EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# Pharmacovigilance in EU:
## where have we come from?

5th Stakeholders forum on the implementation of the new pharmacovigilance legislation

June M Raine
PhVWP Chair

An agency of the European Union

# Outline of presentation

The early days
Regulatory evolution
Tackling the key issues
Challenges to come


LÄÄKELAITOS
LÄKEMEDELSVERKET
NATIONAL AGENCY
FOR MEDICINES


IRISH MEDICINES BOARD


MINISTERIO
DE SANIDAD
Y CONSUMO


agencia española
de medicamentos y
productos sanitarios


MHRA


BfArM


infarmed
Instituto Nacional da Farmácia
e do Medicamento


COLLEGE
TER BEOORDELING VAN
GENEESMIDDELEN
C B G
M E B
MEDICINES
EVALUATION
BOARD


Lareb


AIFA
Agenzia Italiana del Farmaco

gence française
e sécurité sanitaire
es produits de santé


LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY


Paul-Ehrlich-Institut
Bundesamt für Sera und Impfstoffe

# Pharmacovigilance Working Party

Established in 1995 as a forum for dialogue

- Organisational matters
- Product related issues at CHMP request
- Other inquiries at request of National Authorities

*Dual mandate – reporting to CHMP, Heads of Agencies*

# Drugs safety shake-up urged

FT 28.01.05

EU watchdog calls for better monitoring ● Slower release times sought for products ● Comments set to spark transatlantic debate

Drug firms warned to publish trial data after safety fears

How do we stop

ARE DRU… MEDICINE?

600,000 users

PHARMACEUTICAL INDUSTRY

Ministers set rules for

Europe urged to keep eagle on drugs

# European Risk Management Strategy

European Medicines Agency

Heads of Medicines Agencies

London, 16 December 2005
Doc. Ref. EMEA/424988/2005

**European Risk Management Strategy (ERMS) Facilitation Group**

**Summary**

At the meeting in Edinburgh in July 2005, HMA Human agreed the membership and remit of a permanent working group of the HMA and the EMEA – The ERMS Facilitation Group. A rolling 2-year Work Programme (2005-2007) has been agreed and is available via the following link (add website link)

**Background**

The HMA Human Ad Hoc Working Group on ERMS was first established in July 2002. The Working Group, comprising participants from Denmark, France, Germany, Spain, UK and EMEA and later joined by the Netherlands and Sweden, produced an initial report on the establishment of the Strategy which was published in January 2003. On 2 May 2005 in Luxembourg, HMA Human agreed to the publication of a progress report on implementation of the ERMS and of an Action Plan. These were published on the HMA and EMEA websites on 11 May 2005.

# European Commission Review

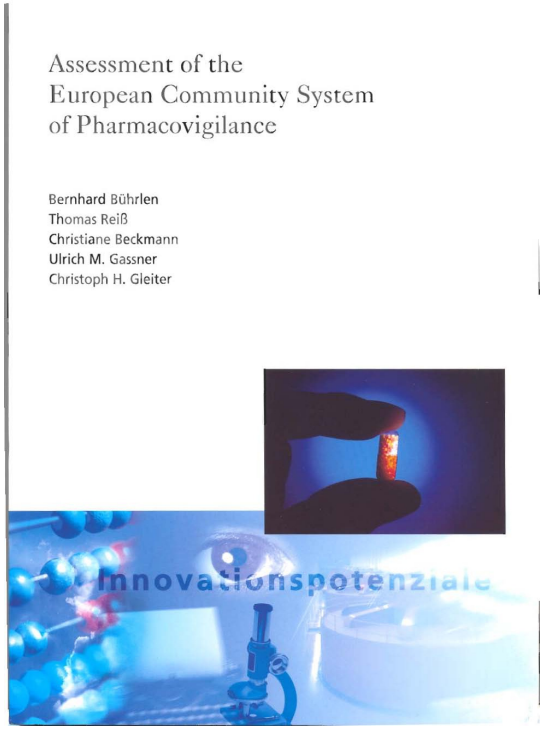
Lack of clear roles & responsibilities

Slow decision-making

Low levels of transparency

Lack of proactive & proportionate monitoring

Lack of inclusiveness of stakeholders




# Pharmacovigilance Working Party

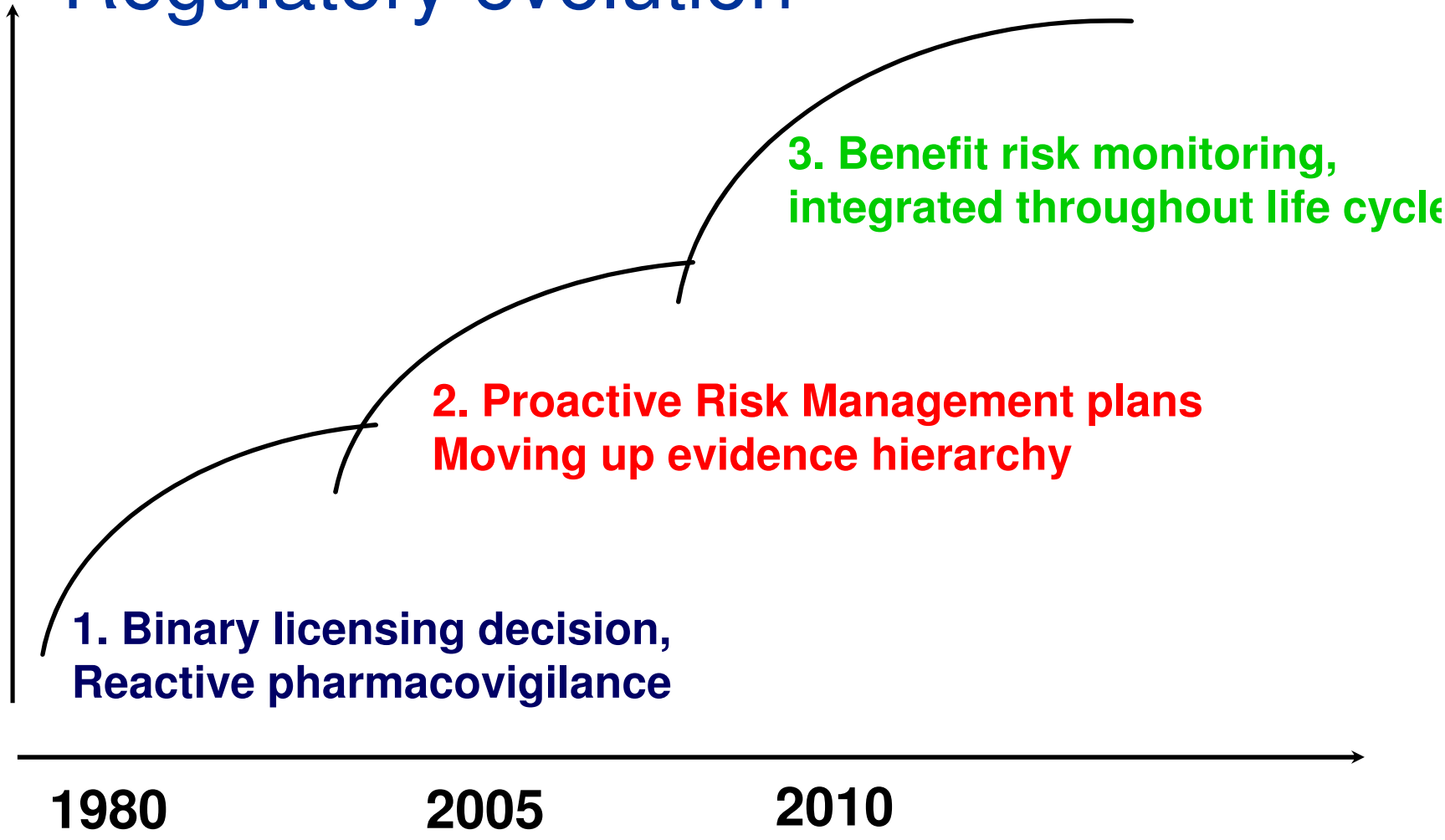
## Mission

" ***To provide advice on the safety of medicinal products authorised in the EU and the investigation of adverse reactions to enable effective identification, assessment and management of risk..... at any phase in the product life cycle"***

# Pharmacovigilance Working Party - activities

- Evaluation of potential signals arising from spontaneous reporting
- Risk management and provision of advice on confirmation and quantification of risk and on regulatory options
- Monitoring regulatory action and the outcomes of such action.
- Setting standards for procedures and methodologies to promote good vigilance practice
- Promotion of communication and exchange of information between the EMA and national competent authorities (NCAs)
- International cooperation

# Regulatory evolution

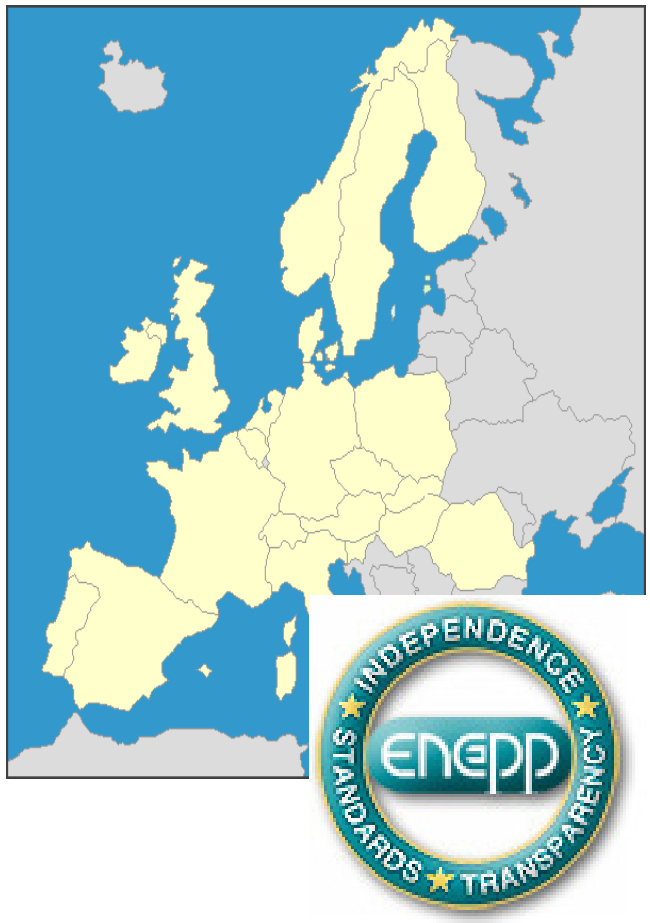


# Tackling the key issues

- Improving science, methodologies
- Filling gaps in expertise
- Involving the patient perspective
- Transparency and communications
- Optimising use of resources

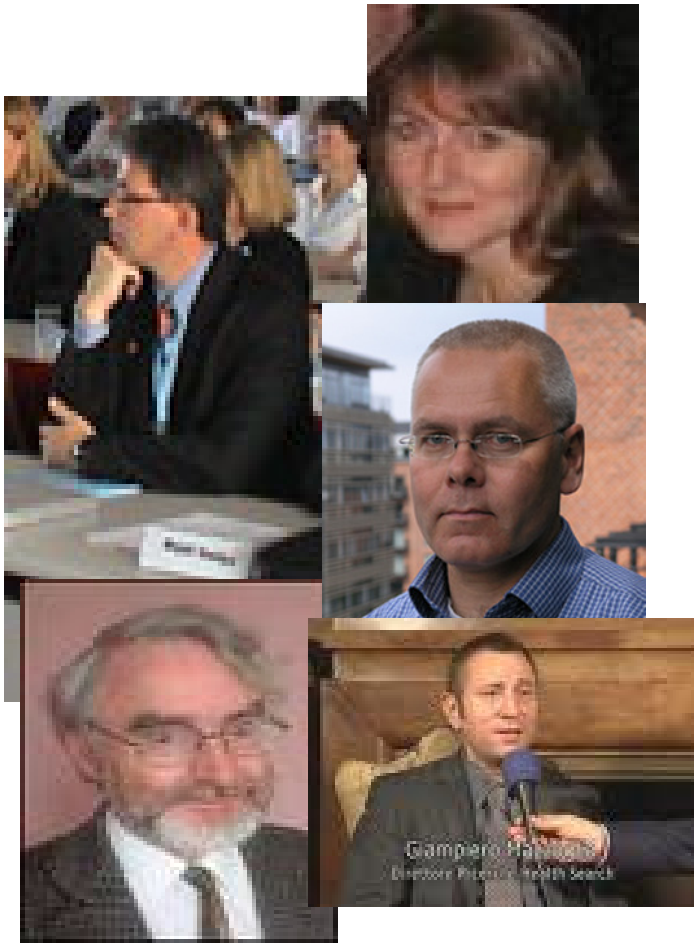
# EudraVigilance

- Common data platform
- Detecting signals for EU population of 500 million
- Pilot projects to develop MS processes for signal detection and signal management




- Identify and promote access to EU pharmacoepi resources
- Facilitate conduct of high-quality, multi-centre, independent PASS
- Improve research standards, independence and transparency
- Stimulate collaboration
  - 102 centres
  - 14 specialist networks
  - 22 data sources

# Filling the gaps in expertise



Co-opted Experts have joined PhVWP from Denmark, France, Germany, Italy, Netherlands, Sweden, and UK in:

- Pharmacoepidemiology
- Biostatistics
- Risk management
- Risk communication
- Biotechnology
- Paediatrics


# Patient Observers

Valuable perspective in Pharmacovigilance Working Party debate

*Albert van der Zeijden*
*Chairman of IAPO*

*Greetje Goossens*
*EMP counsellor*

*Cristina Cabrita BEUC*

# Communications and transparency

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

HMA
Heads of Medicines Agencies

26 April 2012
EMA/CHMP/PhVWP/262424/2012
Patient Health Protection

## PhVWP Monthly report on safety concerns, guidelines and general matters

April 2012 – Issue number: 1204

The CHMP Pharmacovigilance Working Party (PhVWP) held its April 2012 plenary meeting on 16-18 April 2012.

### Safety concerns

Discussions on non-centrally authorised medicinal products are summarised below in accordance with the PhVWP publication policy. The positions agreed by the PhVWP for non-centrally authorised products form recommendations to Member States. For the publication policy, readers are referred to http://www.ema.europa.eu/docs/en_GB/document_library/Report/2009/10/WC500006181.pdf.

The PhVWP also provides advice to the Committee for Medicinal Products for Human Use (CHMP) on centrally authorised products and products subject to ongoing CHMP procedures at the request of the CHMP. For safety updates concerning these products, readers are referred to the meeting highlights from the CHMP published under http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/landing/news_and_events.jsp&mid=.

***Blue dyes (e.g. Patent Blue V, Sulphan Blue) – Risk of serious allergic reactions***

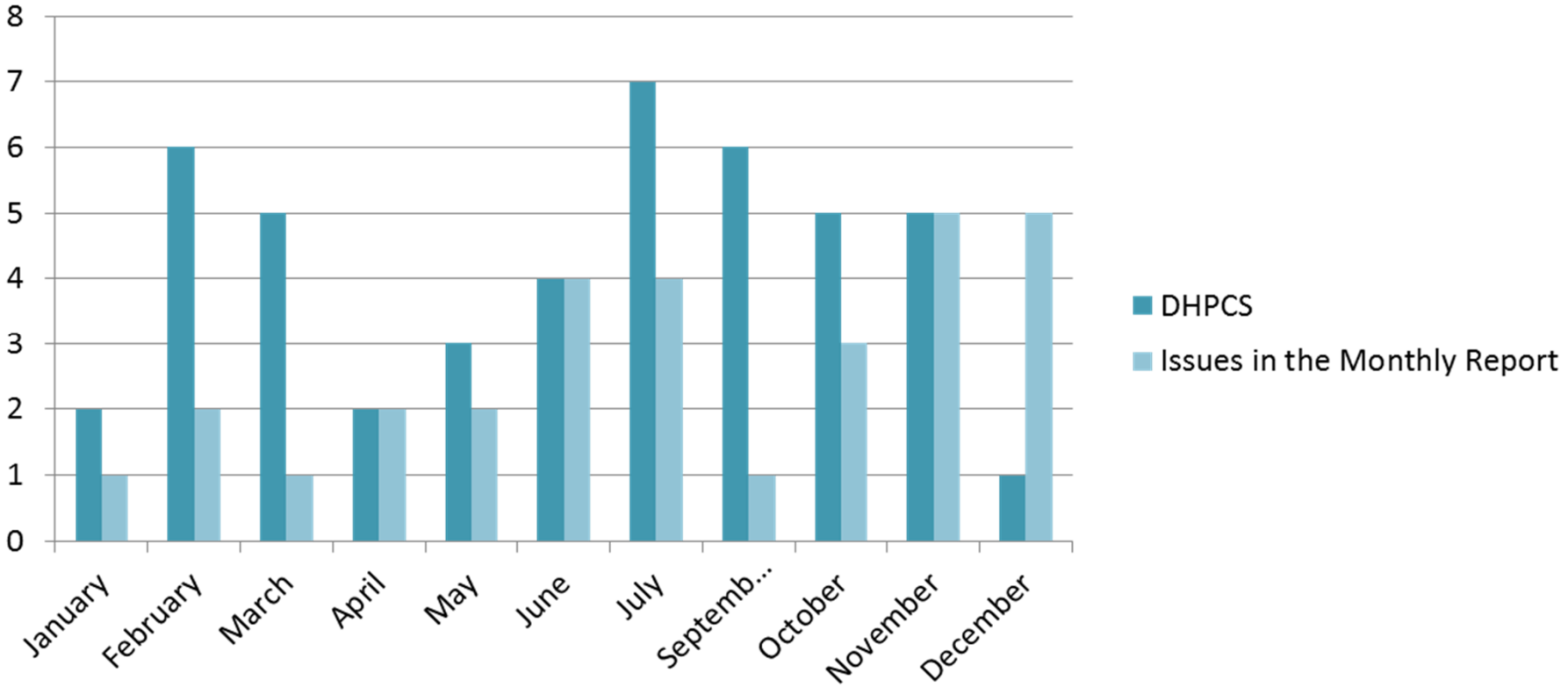
**Blue dyes used for lymphatic mapping during breast tumour surgery may cause serious allergic reactions, including anaphylaxis, and it is recommended that emergency facilities are available for at least 1 hour after their administration.**

First monthly report

- Sept 2009

30 issues published so far

# PhVWP communication and transparency 2011



CMDh

For further details, please see the relevant PhVWP Monthly Report and the related Publication Policy published on the EMEA website under CHMP Pharmacovigilance Working Party
?

Fluoroquinolones and risk of QT-interval prolongation

- Agreed wording in SmPC and PL

Selective serotonin reuptake inhibitors (SSRIs) (fluvoxamine, citalopram, escitalopram, fluoxetine and sertraline, paroxetine) and possible risk of male infertility due to sperm impairment

- Agreed wording in SmPC and PL

Class effect of Gonadotropin-releasing hormone agonists (buserelin, goserelin, histrelin, leuprorelin, nafarelin, triptorelin) on depression

- Agreed wording in SmPC and PL

Prescription-only proton pump inhibitors (omeprazole, esomeprazole/naproxen, omeprazole/ketoprofen, esomeprazole, lansoprazole, pantoprazole, rabeprazole) and risk of fractures of the hip, wrist and spine

- Agreed wording in SmPC and PL

Class effects of proton-pump inhibitors (dexlansoprazole, esomeprazole, lansoprazole, omeprazole, rabeprazole, pantoprazole) on magnesium blood levels in long-term users

- Agreed wording in SmPC and PL

Antiepileptics and possible risk of bone disorder

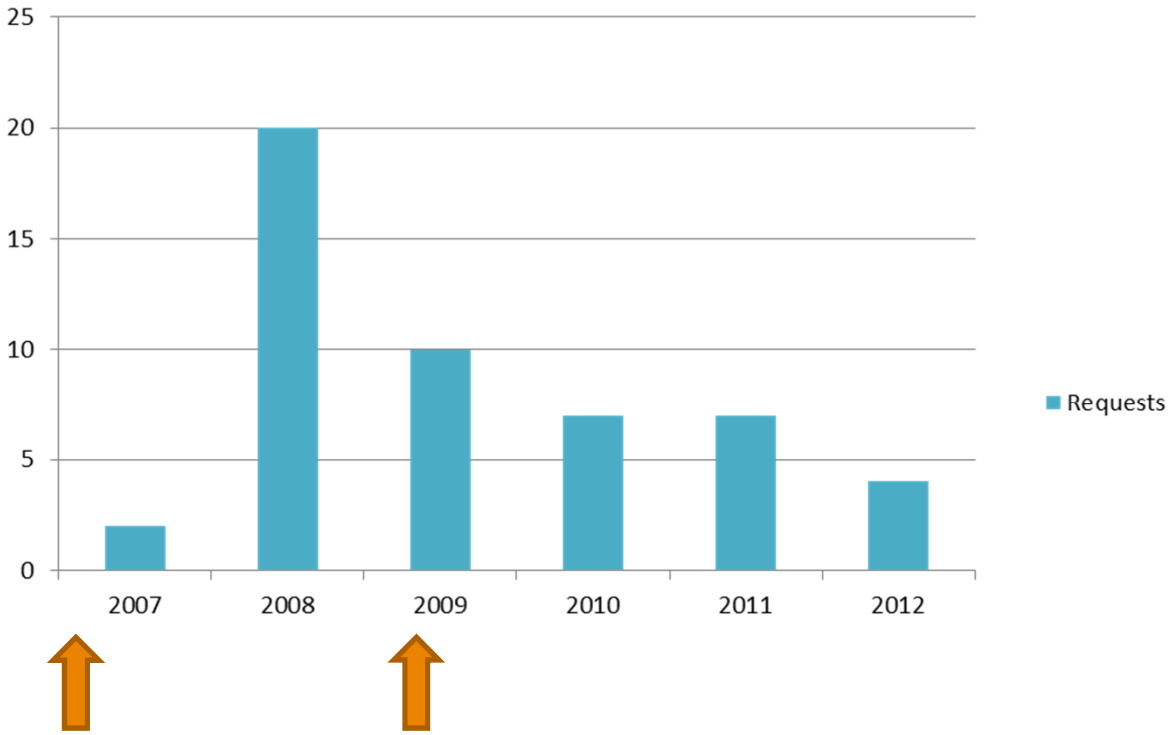
- Agreed wording in SmPC and PL

# Transparency

52 PhVWP recommendations published on HMA website since Jan 2008

More than 320 substances covered

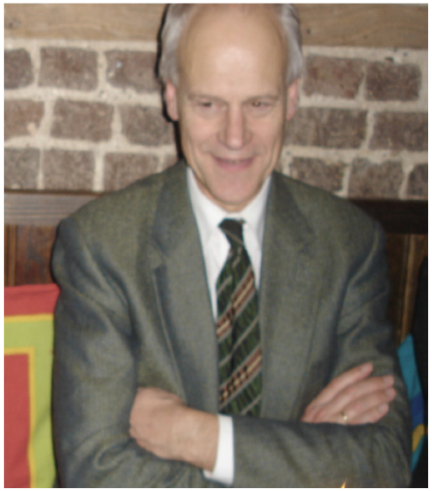
# Access to PhVWP documents




Dec 2006 - EMA Management Board Rules implementing Reg 1049/2001 on Access to documents

Publication first PhVWP Monthly Report

# Optimising use of resources



Heads of Medicines Agencies: PSSG - PSUR synchronisation Sub Group

jump to navigation
jump to content

HMA
Heads of Medicines Agencies: PSSG - PSUR synchronisation Sub Group

## EU-Harmonised Birth Dates and Data-Lock-Points

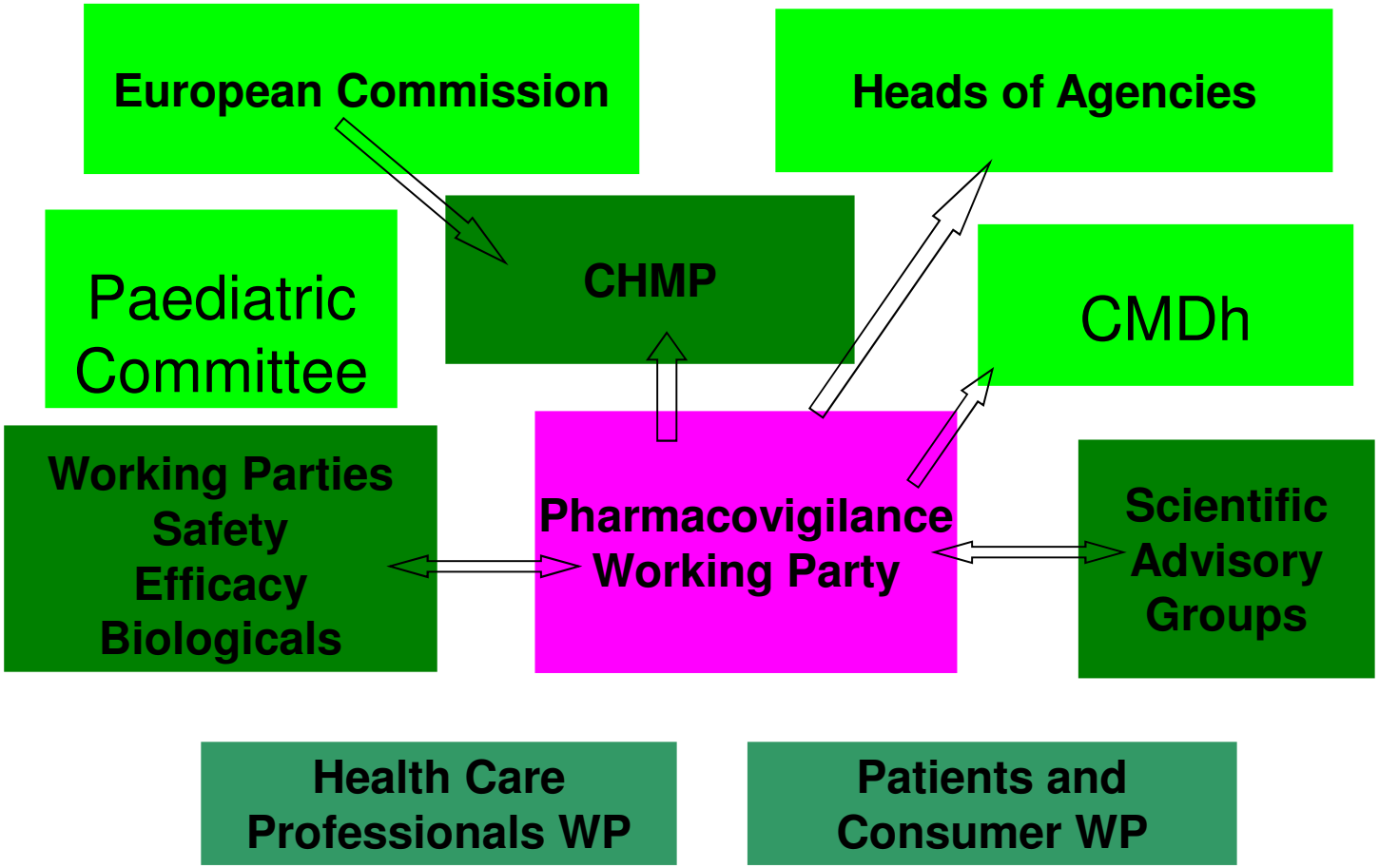
EU Harmonised Birth Dates, related Data Lock Points, allocated RMS (Pilot phase 2H2008 (41.09 kb)
Oct 2008
EU Harmonised Birth Dates, related Data Lock Points, allocated RMS (Pilot phase 1H2008) (24.97 kb)
Sep 2008

## PSUR-Harmonisation, Synchronisation and Worksharing Documents

Q & A Document to PSUR-Synchronisation and Harmonisation (28.34 kb) Oct 2008
Informative letter to MAHs (dated Feb 2008) (47.23 kb) Sep 2008
PSUR Work-sharing concept for veterinary medicinal products - Concept paper (Nov 2007) (222.57 kb)
Sep 2008

- *4:* Credits & Disclaimer

- Worksharing of periodic safety update reports
- Agreed analysis of latest information on safety in use


European Commission
Heads of Agencies
Paediatric Committee
CHMP
CMDh
Working Parties
Safety
Efficacy
Biologicals
Pharmacovigilance Working Party
Scientific Advisory Groups
Health Care Professionals WP
Patients and Consumer WP

# Challenges to come…

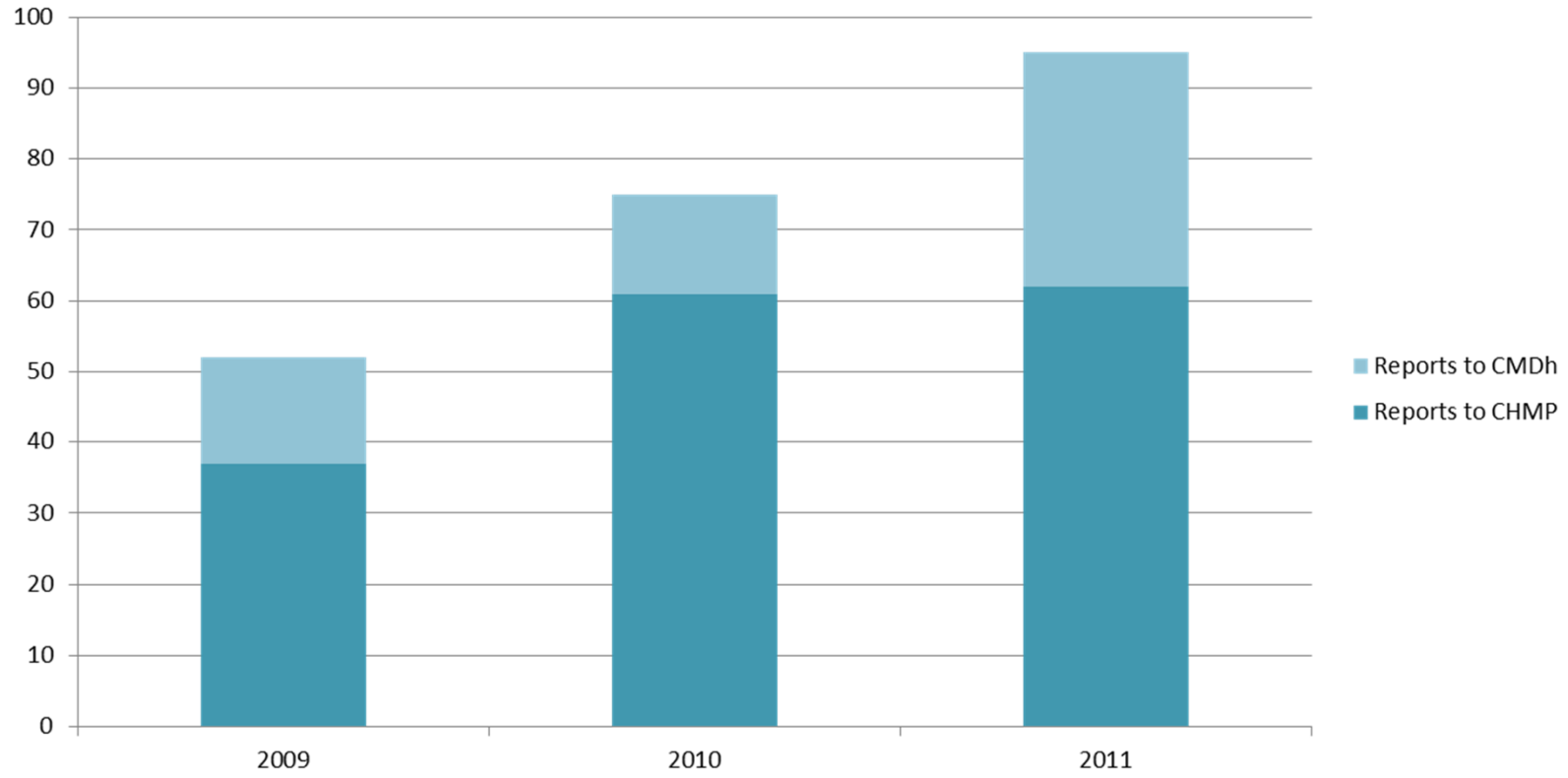
Maximising benefits of the new pharmacovigilance approaches while minimising burdens

Maintaining operational efficiency and quality systems

Continuing to strengthen science and methodologies

Making a real difference - effective risk minimisation

# PhVWP Reports for Centrally and Nationally authorised products 2009/2011



# Outcome of inspections of MAHs' Pharmacovigilance Systems

# Post-authorisation studies

PHARMACOEPIDEMIOLOGY AND DRUG SAFETY (2011)
Published online in Wiley Online Library (wileyonlinelibrary.com) **DOI**: 10.1002/pds.2209

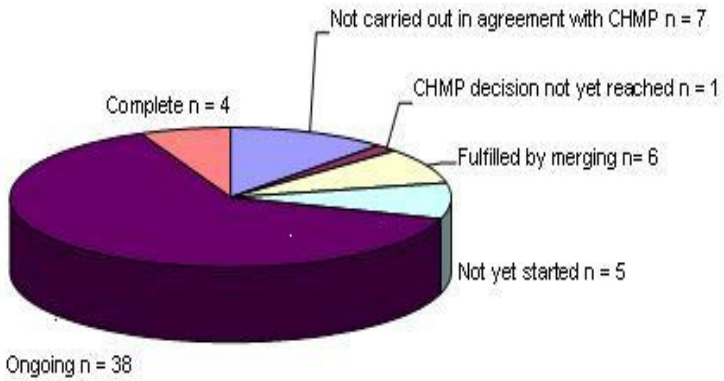
ORIGINAL REPORT

## European Medicines Agency review of post-authorisation studies with implications for the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

Kevin V. Blake[1]*, Stefanie Prilla[1], Sophie Accadebled[1], Peter Arlett[1], Stella Blackburn[1] and Henry Fitt[1]

[1] *Pharmacovigilance and Risk Management Sector, Patient Health P*
[2] *Medical Products Agency, Uppsala, Sweden*

When four new study reports from existing registries are excluded, for the remaining 43 studies, the median time to starting from the date of the positive CHMP opinion was 12.5 months (mean=14.5 months). The median planned duration of the 47 studies that were 'carried out' was 30 months (mean=42 months).



# Public health outcomes

Demonstrably  strengthening protection of public health– what this is all about

# Summary

Building on experience, pharmacovigilance in Europe has evolved into a co-ordinated network function

New legislation provides for clarity, proportionality and involvement of stakeholders

New legislation will support delivery of health outcomes based on better evidence

Opportunity to maximise public health protection while making best use of resources