The Pharmaceutical Risk Assessment Committee (PRAC) of the EMA

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History of Medicines Regulation and Pharmacovigilance

- 1930: The Food, Drug and Insecticide Administration becomes the Food and Drug Administration (USA)
- 1938: The Federal Food, Drug and Cosmatic Act introduced the requirement that safety has to be shown before selling the product
- 1963: Start of the current regulatory praxis in European countries and the USA after the thalidomide schandal
- 1995: European Medicines Evaluation Agency, now European Medicines Agency (EMA)
- 2010: New Pharmagovigilance Legislation in the EU, PRAC since July 2012

Directive 2010/84/EU and Regulation (EU) no 1235/2010

- Pharmacovigilance rules are neccessary for the protection of public health in order to prevent, detect and assess adverse reactions to medicinal products placed on the Union market, **as the full safety profile of medicinal products can only be known after they have been placed on the market.**

Composition of the PRAC

- Chair
- 28 representatives: 1 of each member state
- 1 representative of Norway and 1 of Iceland
- 6 independant scientific experts
- 1 representative of patients and 1 of health care professionals
- 1 alternate per member
- Support of a secretariat
- Observer of the EU Commission

Relationship of PRAC with CHMP and CMDh

- Committee for Medicinal Products for Human use (CHMP): responsible for all centrally authorised medicinal products (CAP's)
- Committee for Mutual Recognition and decentralised procedure-Human (CMDh): responsible for the coordination of nationally authorised products (NAP's)
- Own PRAC opinion on centrally authorised products: Advices to CHMP for CAP's and CMDh for products marketed in at least two memberstates

The activities of the PRAC

- Core business is the detection of signals and the assessment of the benefits and risks of medicines
- The Eudravigilance data-base, studies, opinions of other agencies (FDA) etc.
- Discussion of a potential signal in the PRAC
- Appointment of a rapporteur
- Assessment of the product(s)
- Routine Pharmacovigilance

A regular PRAC agenda (66 pages,209 items)

- EU referral procedures for safety reasons: urgent EU procedures (4 items)
- EU referral procedures for safety reasons: other EU referral procedures (11 items)
- Signal assessment and prioritisation (12 items)
- Risk Management Plans (RMP) (53 items)
- Periodic Safety Update Reports (PSUR) (35 items) and Periodic Safety Update Single Assessment (PSUSA) (3 items)

A regular PRAC meeting (2)

- Post Authorisation Safety Studies (PASS) 23 items
- Renewals of marketing authorisation, conditioal renewals and annual reassessments (15 items)
- Product related pharmacovigilance inspections (4 items)
- Other safety issues for discussion, requested by the CHMP, the EMA or member states (9 items)
- Organisational, regulatory and methodological matters (Orgam) (40 items)

Referrals and the Role of the PRAC

- A referral is a request of the European Union (EU) to conduct a scientific assessment of a particular medicine, or class of medicines.
- Safety related referrals are assessed by the PRAC and then either by the CHMP or the CMDh.
- All other referrals are assessed by the CHMP

Referral Procedures

- Article 107i: Urgent action is necessary because of a safety issue
- Article 20: CAP's in case of manufactory and safety issues
- Article 31: Concerns relating to quality, safety or efficacy issues
- Other referrals: Article 29; Article 13; Article 29(4) and Article 30

The Role of the Patient Expert

- Same as all other members with special expertise
- Add patients' experience and perspectives to the expertice of regulators and other experts
- Bridging the gap between the statistical reality of the regulatory system and the personalised reality of clinical practice
- Is not and cannot be the watchdog of patients organisations: Confidentiality Agreement
- Contribute to the opinion building on benefit – risk assessments of medicines, readability of texts like Package Leaflets (PL) and Dear Healthcare Professional Comunications (DHPC's)etc.

Involvement of patients in PRAC procedures

- Member and alternate of the PRAC (both reimbursed)
- Member of Scientific Advisory Group (SAG)
- The Prac asks advice of the Patients' and Consumers' Working Party (PCWP
- Involvement in a so-called special interest group
- A new instrument: the public hearing

Definition of Public Hearing

- A **forum** to which the **public is invited to express its views and concerns** on a **pre-defined set of questions on issues related to the safety,** whilst also considering the **therapeutic effects** of a particular medicine.
- A **channel** (for the PRAC) **to take the public's views and concerns into account,** particularly once all available data and evidence have been assessed and options for regulatory actions and risk management activities will need to be considered **in a wider public health context.**

Purpose of a Public Hearing within Referrals

- To seek public opinion, suggestions and recommendations on the **acceptability of the risks** associated with the medicine/class of medicines concerned, particularly **in relation to its therapeutic effects and therapeutic alternatives** as well as on the **feasibility and acceptability of risk management and minimisations** activities.
- To **inform the debate of the PRAC,** which continues to have the **sole responsibility for giving its scientific recommendation** on the safety of the medicine concerned.

More abot the Public Hearing

- Participants can attend in person, submit their contribution in writing or watch a live vide-stream. The sole language is English
- Open for all members of the public, but priority for representatives of groups of patients, health care professionals, academics etc
- Assessment report reflects how the outcome of the public hearing has impacted decision-making
- The public hearing will be held as a part of a PRAC meeting, MAH(s) are invited to present their views

Following the PRAC

- The agenda of the PRAC meeting available from the Tuesday after the start of the meeting
- The minutes of the PRAC meeting: a month after the meeting
- Highlights of the meeting the day after the meeting from 12.00 GMT
- Always available the meeting dates, the members and alternates and their Declaration Of Interest (DOI) and CV