EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

The Pharmacovigilance Risk Assessment Committee (PRAC) Mandate, composition and tasks

Training session on the new pharmaceutical legislation
Thursday, 29 November 2012

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Scientific Committees Support Section – PRAC secretariat

An agency of the European Union

What is the PRAC?

The PRAC is one the 7 Scientific Committees of the Agency

It was created to ensure the availability of the necessary expertise and resources for pharmacovigilance assessments at European Union level

The PRAC – quick facts:

- is the most recently established committee of the Agency
- held its first meeting in July 2012
- meets on a monthly basis

Composition of the PRAC

27 EU Member States

(1 Member + 1 Alternate)

3 EEA States Norway, Iceland and Liechtenstein

(1 Member + 1 Alternate – do not vote)

10 Members nominated by the Commission

- 6 independent scientific experts
- Representative healthcare professionals (1 member + 1 alternate)
- Representative patient organisations (1 member + 1 alternate)

Nominations for civil society representatives are awaited for 2013

PRAC Chair elected in 2012: Dr June Raine

"The PRAC is set to play a pivotal role in delivering the public health benefits of the new European pharmacovigilance legislation," said Dr Raine on accepting her election. "My ambition is to make sure that this unique opportunity to strengthen public health protection is fully realised for the benefit of all citizens in the European Union. The new legislation provides powerful tools to strengthen the protection of public health in Europe and the effective use of these tools will depend on clarity of vision, strong leadership, sound scientific judgement and excellent communication by the PRAC."

What the PRAC does?

The PRAC is the committee at the European Medicines Agency which is responsible for assessing and monitoring safety issues for human medicines

Regulation (EU) No 1235/2010 provides the following mandate for the PRAC:

"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 medicinal product, the design and evaluation of post-authorisation safety studies and pharmacovigilance audit".

It's a PRAC business...

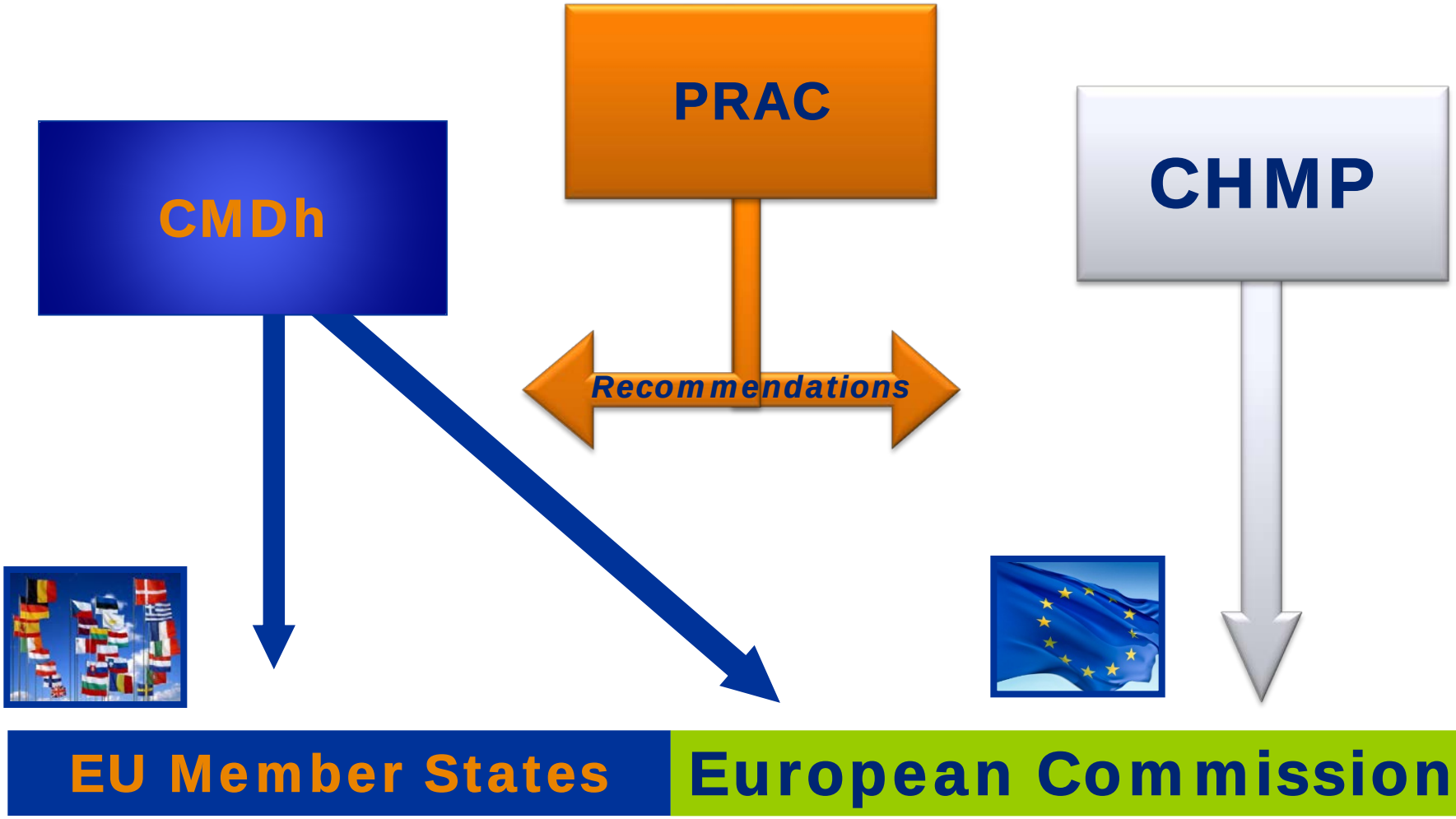
- **New safety signals**
- **Urgent and non urgent union procedures** triggered due to safety concerns identified in medicinal product(s) authorised in more than one MS
- **Risk Management Plans**
- Non-interventional safety study protocols and study reports, if the need for a **non-interventional post-authorisation safety study (PASS)** is identified
- **Periodic Safety Update Report (PSUR**)
- Recommendations on the need and scope of **"for cause" pharmacovigilance inspections** related to medicinal products of Community interest
- List of **medicines under additional monitoring**

PRAC Rapporteur Appointment

- PRAC Rapporteur is involved throughout the lifecycle of a product
- Whenever possible the PRAC Rapporteur should be appointed from a different Memebr State compared to the CHMP Rapporteur/Co-Rapporteur, PRAC Rapporteur is the lead expert on safety/risk management for specific medicines/active substances

		Initial Authorisation Phase	Post-authorisation Phase
New MAAs as of September 2012	CHMP Rapporteur	A[1]	A[1]
	CHMP Co-Rapporteur	B[1]	B[1]
	PRAC Rapporteur	X[2]	X[2]
	PRAC Co-Rapporteur	A[1]	A[1]

How does the PRAC Work?



Where can I find out what the PRAC is discussing?

On the web


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

Email Print Help Sha

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 October 2012.

Since the first meeting of the PRAC in July 2012, the Committee's agenda has expanded substantially. At their most recent meeting, PRAC experts evaluated an increasing volume of information on new safety signals generated from European- Union (EU) reporting systems as well as a growing number of updated risk-management plans for certain medicines.

Related information

- Diclofenac: Article 31 referral
- Pharmacovigilance Risk Assessment Committee (PRAC) 29-31 October 2012
- European Medicines Agency finalises review of recent publish data on cardiovascular safety of NSAIDs (19/10/2012)
- Acronyms and abbreviations used in PRAC minutes (05/10/2012)

Contact point:

Monika Benstetter

- **Agendas**
- **Meeting highlights**
- **Minutes**
- **Other outcome documents**

More information…