

# Pharmacovigilance

Safety Monitoring of Medicines  
from an European perspective

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EMA slides, facts & figures by authorisation of Dr.Brosch, EMA © 1995-2007

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## Introduction

- The specific aims of pharmacovigilance (WHO-definition)
  - *improve patient care and safety* as well as
  - *improve public health and safety* in relation to the use of medicines,
  - contribute to the *assessment of benefit, harm, effectiveness and risk of medicines*,
  - encouraging their *safe, rational and more effective* (including cost-effective) use.
  
- Medicines should fulfil the aspects of
  - quality
  - safety and
  - efficacy.

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## Involved Partners

- \* □ Health Professionals
- \* □ Hospitals and Academia
- \* □ Patients
- \* □ Pharmaceutical Industry
- \* □ National Pharmacovigilance Centres
- \* □ International Pharmacovigilance Centres
  - European Medicines Agency, London
  - WHO Monitoring Centre, Uppsala
- \* □ ...

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## Pharmacovigilance in the Medicines Life-Cycle & Reporting

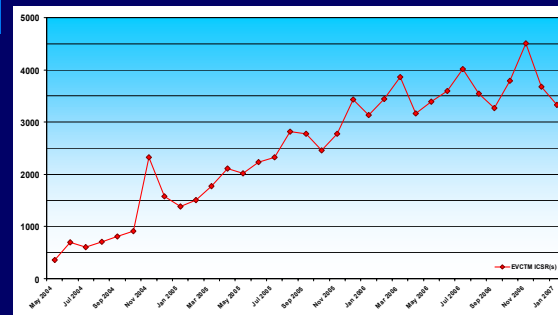
- The need of reporting
  - importance of *structured **communication*** (!)
  - "If you don't show up, no one will know"
  
- Types of reporting
  - Spontaneous reporting
  - Periodic reporting (especially for new products on the market)
  
- The Medicines Life-Cycle
  - Pre-Marketing Authorisation
    - Clinical Studies
  - Post Marketing Authorisation

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## Pre-Authorisation Reporting

- All Suspected Unexpected Serious Adverse Reactions (SUSARs)
- Sponsors to report to
  - Concerned Member State(s) (paper or electronically)
  - *Concerned Ethics Committees (on paper)*
  - EudraVigilance Clinical Trial Module (EVCTM) at the EMEA (electronically)
- Legal Basis: Volume 10 of EudraLex – Applicable to sponsors for all interventional clinical trials as of 1 May 2004

## Topic 1: e-Reporting Pre-Authorisation (2)

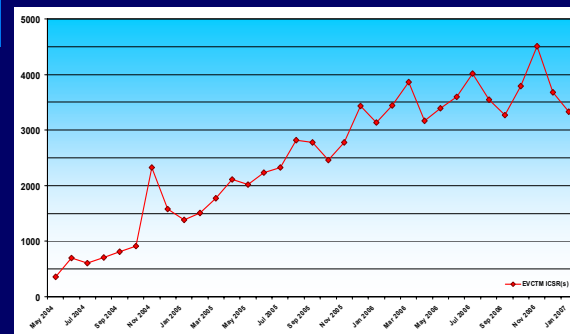


Number of ICSRs transmitted per month by Sponsors to EVCTM from May 2004 - Jan 2007

## Post-Authorisation Reporting

- Adverse Drug Reactions / Individual Case Safety Reports (ICSRs)
- Electronic reporting:
  - Mandatory e-reporting of ICSRs
    - As of 20 November 2005 for all medicinal products authorised in the EEA, independent of the authorisation procedure
  - Definition of exceptional circumstances that prevent electronic reporting
    - Mechanical, program, electronic or communication failure
  - Fall-back procedures to maintain expedited reporting compliance are established
- Periodic Safety Update Reports PSURs (from Marketing Authorisation Holders to the Competent Authorities)
- Legal Basis: Volume 9A of EudraLex

## e-Reporting Post-Authorisation

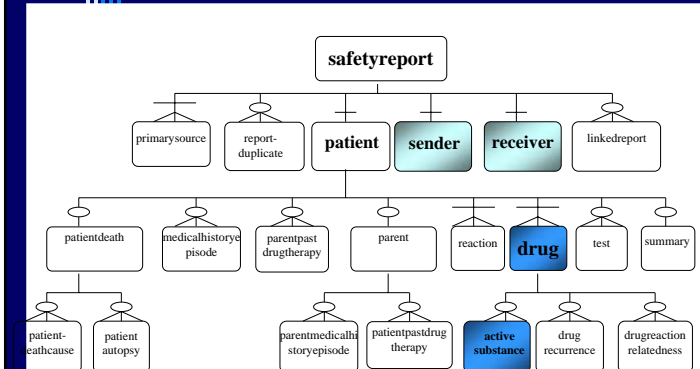


Number of ICSRs transmitted per month by MAHs to EVPM from Jan 2003 - Jan 2007

# EudraVigilance

## Main System Components

## Content of ICSRs (ICH-definition E2.)



## System Components & Acronyms

- \* □ EVWEB: EudraVigilance Web Application
- \* □ EVDBMS: EudraVigilance Database Management System
- \* □ EVCTM: EudraVigilance Clinical Trial Module
- \* □ EVPM: EudraVigilance Post-Authorisation Module
- \* □ EVMPD: EudraVigilance Medicinal Product Dictionary
- \* □ EVDAS: EudraVigilance Data Analysis System

## EudraVigilance Gateway

- \* □ One common electronic reporting point within the European Union
  - \* ■ Re-routing of messages to the specified receiver
- \* □ One standard for all Competent Authorities and Sponsors
  - \* ■ Compliant with ICH M2 standards (XML)
  - \* ■ Exchange SUSARs in E2B(M) format
  - \* ■ Provide Non Repudiation through Message Disposition Notification (MDN)
  - \* ■ Provide acknowledgment of acceptable file structure and validation outcome



## EVDBMS

- \* □ Fully compliant with ICH E2B(M), M1 and M2 standards
- \* □ Automated message processing, validation, classification and storage of ICSRs/SUSARs depending on the module specified as receiver
- \* □ Interface with EVWEB for
  - Interactive data entry with full access to all standard terminologies
  - Scientific and administrative queries (restricted access)

## The Future...

- \* □ Obvious Trend to integrated Healthcare Record Systems (HCR, EHR...)
  - US-initiatives
  - EU action plan on eHealth
  - -> Pharmacovigilance aspects to be considered in EHRs
- \* □ The challenge of Interoperability (Large-Scale-Pilots in the EU...)
- \* □ ...
- \* ...a study analysing effects of new technologies is in progress ...

**Thank You**

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