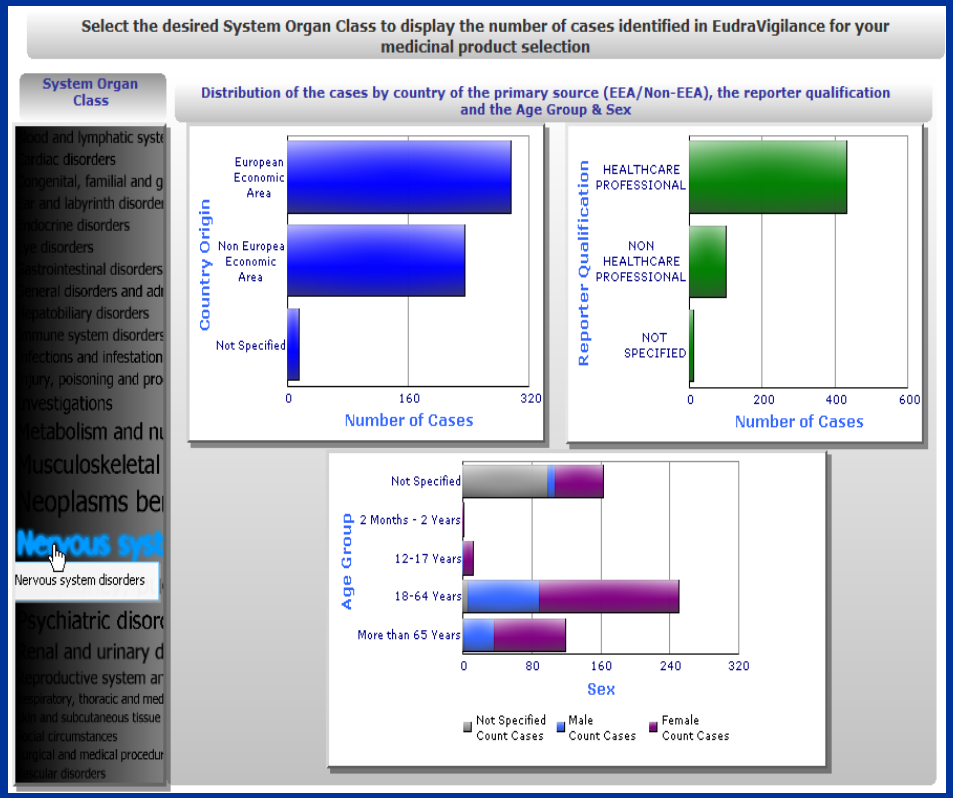
Publication of data

- Development of a draft dashboard for the publication of aggregated data at EMA level
- Dashboard provide functionalities to combine multiple reports, user-friendly for visualisation and navigation, dynamic interface
- Draft dashboard + feedback questionnaire sent to the EV Users Group for review and comments by Thursday 08 Sep. 2011

EV Access Policy implementation strategy (3)

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

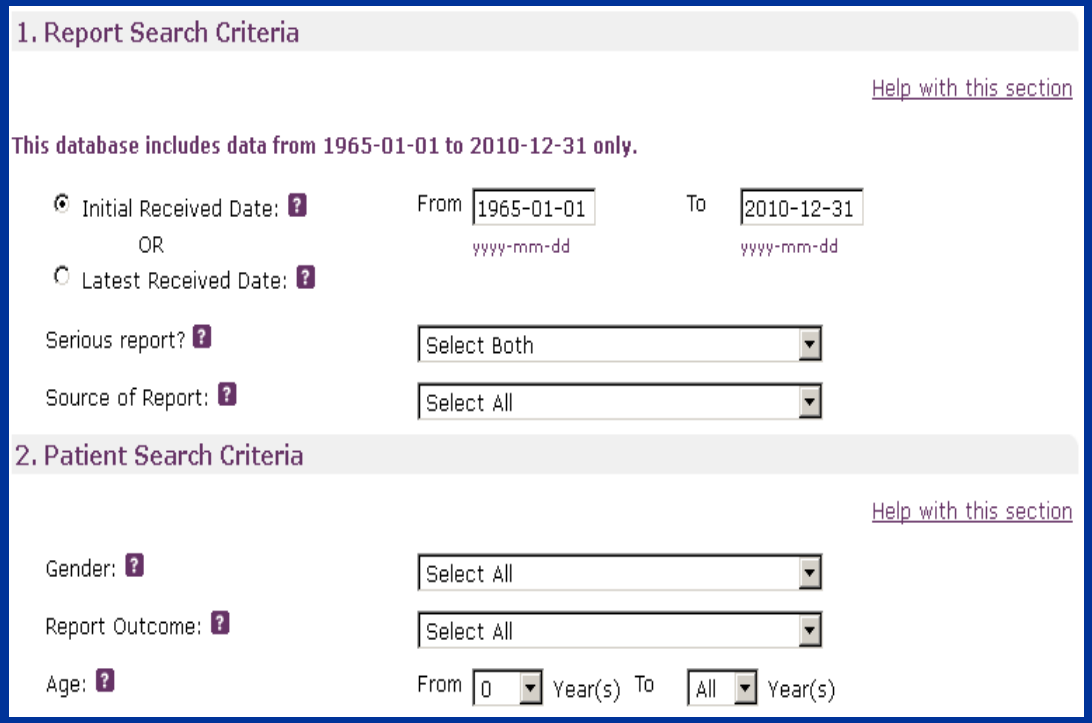




EV Access Policy implementation strategy (4)

How does EMA proposal compare to Health Canada implementation?

HEALTH CANADA



PROPOSAL

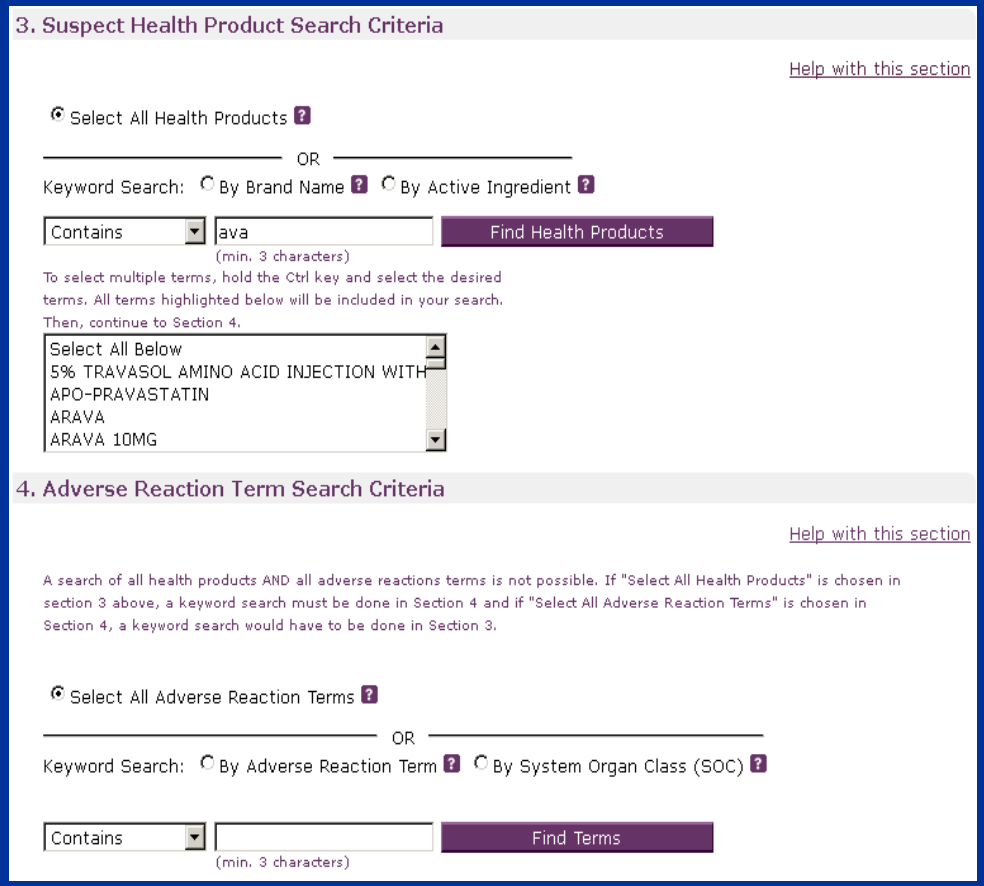
No selection for the users -> report contains aggregated data up to the date when the report is run

No selection for the users

-> information included in the output

EV Access Policy implementation strategy (5)

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

Access to EudraVigilance - dashboard demonstration

Reminder

- Draft dashboard demonstration related to Phase 1 - publication of aggregated data for Centrally Authorised Products
- Phase 2 - publication of aggregated data for all Medicinal Products & Access to restricted data elements information –> 2012

- Feedback questionnaire was focusing on user-friendliness, layout, level of details, navigation, relevance of available information
- Layout, font size, colors….. will be fixed in the final product

Dashboard feedback from EV Users Group (1)

- The feedback received is overall positive
- EMA to review and address the comments categorised as follow:

Format

- Layout/font size -> fixed in final product
- Labels/vocabulary -> to review in line with the guidance

Relevance

- Reporter qualification -> more detailed vs. not relevant ?
- Origin country EEA/Non-EEA -> not always seen as a useful information
- Seriousness criteria -> reporting rules: currently only serious cases are reportable

Dashboard feedback from EV Users Group (2)

Data

- Seriousness Criteria, Duration Reaction/Event, Time interval administration/reaction, Reaction recur on re-administration, Outcome reaction/event, Evaluation of Causality, Indication/Concomitant Treatments - > available in Phase 2

- Age Groups 64-80 and 80+ needed -> feasibility to assess

- Split by Year -> technically difficult (size and performance)

Guidance

- Glossary/explanation, interpretation, detailed guidance -> work ongoing at the EV-Expert Working Group level; when mature, guidance to be circulated to the EV Users Group for review and comments

Conclusion

- Dashboard to be finalised following the feedback received from the EV Users Group
- Guidance to be circulated to the EV Users Group for review and comments
- Phase 1 release planned by end 2011 – aggregated data information for Centrally Authorised Products
- Phase 2 release planned by end 2012 - aggregated data information for all medicinal products + access to restricted data fields