EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

FDA-EMA MOU interactions concerning COA qualification

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EMA-Landscape

EMA committees

SAWP

CHMP
(Committee for Human Medicinal Products)
Chair : Dr. E. Abadie – Vice Chair: Dr. T. Salmonson

COMP
(Committee for Orphan Medicinal Products)
Chair : Dr. K. Westermark – Vice Chair: Mrs. B. Byskov Holm

HMPC
(Committee for Herbal Medicinal Products)
Chair: Dr. K. Keller - Vice-Chair: Dr. I. Chinou

PDCO
(Paediatric Committee)
Chair: Dr. D. Brasseur - Vice-Chair: Dr Dirk Mentzer

CAT
(Committee for Advanced Therapy Medicinal Products)
Chair: Dr. C. Schneider - Vice-Chair: Prof. P. Salmikangas

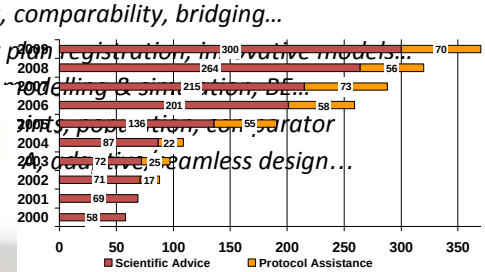
Scientific Advice Working Party

standing WP of the CHMP (Reg. 726/2004)

CHMP peer-review, *ad hoc* discussions, adoption final advice letter

multidisciplinary expert group (28) selected by expertise (not MS)

- 16 NCAs, 12 academia; EMA committees 3 COMP, 1 CAT, 2 PDCO
- CMC: *starting materials, specs, comparability, bridging…*
- non-clinical: *overall toxicology plan registration, innovative models…*
- clinical pharmacology: *PK/PD modelling & simulation, BE…*
- *SMEs, population, comparator*
- *Adaptive, seamless design…*



Qualification of Novel Methodologies

European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 22 January 2009
Doc. Ref. EMEA/CHMP/SAWP/72894/2008 Corr[1]

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

QUALIFICATION OF NOVEL METHODOLOGIES FOR DRUG DEVELOPMENT: GUIDANCE TO APPLICANTS

DRAFT AGREED BY SAWP	27 February 2008
ADOPTION BY CHMP FOR RELEASE FOR CONSULTATION	24 April 2008
END OF CONSULTATION (DEADLINE FOR COMMENTS)	30 June 2008
FINAL AGREED BY CHMP	22 January 2009

EMA-Qualification procedure

CHMP Qualification Opinion

- on the acceptability of a specific use of the proposed method (e.g. use of a BM) in a R&D context (non-clinical or clinical), based on the assessment of data, not product-specific
- Qualification team, peer review, public consultation, publication

CHMP Qualification Advice

- on future protocols and methods for further method development towards qualification, based on the evaluation of the scientific rationale and on preliminary data submitted, confidential

Aims

- SAWP/CHMP early involvement in the design of the strategy
- commitment to evaluate the data obtained from the agreed studies and to provide a Qualification Opinion
- speed up drug development

EMA-Procedure

- Presubmission phase with Scientific Administrator and coordinator
- We will guide the company or consortium with the questions to ask and the information necessary to support the company‘s position.
- Company will submit a brifing book with the question and the company‘s position with their information
- SAWP will discuss the request and produce a list of questions with the requirements for further information

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EMA-Procedure

- Discussion meeting with the consortium
- Further asessment of data
- SAWP will produce a document with their scientific advice to the CHMP
- CHMP peer review
- CHMP presentation by Scientific Advice administrator/Chairman SAWP during the CHMP plenary
- CHMP Opinion

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EMA-Experience to date

- 5 procedures for Qualification in Alzheimer, including more than 7 biomarkers
- Several PRO under review
- Currently several sponsors in contact to initiate the procedure
- **C-Path,** Drug Companies
- applicants are encouraged to apply in parallel to the EMA and **FDA** (confidentiality agreement), who communicate during the assessment and meet with the Applicant together.

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MOA-Parallel SA

- Companies can ask for Scientific Advice to the EMA and to the FDA
- They will be able to submit the same briefing packages and the same questions for discussion
- This is an opportunity for consortiums and companies to have at the same time views about the development.
- It will give a change to have a discussion meeting at the same time with the both agencies
- Each agency will give you the own advices

Links

- **EMA guidance for companies requesting SA or PA** http://www.emea.europa.eu/pdfs/human/sciadvice/426001en.pdf
- **Qualification of novel methodologies for drug developments**
- http://www.emea.europa.eu/pdfs/human/biomarkers/7289408en.pdf
- **Scientific guidelines**
- Http://www.emea.europa.eu/htms/human/humanguidelines/background.htm

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