EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

First experiences:
PRAC transparency

6th Stakeholders forum on the implementation of the new pharmacovigilance legislation

June M Raine
Chair, Pharmacovigilance Risk Assessment Committee

Outline of presentation

Where we have come from - legislative aims

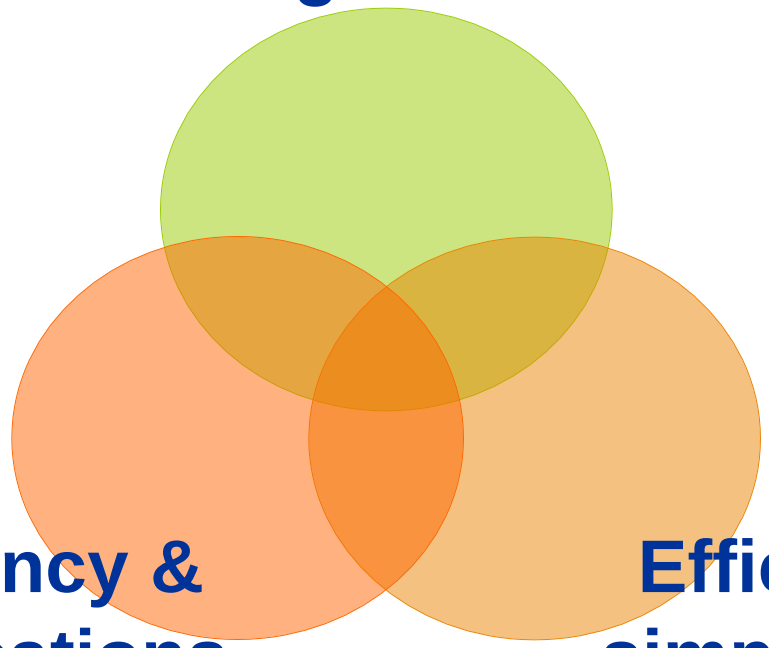
What is new - PRAC publications

- agendas and minutes
- safety communication
- notification of referrals

How is it working - first experiences

Where next - looking ahead

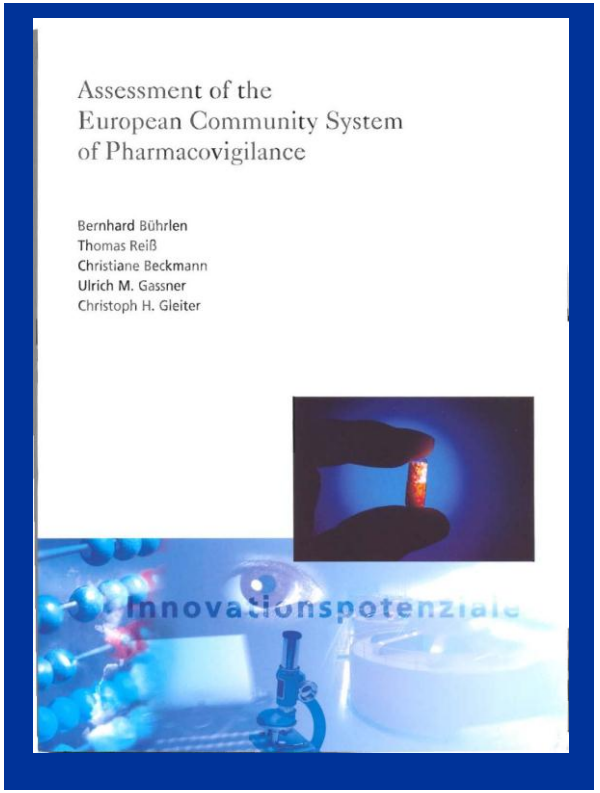
Pharmacovigilance legislative aims



European Commission Review 2006 found:

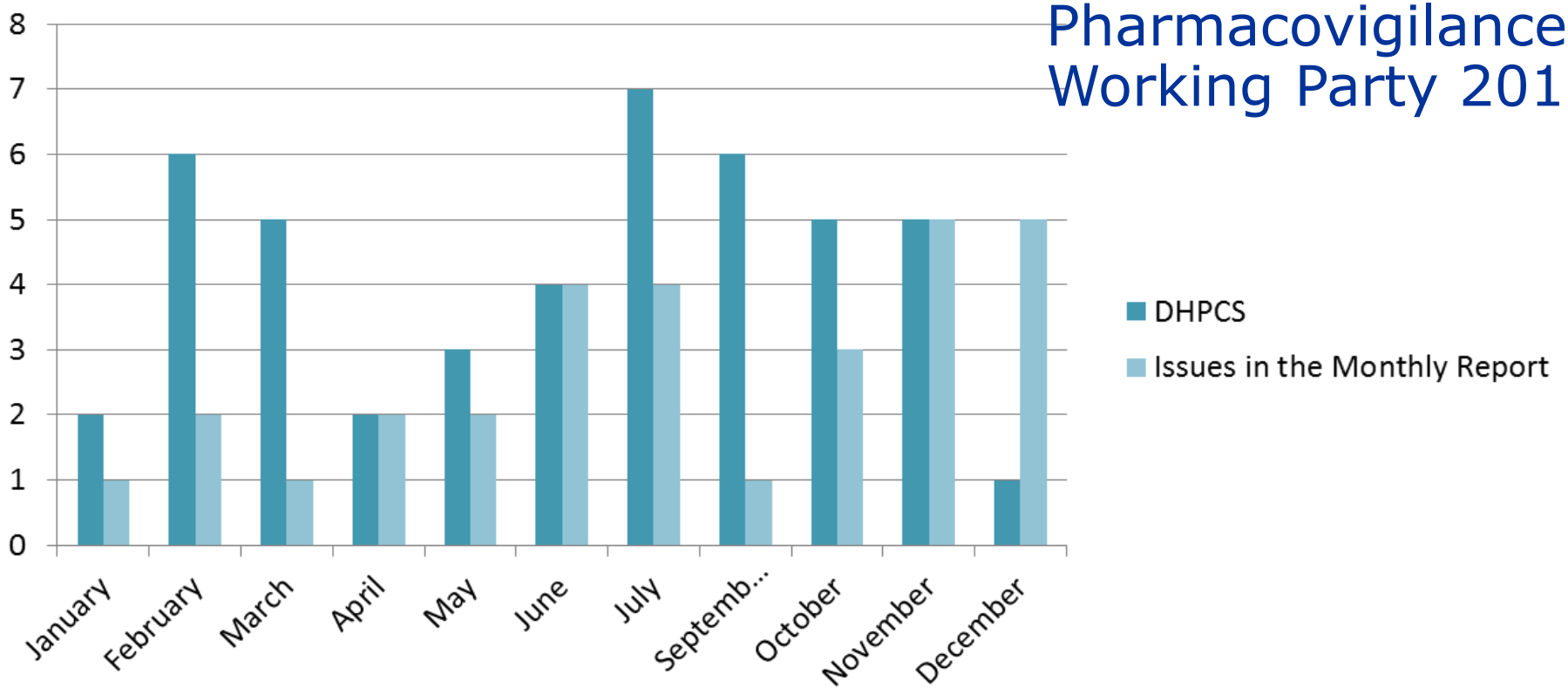
- Low levels of transparency

- Lack of inclusiveness of stakeholders

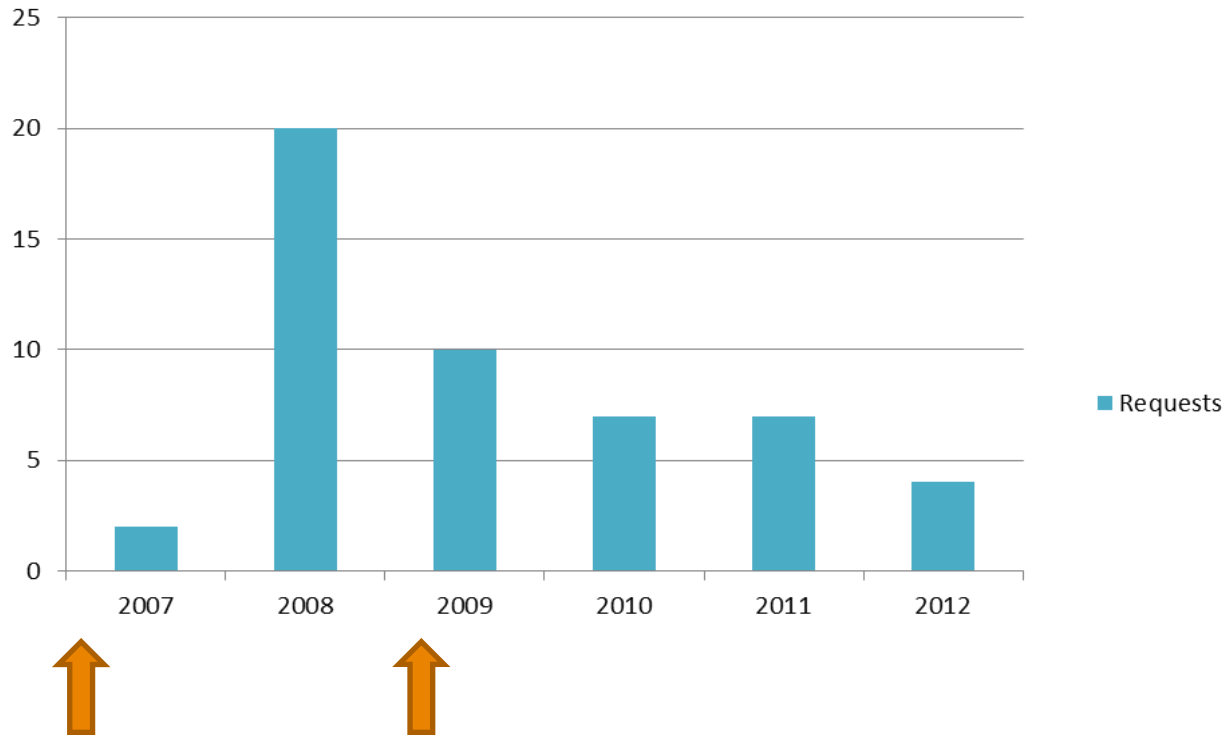


Transparency – first steps

Publications from Pharmacovigilance Working Party 2011



Requests for access to pharmacovigilance documents



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

Publication first PhVWP Monthly Report

Transparency- *H1N1 vaccines*

Regular publication of summary ADR data and signals

EMA published weekly summary of Eudravigilance data and signals

Highlighted importance of transparency on emerging safety data

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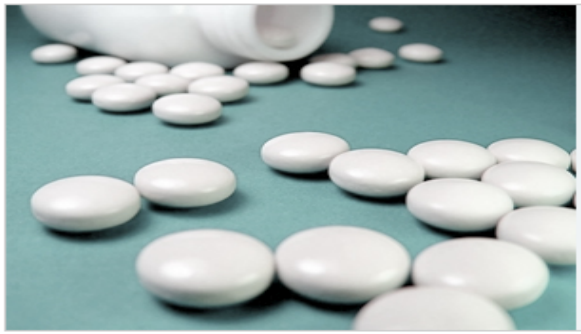
European database of suspected adverse drug reaction reports

Online access to suspected side-effect reports



On this website you can view data on **suspected side-effects** also known as suspected adverse drug reactions for authorised medicines in the European Economic Area (EEA).

This data is presented in a format called a **web report**. Currently the data only relates to medicines approved through the **centralised authorisation procedure**.

Search for a report

Search here for suspected adverse drug reaction reports

News

31/05/2012 European Medicines Agency boosts EU transparency with online publication of suspected side effect reports.

More news...

How to report a side-effect

Regulation (EU) No 1235/2010

Via a medicines web-portal the Agency shall make public *inter alia* (Art 26):

- Agendas and minutes of each meeting of PRAC
- Summary of risk management plans for CAPs
- List of medicines subject to additional monitoring
- Information about how to report to national competent authorities suspected ADRs and standard web-forms
- Initiation of procedures via Art 107i to 107k
  - the active substances or medicinal products concerned
  - The issue being addressed
  - Any public hearings pursuant to the procedure
  - Information on how to submit information and to participate in public hearings

European Medicines Web-portal

European medicines web portal

The Agency's website will serve as the **European medicines web portal** for the dissemination of information on medicinal products authorised in the European Union and shall make public all relevant information in accordance with Article 26 of Regulation (EC) No 726/2004, as amended by Regulation (EU) No 1235/2010.

What we do
Who we are
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PRAC: Agendas, minutes and highlights

This page lists the **agendas**, **minutes** and **meeting highlights** from the Pharmacovigilance Risk Assessment Committee (PRAC) plenary meetings.

PRAC meeting highlights

- Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 1-3 October 2012
- Pharmacovigilance Risk Assessment Committee (PRAC) elects chair and vice-chair (07/09/2012)

Table of contents

Agendas

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Document(s)	Language	Status	First published	Last updated	Effective Date
Agenda - PRAC draft agenda of meeting 29-31 October 2012	(English only)	draft	29/10/2012		
Agenda - PRAC draft agenda of meeting 1-3 October 2012	(English only)	draft	01/10/2012		
Agenda - PRAC draft agenda of meeting 3-5 September 2012	(English only)	draft	03/09/2012		
Agenda - PRAC draft agenda of the inaugural plenary meeting 19-20 July 2012	(English only)	draft	18/07/2012		

PRAC publications to date 2012

Agendas – July, September, October, November

Highlights - July, September, October, November

Minutes - July, September, October

Referrals – Codeine Article 31, Diclofenac Article 31

PRAC publications - principles

Timeliness

- Clear predictable timelines

Comprehensibility

- Explanatory notes
- Acronyms and abbreviations

Accessibility

- EMA Web-portal
- Linkages at national level
- Ongoing development

PRAC Publications timing schedule

Agenda	Day 1 of PRAC by mid-day
Highlights	Thursday of PRAC week
Safety referrals	Thursday of PRAC week
Minutes	Following month after adoption

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 October 2012
EMA/PRAC/519417/2012
Patient Health Protection

Pharmacovigilance Risk Assessment Committee (PRAC)

Draft agenda of meeting **29-31 October 2012**

The Notes give a brief expla
Agenda

Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 29-31 October 2012

News

31/10/2012

Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 29-31 October 2012

PRAC begins second referral procedure

The European Medicines Agency's Pharmacovigilance Risk Assessment Committee (PRAC) held its fourth meeting from 29 to 31

Since the first meeting of the PRAC in July 20 expanded substantially. At their most recent increasing volume of information on new saf systems as well as a growing number of up medicines.

NOTIFICATION OF A REFERRAL UNDER ARTICLE 31 OF DIRECTIVE 2001/83/EC
FAX NUMBER –44 20 75237051

This notification is an official referral under Article 31 of Directive 2001/83/EU made by the United Kingdom

Product Name(s), if appropriate,	Diclofenac containing medicinal products
Active Substance	Systemic formulations of diclofenac (eg oral, IM, and IV)
Marketing Authorisation Holder(s)	Various

Diclofenac is a non-selective Non-Steroidal Anti-Inflammatory Drug (NSAID) which is authorised for the relief of pain and inflammation in a wide range of conditions including arthritic conditions and acute musculoskeletal disorders. It is currently available in the EU in a number of different

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SCIENCE MEDICINES HEALTH

5 September 2012
EMA/PRAC/520121/2012
Patient Health Protection

Pharmacovigilance Risk Assessment Committee (PRAC)

Minutes of the inaugural plenary meeting 19-20 July 2012

Centre Albert Borschette, Conference Room AB-0C
Rue Froissart 36, 1040 Brussels, Belgium

1. Introduction

1.1. Welcome and keynote address by the EM

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SCIENCE MEDICINES HEALTH

05 October 2012

EMA/PRAC/571481/2012 Final
Patient Health Protection

Pharmacovigilance Risk Assessment Committee (PRAC)

Minutes of meeting 3-5 September 2012

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31 October 2012
EMA/PRAC/635842/2012
Patient Health Protection

Pharmacovigilance Risk Assessment Committee (PRAC)

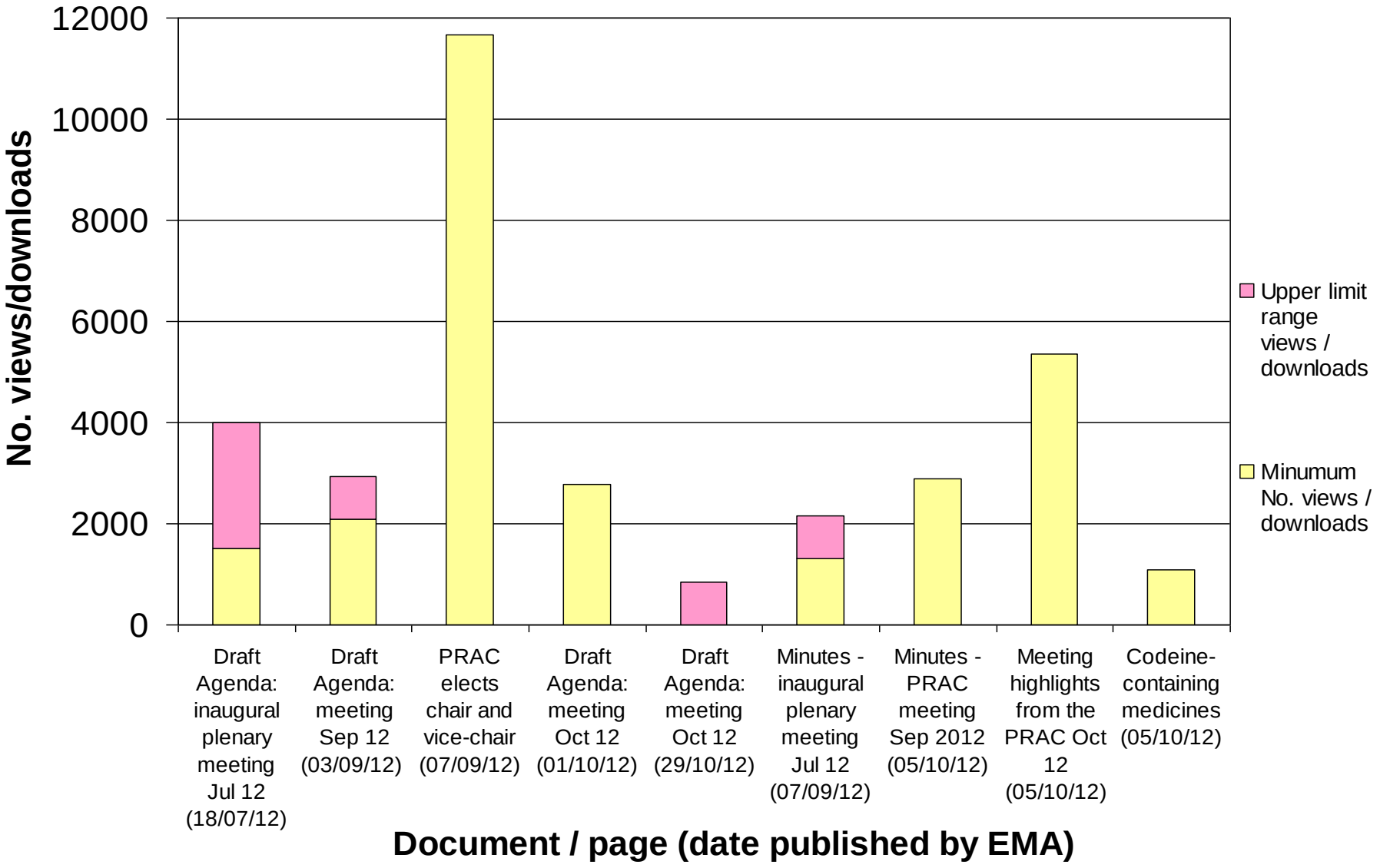
Minutes of the Meeting 1-3 October 2012

Explanatory notes

The Notes give a brief explanation of relevant Minutes items and should be read in conjunction with the Minutes

EU Referral procedures for safety reasons: Urgent EU procedures and Other EU referral procedures
(Items 2 and 3 of the PRAC agenda)

EMA Website Views and downloads



Explanatory Notes

Explanatory notes

The Notes give a brief explanation of relevant Agenda items and should be read in conjunction with the Agenda

EU Referral procedures for safety reasons: Urgent EU procedures and Other EU referral procedures
(Items 2 and 3 of the PRAC agenda)

A referral is a procedure used to resolve issues such as concerns over the safety or benefit-risk balance of a medicine or a class of medicines. In a referral, the EMA is requested to conduct a scientific assessment of a particular medicine or class of medicines on behalf of the European Union (EU). For further detailed information on safety related referrals please see:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000150.jsp&mid=WC0b01ac05800240d0

Signals assessment and prioritisation
(Item 4 of the PRAC Agenda)

A safety signal is information on a new or incompletely documented adverse event that is potentially caused by a medicine and that warrants further investigation. Signals are generated from several sources such as reports of adverse events from healthcare professionals or patients (so called spontaneous reports), clinical studies and the scientific literature. The evaluation of safety signals is a routine part of pharmacovigilance and is essential to ensuring that regulatory authorities have a comprehensive knowledge of a medicine's benefits and risks.
The presence of a safety signal does not mean that a medicine has caused the reported adverse event. The adverse event could be a symptom of another illness or caused by another medicine taken by the patient. The evaluation of safety signals is required to establish whether or not there is a causal relationship between the medicine and the reported adverse event.
After evaluation of a safety signal the conclusion could be that the medicine caused the adverse reaction, that a causal relationship with the adverse event was considered unlikely, or that no clear answer could be given and the signal therefore is to be further investigated. In cases where a causal relationship is confirmed or considered likely, regulatory action may be necessary and this usually takes the form of an update of the product information (the summary of product characteristics and the package leaflet).
For completeness the information on signals is complemented, when available, by information on worldwide population exposure.

Risk Management Plans (RMPs)
(Item 5 of the PRAC Agenda)

The RMP describes what is known and not known about the safety of a medicine and states how the side effects will be prevented or minimised in patients. It also includes plans for studies and other activities to gain more knowledge about the safety of the medicine and risk factors for developing side effects.
RMPs are continually modified and updated throughout the lifetime of the medicine as new information

Acronyms translated

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

5 October 2012
EMA/441950/2012
Patient Health Protection

Acronyms and abbreviations used in Pharmacovigilance Risk Assessment Committee (PRAC) Minutes

Annex 1 to the PRAC Minutes

ADR(s)	Adverse Drug Reaction(s)
Ad Hoc PhVIWG	Ad Hoc Pharmacovigilance Inspectors Working Group
AE(s)	Adverse Event(s)
AEFI(s)	Adverse Event(s) Following Immunisation
AR(s)	Assessment Report(s)

Safety communication
Art 106a 2001/83/EC

"For active substances contained in medicinal products authorised in more than one Member State the Agency shall be responsible for the coordination between national competent authorities of safety announcements

Under the coordination of the Agency, the Member States shall make all reasonable efforts to agree on a common message

The PRAC shall at the request of the Agency provide advice on those safety announcements"

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 October 2012
EMA/696434/2012
Press Office

EMBARGO – DO NOT PUBLISH BEFORE FRIDAY 26 OCTOBER 2012, 18:00 HRS UK TIME

Press release

Update on seasonal influenza vaccines produced by Novartis Vaccines

European Medicines Agency supports Members States in coordinating action

News Bulletin

Flu jab batches recalled over contamination

Tens of thousands of doses of the flu jab are being recalled after two batches were found to be contaminated.

Regulators said 160,000 doses of the *novartis* vaccine, Agrippal, were being recalled after "particles" were found in the phials.

A spokesman for the Medicines and Healthcare products Regulatory Agency said there was no safety issue and the recall was a precaution.

GPs are in the middle of their annual flu vaccination programme, with millions of people aged over 65, and with long-term conditions being called in for their jab.

Officials said the recall should not affect supplies as there were 17 other flu vaccines available. Other batches of Agrippal are not affected by the recall.

Looking ahead

Adding new resources

Summary RMPs, medicines under additional monitoring, public hearings

Promoting awareness

at national level – web-portals, co-ordinating national communications, "suite" of documents

Monitoring impact

on ADR reporting, better informed prescribers, patients and public

Summary

Transparency and communication on drug safety is key to protection of public health

Timely access to pharmacovigilance information and decisions is the basis of stakeholder engagement

Commitment of PRAC already demonstrated via timely publication of agendas, highlights and minutes

There is much more to come

Pharmacovigilance Risk Assessment Committee

"All aspects of the risk management of the use of medicinal products including the detection, assessment, minimisation and communication relating to the risk of adverse reactions, having due regard to the therapeutic effect of the medicine"