EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EudraVigilance New Developments and Access to EudraVigilance Data

Second Stakeholders Forum on the implementation of the new Pharmacovigilance legislation, 17 June 2011

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Topics to be addressed

- Update on enhanced EudraVigilance functionalities in the context of the new legislation
- Access to adverse reaction data held in EudraVigilance

Support use of international standards

- Implementation of the new ISO Individual Case Safety Report (ICSR) standard
  - Final standard expected end of 2011/beginning 2012

➡ Improved adverse reaction reporting and analysis

- Implementation of the new ISO Identification of Medicinal Product (IDMP) standards
  - Final standards expected end of 2011/beginning 2012

➡ Enhanced data quality, analysis and signal detection

Support new adverse reaction reporting rules

- Reporting by patients and consumers

Health Care Professionals

National Competent Authority

Patients Consumers

Reporting by patients, consumers and health care professionals to national Competent Authority

Support new adverse reaction reporting rules

- Simplified reporting rules for marketing authorisation holders

Health Care Professionals

Marketing Authorisation Holder

EudraVigilance Human

Patients Consumers

Reporting by marketing authorisation holders to EudraVigilance only

Support new adverse reaction reporting rules

- Re-routing of ICSRs to the Member State where the adverse reaction occurred

Health Care Professionals

National Competent Authority

Marketing Authorisation Holder

EudraVigilance Human

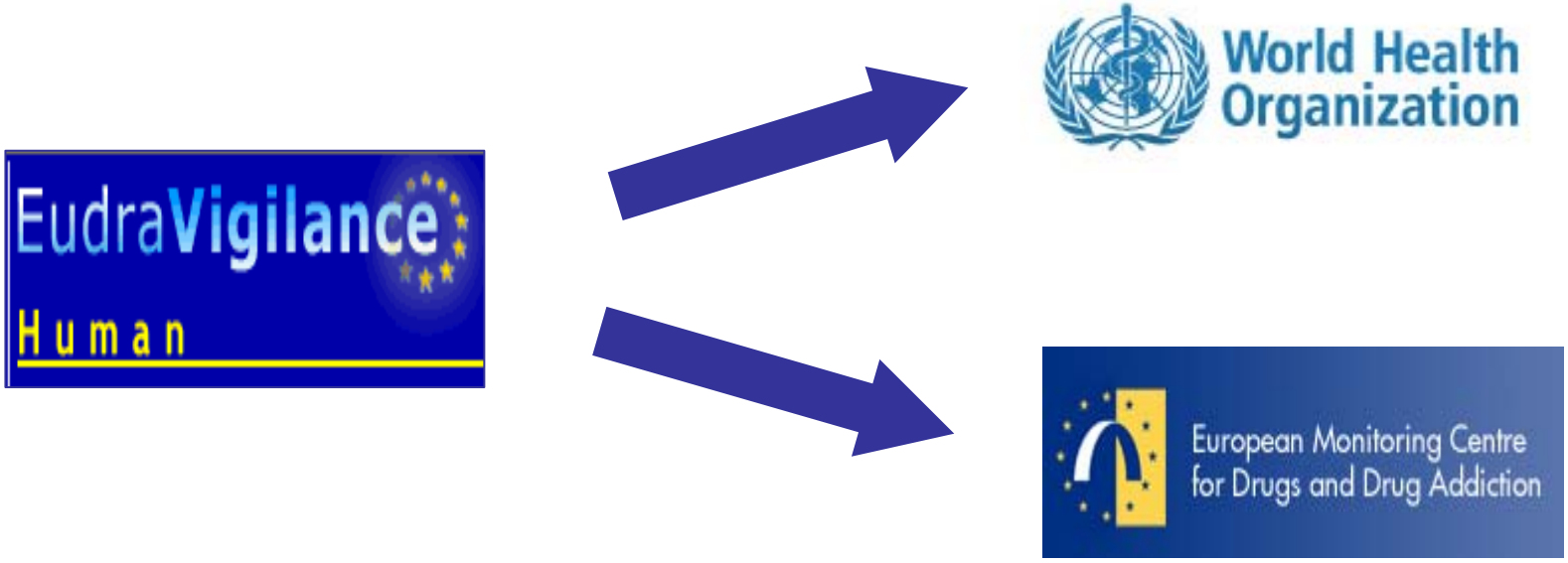
Patients Consumers

Re-routing of adverse reactions to the national Competent Authority of the country where the adverse reaction occurred

Support new adverse reaction reporting rules

- Reporting of ICSRs by the Agency to WHO
- Exchange of information on abuse of medicinal products with the Agency and the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA)

Adverse reactions
occurring in the EU/EEA



Adverse Reactions resulting
from abuse
of medicinal products

High quality of adverse reaction data

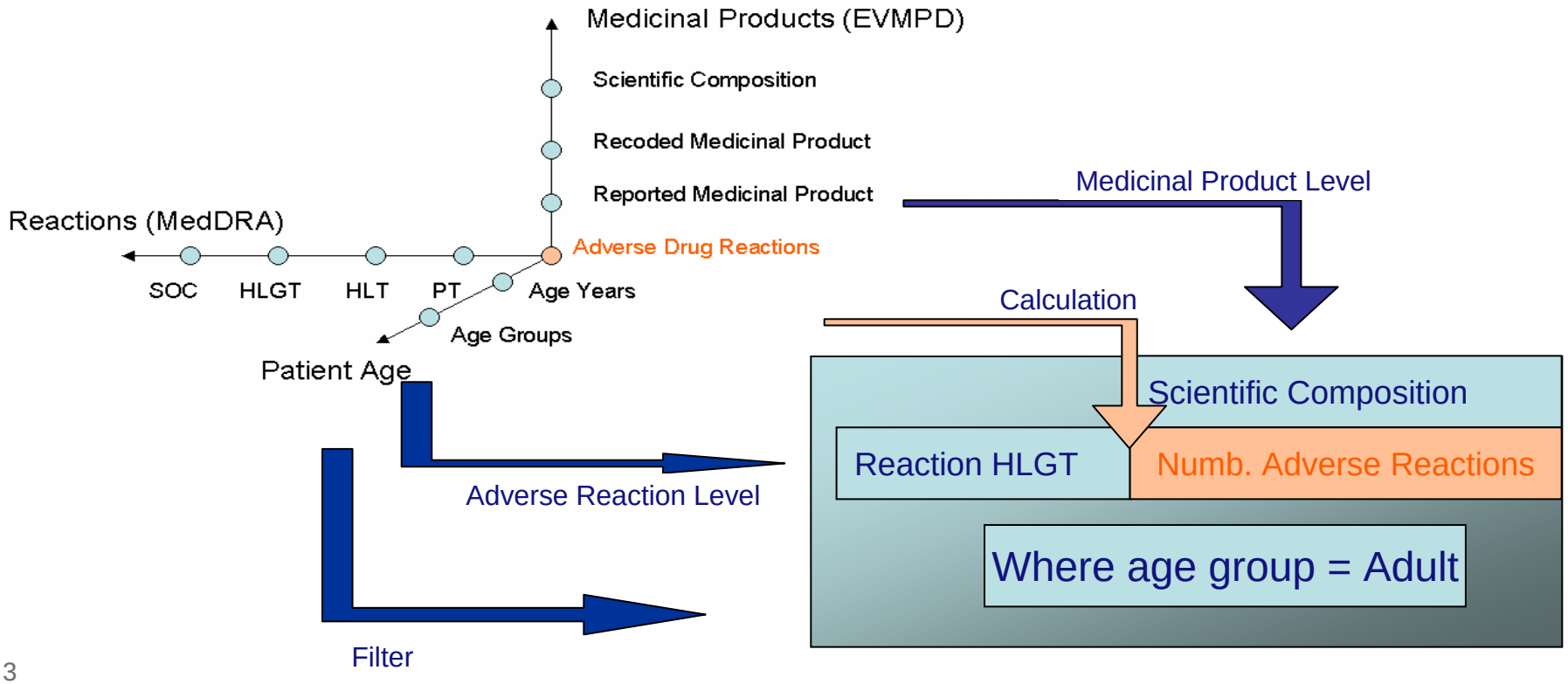
- Functionalities to support the operation of procedures that ensure quality and integrity of the information collected in EudraVigilance
  - Validation or ICSRs against defined business rules
  - Duplicate detection and management
  - Coding of product information
  - ICSR data quality review

➡ Important for conduct of signal detection and benefit risk assessment

➡ Ensure that accurate and reliable data held in EudraVigilance are made available (EudraVigilance Access Policy)

Support Signal Detection and Evaluation

- Enhanced functionalities for NCAs, Agency and MAHs
  - Access defined at the level of the EV Access Policy

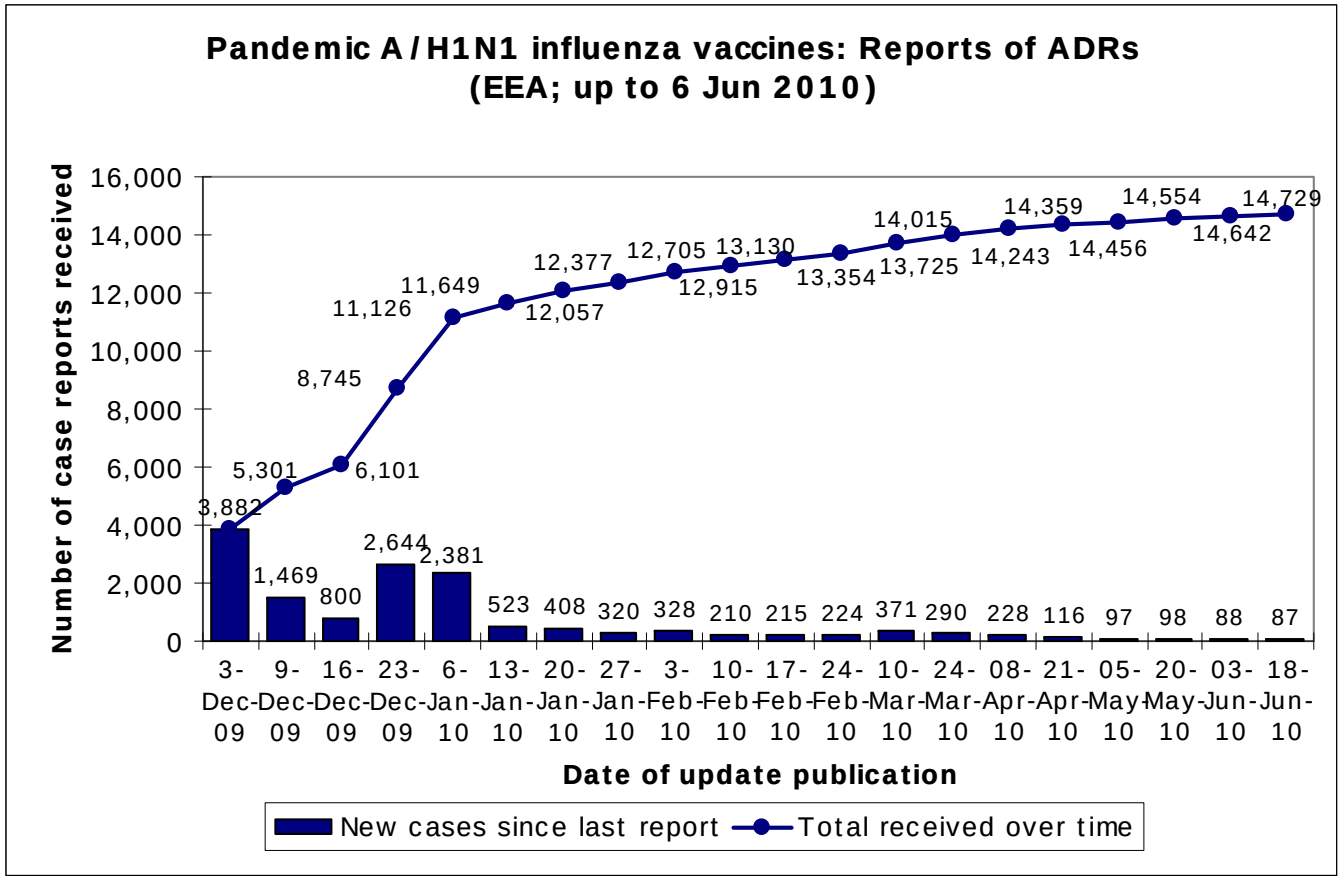


Access to data held in EudraVigilance

- Full access to EEA Competent Authorities of the Member States, to the Agency and the Commission
- Access to be implemented for patients, consumers and health care professionals
  - Data set for spontaneous reports
  - Compliance with EU personal data protection legislation
  - Access to be provided by easy to use data retrieval functions and report outputs at the Agency's website

    e.g. as aggregated summary reports or individual case report forms

Access to data held in EudraVigilance



Access to data held in EudraVigilance

- Access for marketing authorisation holders planned as follows:
  - Data set for spontaneous reports
  - Compliance with EU personal data protection legislation
  - Access to EudraVigilance Data Warehouse and Analysis System (EVDAS) and data analysis and signal detection tools
  - Results of EVDAS queries to be downloadable and printable either in aggregated format (e.g. as tabular or graphic presentations, line listings) or as individual report forms
  - Downloads in ICH E2B format and in accordance with the ICH M2 message specifications

Access to data held in EudraVigilance

- Access to research organisations planned as follows:
  - Ad-hoc committee to review requests for research
  - Agency may refuse access if there is no public health value or if there is conflict with legal responsibilities of the Agency
  - Data set for spontaneous reports
  - Compliance with EU personal data protection legislation
  - Access to EVDAS and its data analysis and signal detection tools
  - Results of EVDAS queries to be downloadable and printable either in aggregated format (e.g. as tabular or graphic presentations, line listings) or as individual report forms

Discussion

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