



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

Presented by: Roberto De Lisa
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

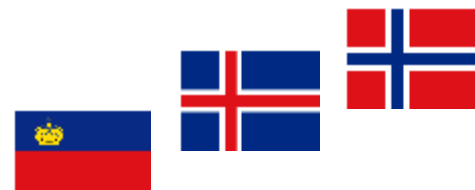
27 EU Member States

(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**



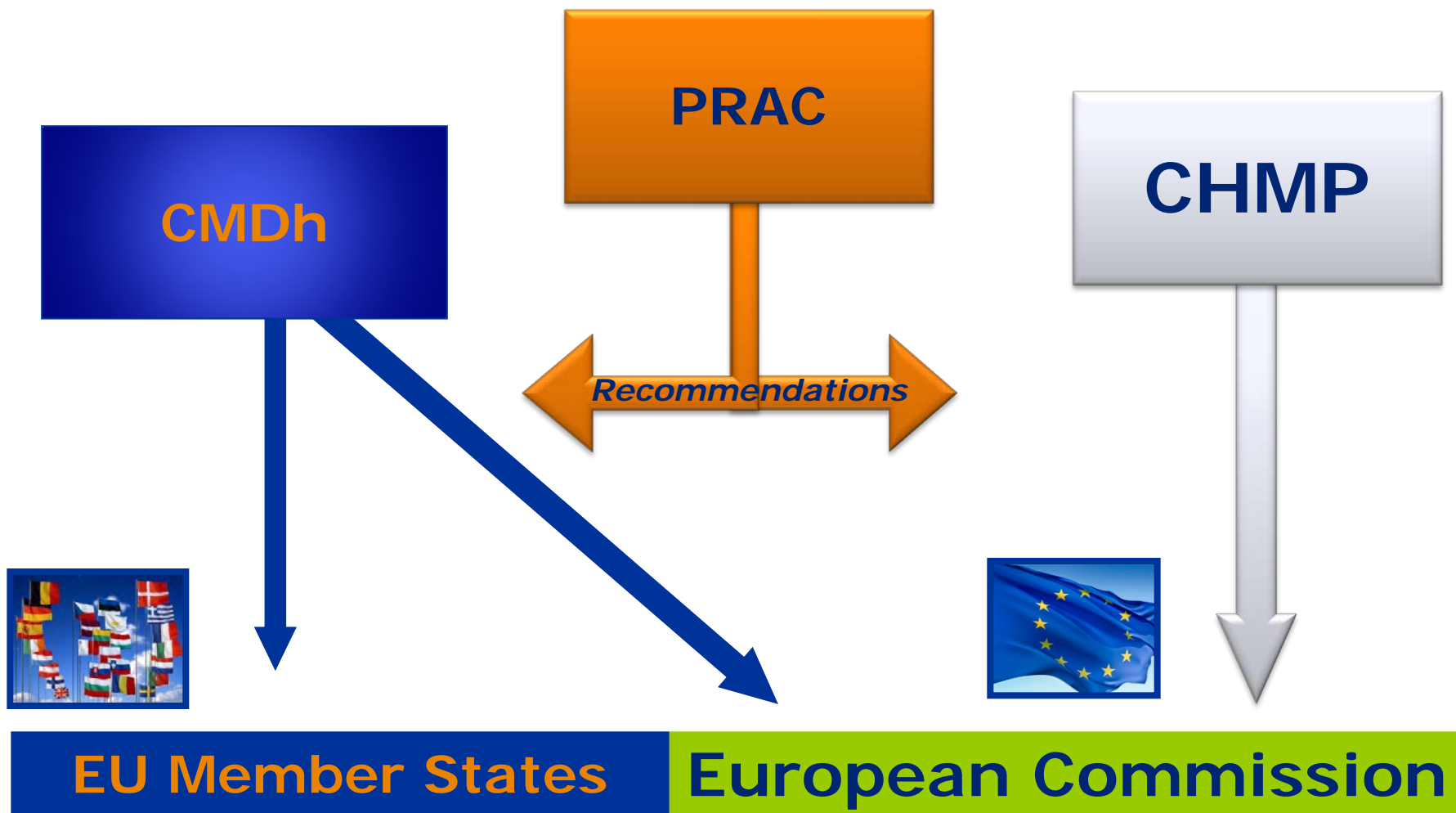
PRAC Rapporteur Appointment

- PRAC Rapporteur is involved throughout the lifecycle of a product
- Whenever possible the PRAC Rapporteur should be appointed from a different Member 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

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

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

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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 published data on cardiovascular safety of NSAIDs (19/10/2012)
- ▶ Acronyms and abbreviations used in PRAC minutes (05/10/2012)

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More information...

The screenshot shows a Windows Internet Explorer browser window displaying the European Medicines Agency (EMA) website. The address bar shows the URL: http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000537.jsp&. The page title is "European Medicines Agency - Committees - Pharmacovigilance Risk Assessment Committee (PRAC)".

The main navigation bar includes links: Home, Find medicine, Regulatory, Special topics, Document search, News & events, Partners & networks, and About us (which is highlighted). A "Quick links" search bar is also present.

The left sidebar contains a menu with the following items: What we do, Who we are, How we work, Committees (highlighted), CHMP, PRAC (expanded), Overview, Members, Meetings, Agendas, minutes and highlights, CVMP, COMP, HMPC, PDCO, CAT, Working parties and other groups, Careers, and Procurement.

The main content area is titled "Pharmacovigilance Risk Assessment Committee (PRAC)". It features a large image of a stylized eye. The text states: "The Pharmacovigilance Risk Assessment Committee (PRAC) is the committee at the European Medicines Agency that is responsible for assessing and monitoring safety issues for human medicines." Below this, it explains that the PRAC's recommendations are considered by the Committee for Medicinal Products for Human Use (CHMP) and the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh). A link is provided to "See the full overview of the PRAC's role".

The "Composition" section states that the members and alternates of the PRAC are nominated by European Union Member States, in consultation with the Agency's Management Board. It also mentions that the European Commission appoints two members and two alternates following consultation with the European Parliament, and that the European Commission also appoints six independent scientific experts.

The text further states that all members serve on the Committee for a period of three years which is renewable once. The PRAC is composed of:

- ▶ a chair and a vice chair, elected by serving PRAC members;
- ▶ one member and an alternate nominated by each of the 27 Member States;
- ▶ one member and an alternate nominated by Iceland and by Norway;

The bottom status bar shows "Local intranet | Protected Mode: Off" and a zoom level of "125%".