EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PCWP

Outline of Revised EudraVigilance Access Policy (medicines for human use)

8 September 2010

EudraVigilance Access Policy

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

Proposals to Progress (1)

EMA assessed all comments made during the public consultation and proposes the following approach in line with the European Ombudsman recommendation:

- Proactive and reactive information disclosure will be complementary in the sense that
  - Maximum data are released proactively
  - Needs of the public are met
  - Requirements of personal data protection are adhered to
- No further reactive information disclosure is required

Proposals to Progress (2)

- European Medicines Regulatory Authorities maintain full access to all data held in EudraVigilance and all tools related to signal detection and data analysis
  - Further enhancements of EudraVigilance will be carried out in line with the EudraVigilance project plan 2010 to 2013 as adopted by the EV-SC at their meeting in February 2010

Proposals to Progress (3)

- Healthcare professionals, the general public, marketing authorisation holders and research organisations will all have access to the same data set for spontaneous reports:
  - EMA carried out an assessment on all ICH E2B ICSR data elements to ensure full compliance with EU data protection legislation (Annex 1 of the policy)
  - Of the approximately 220 data elements access will be granted to around 25% of the data elements

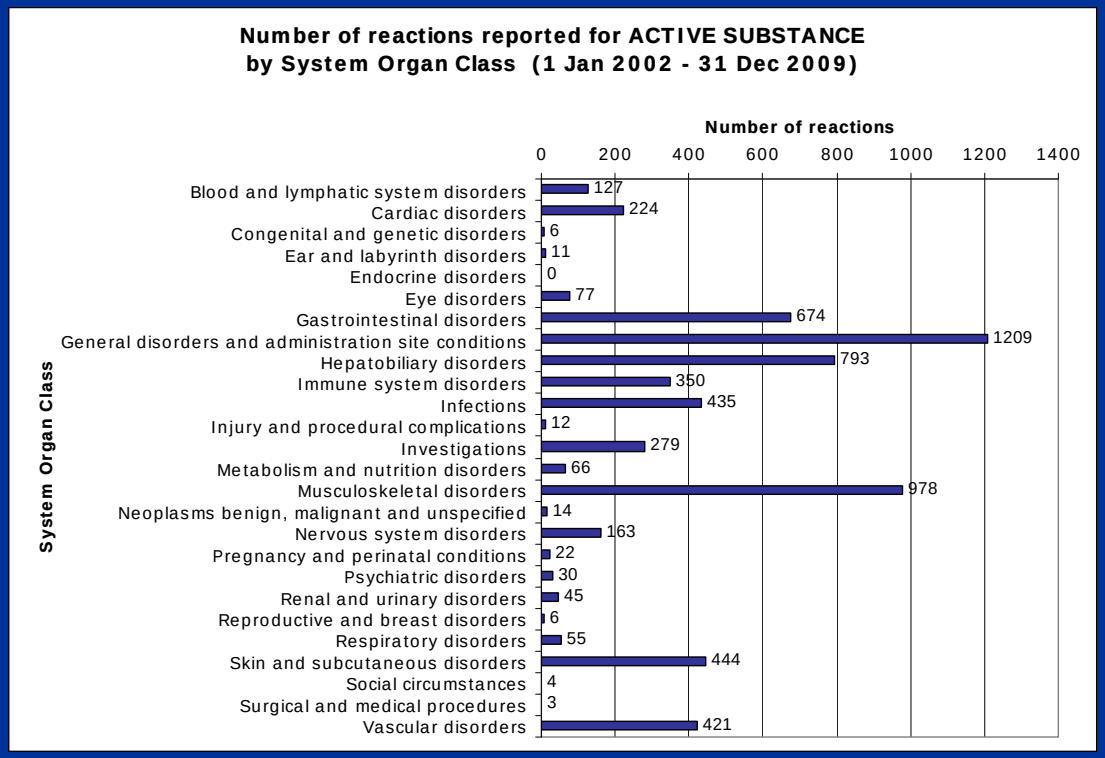
Proposals to Progress (4)

Tools by which access to EV data will be provided:
Healthcare professionals and the general public

- In line with EO recommendations – 'a form which best serves their interest' and 'most comprehensible to them'
  - Aggregated adverse reaction data on the EMA website searchable by defined parameters (e.g. product, active substance, reaction, age group, gender, time period)
  - Download/Print functions for search results (e.g. summary line listings or individual reports based on defined data elements ensuring compliance with personal data protection legislation)
  - Clear guidance on interpretation of the data

Proposals to Progress (4)

Example of aggregated adverse reaction data (Annex 2 of the policy)



Proposals to Progress (4)

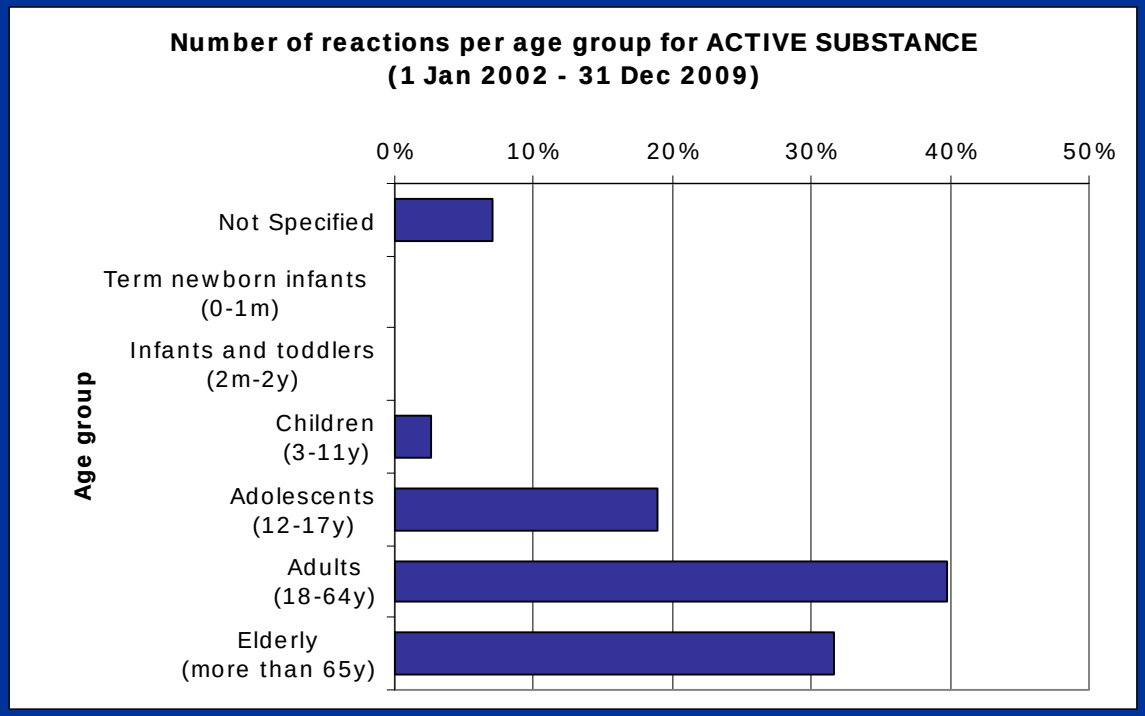
Example of aggregated adverse reaction data (Annex 2 of the policy)

Number of reactions reported at Preferred Term level per System Organ Class (SOC)

SOC	Reaction Preferred Term	Total	EEA	Non EEA
Cardiac disorders				
	Acute myocardial infarction	6	0	6
	Angina pectoris	1	0	1
	Arrhythmia	19	5	14
	Arteriosclerosis coronary artery	3	0	3
	Atrial fibrillation	22	2	20
	Atrioventricular block	5	2	3
	Cardiac failure	14	11	3
	Cardiotoxicity	10	0	10
	Hypertensive heart disease	2	0	2
	Myocardial fibrosis	1	0	1
	Myocardial infarction	36	11	25
	Myocardial ischaemia	2	1	1
	Nodal arrhythmia	1	0	1
Congenital, familial and genetic disorders				
	Cleft lip and palate	1	1	0
	Congenital anomaly	2	1	1
	Congenital aortic stenosis	1	0	1
	Congenital eyelid malformation	1	1	0
	Dysmorphism	3	2	1
	Epidermolysis	1	1	0

Proposals to Progress (4)

Example of aggregated adverse reaction data (Annex 2 of the policy)



Proposals to Progress (5)

Tools by which access to EV data will be provided:
Marketing Authorisation Holders*, ** and Research Organisations

- In line with EO recommendations – 'a form which best serves their interest'
  - Signal detection and data analysis tools in the EudraVigilance Data Warehouse and Analysis System (EVDAS)

* **Sender based access to ICSRs will be maintained**

** **Product specific detailed ICSR access will be granted once the new legislation comes into force and the new IDMP standards will be available**

Proposals to Progress (6)

Pre-requisites

- Initiation of the EudraVigilance Data Quality Management Process
- Conduct technical adaptations to EudraVigilance in line with the project plan agreed with the EV-SC in February 2010

Proposals to Progress (7)

Implementation in a stepwise approach

- Healthcare professionals and the general public
- Marketing Authorisation Holders and Research Organisations
  - Initially centrally authorised medicinal products stepwise extended to all products authorised in the EEA
- Until the Access Policy is technically implemented, reactive information requests will be dealt with by the Agency in line with the proposals as described above

Proposals to Progress (8)

Follow-up of the recommendations of the EDPS

- Develop a harmonised approach in the areas recommended by the EDPS jointly with Member States
  - EV-EWG has initiated review of the EDPS recommendations in collaboration with the EV-SC
  - Guidance is under development in line with the EV-EWG work programme 2010

Proposals to Progress (9)

- Proposal was discussed and supported by:
  - EV-SC at their meeting on 3 June 2010
  - HMA at their meeting on 6 July 2010
- Discussion of the approach at the September/October meetings of the PCWP, HCPWG, CHMP, CHMP PhVWP, EV-EWG
- EMA aims to adopt the EV Access Policy at the autumn 2010 Management Board and HMA meetings

Proposals to Progress (10)

- Establish a 'EV Access Policy Users Group' with representatives from the PCWP and the HCPWG to discuss implementation aspects e.g.
  - Query functions and output formats
  - Drafting of guidance to stakeholders on the usage and interpretation of the data
- First meeting to be organised on 28 October 2010 in the context of the HCPWG

Acronyms

EO: European Ombudsman

EV-SC: EudraVigilance Steering Committee

EDPS: European Data Protection Supervisor

HMA: Heads of Medicines Agencies

HCPWG: Healthcare Professionals' Working Group

CHMP: Committee for Medicinal Products for Human Use

CHMP PhVWP: Pharmacovigilance working party

EV-EWG: EudraVigilance Expert Working Group