Pharmacovigilance Risk Assessment Committee (PRAC)
responsible for assessing all aspects of the risk management of medicines for human use

detection, assessment, minimisation and communication relating to the risk of adverse reactions

taking the therapeutic effect of the medicine into account

design and evaluation of post-authorisation safety studies
PRAC members

- Members nominated by the Member States
- Independent scientific experts nominated by the European Commission
- Representative of healthcare professionals nominated by the European Commission
- Representatives of patients organisations nominated by the European Commission
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PRAC

Recommendations to

CHMP

PRAC

CMDh

Zentrale Zulassung

Nat. und dezentrale Zulassungen

AGES
PRAC concludes there is no clear and consistent evidence of a difference in inhibitor development between classes of factor VIII medicines

- Factor VIII is lacking in patients with haemophilia A. Factor VIII products replace the missing factor VIII and help control bleeding. However, the body may develop inhibitors as a reaction to these medicines, particularly in patients starting treatment for the first time. This can block the medicines’ effect, so bleeding is no longer controlled.
- The review was started following publication of the SIPPET study,\(^1\) which concluded that inhibitors develop more frequently in patients receiving recombinant factor VIII medicines than in those receiving plasma-derived factor VIII medicines.
- The studies reviewed differed in their design, patient populations and findings did not provide clear evidence of a difference in the risk of inhibitor development between the two classes of factor VIII medicines.
- The PRAC recommended that the prescribing information should be updated to reflect the current evidence.
PRAC concludes assessment of gadolinium agents used in body scans and recommends regulatory actions, including suspension for some marketing authorisations

- Review finds evidence of gadolinium deposits in the brain after MRI body scans but no signs of harm

- The four agents recommended for suspension are referred to as linear agents. Linear agents have a structure more likely to release gadolinium, which can build up in body tissues. Other agents, known as macrocyclic agents, are more stable and have a much lower propensity to release gadolinium.
Implementation of public hearings at the PRAC: Draft revised rules of procedure and impact assessment

PRAC – 11-14 April 2016

Agenda topic 12.18.1, for adoption (draft revised rules of procedure) and for information (impact assessment)

Noël Wathion
Deputy Executive Director
EMA/251896/2016
PRAC public hearing

Key characteristics of public hearings at the PRAC

Aim of public hearing is to hear the public’s view on:

• The acceptability of the risks of a medicine, in relation to its therapeutic effects and therapeutic alternatives available
• The feasibility and acceptability of risk management/minimisation activities

Public hearings are open to:

• All members of the public (have to register in advance)
• MAH(s) has/have the opportunity to present its/their views
• Media organisations may follow the public hearings as observers
• CHMP Chair, CHMP (Co)-Rapporteurs, or alternatively CMD(h) Chair, CMD(h) Rapporteurs will be invited to attend