EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

First Experiences with the PRAC

Management Board Meeting – Agenda Point B5
04 October 2012

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Establishment of the PRAC

- Document "Countdown to July 2012: the Establishment and Functioning of the PRAC" – Status Report 28 June 2012, was published on EMA website
- Document summarises the outcome of the discussions within the EU Regulatory Network on topics including
  - PRAC mandate and tasks
  - PRAC outputs
  - PRAC Rapporteur appointment principles
  - Transparency and communication
  - PRAC-CHMP-CMD(h) interaction

PRAC Inaugural Meeting (1/2)

- Held on 19-20 July 2012 in Brussels
- First, information was provided on aspects such as the new legal provisions, the key interactions between PRAC-CHMP-CMD(h), transparency, conflicts of interests, the Rapporteur appointment process, the PhVWP legacy, the EURD list, signal management, additional monitoring and black symbol

PRAC Inaugural Meeting (2/2)

- Subsequently the PRAC Rules of Procedure (RoP) were presented and discussed at length
- Finally PRAC adopted its RoP by majority (25 members in favour out of 31)
- Divergent views expressed related to concerns that members appointed by the European Commission would not be able to act as Rapporteur
- PRAC minutes were published on 7 September 2012

PRAC September Meeting (1/3)

- Preparation of PRAC September meeting
  - Draft PRAC Agenda (including legal references for the various topics for discussion) was sent – as agreed – to the EU Regulatory Network (the Network) prior to the PRAC meeting (on 31 August)
  - Since no publication of dedicated Press Releases or Q&A documents was envisaged there was no need to send out the Early Notification System (ENS)
  - LTT were also circulated to the Network on 31 August in view of the release of information through the PRAC Agenda on signals under discussion
  - PRAC Agenda was published prior to the PRAC meeting (on 3 September 2012), together with an Explanatory Note

PRAC September Meeting (2/3)

- Was a 2,5 day meeting, the first day being dedicated to further training for PRAC members
- Main focus was on
  - Election of Chair (J. Raine) and Vice-Chair (A. Spooner)
  - Signals assessment and prioritisation (n=13)
    - 11 new signals detected from EU spontaneous reporting systems
    - 1 new signal detected from other sources
    - 1 signal follow-up

PRAC September Meeting (3/3)

- Main focus was on (cont'd)
  - Risk Management Plans pre-authorisation (n=1)
  - Pharmacovigilance inspections (n=2)
  - Organisational, regulatory and methodological matters
    - EURD list: was adopted by the PRAC
    - List of substances subject to signal management worksharing: was adopted by the PRAC for submission to CMD(h) to appoint lead MSs
    - Selection of the signal for products subject to additional monitoring: trend vote (black inverted triangle favoured) in view of final discussion in October

PRAC First Experiences (1/2)

- Initial feedback from PRAC members was very positive
- Agenda was "light" but is expected to grow quickly over the next months
- Product related discussions focused on signal management
- Increased transparency on agendas and minutes will drive communication at national level – EMA will support where needed (e.g. LTT on signals under discussion)

PRAC First Experiences (2/2)

- Timelines are challenging and meeting preparation at NCA level is a key success factor to deliver
- Need for interaction at national level between PRAC members and their CHMP counterparts (e.g. awareness of existing Rapporteur responsibilities in case of transfer of CHMP Rapporteur allocation to the PRAC, Rapporteur appointment and bidding process)

Ongoing Issues

- Cover amongst other topics
  - Finalisation of the PRAC RoP (discussion at the October 2012 MB meeting since the written procedure has been suspended)
  - Clarification of the role of the PRAC Co-Rapporteur (further discussion at the October 2012 PRAC meeting)

In Conclusion

- First experiences with the PRAC are very positive
- However, the agenda of the first meeting was rather light
- Preparation and internal communication at national level are key success factors
- Work is still in progress in a number of fields and the previously agreed prioritisation will result in a phased implementation
- Close monitoring is put in place