EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Feedback from the informal Heads of Medicines Agencies (HMA) meeting on 5th October 2011

Presented by: Jytte Lyngvig
Chief Executive Officer, Danish Medicine Agency

Feedback from informal HMA meeting on implementation of the new PhV legislation

- Held at the EMA on 5th October 2011

- Objectives:
  - Address strategic issues requiring HMA orientation
  - Challenging aspects and impact on National Competent Authorities
  - Raise awareness in specific areas

Topics discussed

- Overall Update on implementation
- Pharmacovigilance and Risk Assessment Committee
- Urgent Union procedure (including the concept of public hearings)
- Periodic safety update reports
- Medicines web-portals
- Coordination of safety announcements
- Pharmacovigilance audits

Pharmacovigilance and Risk Assessment Committee (1)

- Composition

  – Expertise required to cover:
    - Pharmacovigilance and risk assessment
    - Efficacy (benefits)
    - clinical practice

  – Nomination process (for membership)

  – EC's call for expression of interest for being member of the PRAC - *published on 30th September 2011*)

Pharmacovigilance and Risk Assessment Committee (2)

- Procedures
  - including interaction with CHMP and CMD(h)/CG
- Definition of PRAC activities
- Issues related to transparency and communication of Committee's outcome
- Smooth transition between PhVWP and PRAC (*first meeting in July 2012*)

Periodic Safety Updates Reports

- Information was provided on the plans for reaching new legislative proposals introducing the new aspect of single EU assessment, legally binding outcomes, electronic submission to EMA only, etc.

- Implementation timelines will depend on prioritisation

EU Medicines web-portal

- The new legislation will lead to even greater amounts of information being released online when it becomes effective in July 2012 (from EMA and from NCAs).
- Building upon existing sites, an European medicines web portal to be launched:
  - Proposed to be a network of websites, which promotes the rational and safe use of medicines
  - Static site which directs users to relevant EU and national websites (NCA, national webportals, EMA, etc.)
  - Consumer-facing design
- Further reflection still needed on many aspects (e.g. multilingualism, IT interoperability, etc)

Coordination of safety announcements

- Purpose: ensure that clear messages on medicines safety are provided timely and consistently across EU
- Requires to balance the need for coordinating and the need to meet transparency demands at national level
- To build on existing operating systems and structures – streamline processes
- Establish links between the EU Regulatory Network (EMA, MSs and EC) and stakeholders (mainly patients, consumers and healthcare professionals)

Pharmacovigilance audits

- New legislation requires pharmacovigilance system audits of MSs and EMA

- Current approach builds on a system audits to be conducted by each NCA and by the EMA by internal auditors or auditors contracted by the NCA

Conclusions

– HMA agreed on a very informative meeting, showed satisfaction with the progress of the implementation and agreed that the meeting objectives were achieved

– HMA will consider the organisation of another informal HMA meeting in 1Q2012

Thank you for your attention