

CMDh Paediatric Assessor Workshop June 2010: Identified issues and Recommendations

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Workshop format

- Presentations and current issues
 - CMDh paediatric work-sharing procedures: principles, guidance and updates in the last year
 - New SmPC guidance for paediatric information
- Case Histories
- Discussion and recommendations

Identified Issue: Appointment of Rapporteurs

- How to ensure same Rapporteur for Art. 30 referral and Art. 45 running in parallel?
- How to ensure the same Rapporteur for Art. 45, 46 and previous referrals?

Identified issues: the dossier (1)

- Incomplete dossiers, old study reports of variable quality, many open questions
- Missing literature
- Lack of information or analysis about known extensive off-label use
- No complete overview on European situation
- No recommendations for SmPC
- Lack of analysis of studies/literature by MAH

Identified issues: the dossier (2)

- Could CAs refuse to assess really badly submitted material? (Example: 200 publications without any overview)

Recommendation:

- Ask for overview during procedure
- Strengthen wording on analysis/overview in assessment guidance
- Emphasise importance to Interested Parties

Identified issues: procedural aspects (1)

- A request for additional information was necessary after day 90, but according to the time table additional questions to MAHs resulting from the assessment of the supplementary information is not foreseen

Recommendation:

Procedures not to restart until complete response received.

Identified issues: procedural aspects (2)

- Different MAH opinions and contact points

Recommendation: Is it possible to have a single contact point for all MAH to facilitate the communication with the Rapporteur?

- Only one MAH in certain MS involved whereas other MAHs/MS might be affected by the data and the evaluation/assessment

Recommendation: There could be informal contact from Rapporteur

Views of Interested Parties welcome

Identified Issues: SmPC recommendations (1)

- How to take into account older studies

Recommendation: Need to evaluate overall benefit/risk - take into account previous studies. Use previous AR, do not re-assess data

- What information to put in 5.1? Especially if previous studies not included

Recommendation: Follow new SmPC guidance and aims of Regulation wrt transparency

Identified Issues: SmPC recommendations (2)

- No compulsory harmonisation for paediatrics - Do we need this?

Recommendation: Paediatric work-sharing is not a harmonisation procedure. Where there are common indications and posology it should be possible to recommend consistent wording. MAH should consider appropriate regulatory action to harmonise indications and posology between MS.

- Concern over elimination of paediatric indications or removal of contra-indications: established differences between MS, legal situations

Recommendation: national implementation or CMDh or other referral if sufficiently important

Identified Issues: SmPC recommendations (3)

- Data concerning off-label use: inclusion in the SmPC?
Recommendation: Include data but do not actively support off-label use. Communicate to PDCO as a paediatric need
- Inconsistencies with clinical guidelines
- What about literature published since line listing especially when the Art. 45 procedure is finalised?