CHMP work programme: practical aspects

Eric Abadie – CHMP Chairman

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CHMP workplan: what is it ?

- Projects worth being pursued besides CHMP core business (product related)
- Projects amenable to impact CHMP relation to its environment
- Each project (N=24): sponsors (CHMP and EMEA)
- Concept paper (objective, actions proposed, expected impact, delivery date) and priorities approved by CHMP

High priorities – ongoing projects

- Review and learning project on RMP
- Advanced Therapies Regulation
- Interaction with PhVWP and delegations of tasks
- Evaluation of Benefit Risk
- Antimicrobial resistance
- Biomarkers Qualification

High priorities – projects to be initiated

- Revision of Role and Mandates of Working Parties
- Paediatric Regulation and PDCO/CHMP interactions
- Optimisation of consultation process of SAGs and Specialised Experts Groups
- Outcome assessment research
- Microbicides
- New Statistical approaches
- Variations Regulation revision

Moderate priorities

- Pharmacovigilance Legislation Review
- Rolling Scientific Evaluation
- Accelerated Review
- Interaction with other Committees
- CHMP/EMEA publication policy
- CHMP interactions with interested parties
- International activities (IMI; WHO; CPATH; Bilateral agreements
- SPC Guideline revision (ongoing)
- Translational Development and briefing meetings (ongoing)
- Scientific Advice Peer review (ongoing)
- ICH (ongoing)

Projects to be addressed today

Evaluation B/R: background

- B/R: evaluation of extensive evidence and subjective judgment, a mix of qualitative and quantitative pieces of information
- None of main Regulatory Authorities has issued a list of B/R assessment criteria
- More transparency, better communication are needed
- CHMP Working group set up in May 2006, final report (Reflection Paper) approved in March 08

Evaluation of B/R : workplan

- Two main objectives following the Reflection Paper
  - To implement the CHMP A.R. new template incorporated in CHMP reflection paper.
  - To adapt or develop tools and processes that could be used to conceptualize and make explicit benefit-risk trade-offs.

- Actions proposed to meet the objectives
  - **Describe the current practice of benefit-risk assessment in the EU regulatory network.**
  - **Assess the applicability of current tools and processes for regulatory benefit-risk assessment.**
  - **Develop and field test tools and processes in order to demonstrate their usefulness.**
  - **Using information from the field test, synthesize a benefit-risk tool and process that can add value in other domains.**
  - **Development of a training programme for regulatory assessors.**

Actions in 2009

- To start the research program on quantitative aspects of B/R balance
- To improve the readibility of the EPAR
  - Incorporate the CHMP discussion
  - Detailing the process of reaching a positive opinion
  - Target population (when appropriate)
  - Relative efficacy (when appropriate)

SAG end of pilot phase: questions raised

- What do SAG members know/SAGs ?
- What do SAG members know/procedures (e.g., appeals) ?
- Could organisational procedures be improved ?
- Are respective functions clearly defined (SAG members, EMEA, rapporteurs, CHMP as a whole) ?
- Should we create new SAGs ?
- Should we increase number of core members ?

- … last but not least : CONFLICTS of INTEREST!

Scientific Advisory Groups

SAG's	Core Members (n)	Chair
Cardiovascular	8	Dargie, H.
Anti-infective	8	Bannister, B.
Clinical Neurosciences	8	Donaghy, M.
Diabetes/ Endocrinology	9	Gale, E.
Diagnostics	6	Talbot, J.N.
HIV/Viral Diseases	8	Weller, I.
Oncology	9	Marty, M.

SAGs 2008 Meetings and Experts

Number of meetings: 15

- 6 Oncology
- 2 Endocrinology
- 2 Anti-infective
- 2 CNS
- 1 Cardiovascular
- 1 HIV
- 1 E + CNS
- 1 E + CVS

Number of experts: Core members (…) + 85 additional experts

Number of experts contacted: There is no complete and centralised tracking system, but it seems that the number is approx. 200

SAG WORKING GROUP

- Questionnaires for SAG members
  CHMP Members

  → After analysis and discussion the Working Group will present results and proposals to CHMP

- Conflict of Interest

SAG WORKING GROUP

Topics included in both questionnaires

- Mandate and composition of SAGs
- Interaction with CHMP (eg feedback from CHMP) and contribution to marketing authorizations process (should SAG be consulted on B/R balance)
- Other ways for SAGs to contribute to CHMP work (eg guideline preparation)
- EMEA role, organisation and conduct of SAGs meetings and role of (co) Rapporteurs at SAGs meetings
- Relationship SAGs and WPs (drafting groups), PDCO and CAT
- Conflict of Interest

Further steps

- Meeting with SAG chairs (based on questionnaire results)
- Reflexion on management of Conflicts of Interest (Management Board June 2009)
- New procedures (training of core members, recruitment, meetings, feed back from CHMP)

Conclusion

- Other topics of the workplan should be mentioned !
  - Reorganisation of WPs
  - Review and learning project on RMP
  - Coordination CHMP/ other Committees
  - Innovation