EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Current involvement of EMA in R&D and future perspectives

Event on best use of medicines legislation to bring new antibiotics to patients, EMA, London, 8th November 2013

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Background

- Increased interaction with patients and healthcare professionals
- Increased interaction with academia/researchers
- Greater involvement in regulatory science
- Involvement ranges from providing a forum for discussion and leading networks of excellence to participating in and leading research projects

➲ **Increasing requests for contribution to research programmes**

Role and level of involvement of the agency

- Most suitable level depending on Conflict of Interest, resources and expected benefits for the agency
- 3 levels distinguished:
  - Coordinator of a research project
  - Participant in research activities
  - Advisory role

Also possible to be an observer

Area of research

1. Applicability to and relevance to the agency's work
2. Added value of contribution from regulators to the project, and
3. Need for continuing and strengthening inter-institutional collaborations

- The agency might support research
  - that is expected to help promoting public health and to improve how the agency evaluates and supervises medicines.
  - in areas closely related to the agency's core role and responsibilities as well as key strategic areas as defined in the Road Map and Work Programme, but also any emerging issues.

EMA will not get involved in activities that are outside its legal role or its mission statement.

SAWP - Qualification Procedure

CHMP Qualification Advice on future protocols and methods for further method development towards qualification

CHMP Qualification Opinion on the acceptability of a specific use of the proposed method (e.g. use of a biomarker) in a research and development (R&D) context (non-clinical or clinical studies), based on the assessment of submitted data

Who can apply? Consortia, Networks, Public / Private partnerships, Learned societies, Pharmaceutical industry

Vision: Speed up/optimise drug development and utilisation, improve public health

Scope for Qualification Procedure

Preclinical development

- pharmacological screening
- mechanism of action
- predict activity/safety

Clinical development

- verify mechanism
- dose-response
- proof of concept
- enrich population
- surrogate endpoint

Drug utilisation

- optimise target population
- guide treatment regimen

Activities related to research projects in the field of prevention and treatment of bacterial infections

1. IMI, COMBACTE, ND4BB, Member of External Advisory Board

2. JPIAMR, Member of Stakeholder Board

3. CPTR (Critical Path to TB Regimens), Members of Scientific Advisory Board and Working Groups

4. IMI, PREDICT-TB, Member of Scientific Advisory Board

5. FP7, ADITEC, Member of External Advisory Board

Areas of research in the field of AMR relevant for regulatory science (1/2)

- Increase our understanding on best evidence to determine efficacy of antibacterials in clinical studies
- Further strengthen the PK/PD methods and the use of pharmacometrics for appraisal of new antibiotics
- Explore the value of companion diagnostics
- Increase the understanding of antibiotics effect in different types of infections
- Explore novel methodological approaches such as bayesian methods

Areas of research in the field of AMR relevant for regulatory science (2/2)

- Progress regulatory science aspects specific to innovative products such as phages and nanomedicines
- Fill gaps in knowledge related to “old antibiotics”
- Support paediatric development of antibacterials
- Interaction with HTAs on best evidence
- Approaches to post-authorisation studies

Support to development of new products in PPP

Due to conflict of interest it is not appropriate to take active part in this kind of initiatives,

however

- The advice of regulators would be beneficial to maximise the chances of regulatory success for projects where public money is involved

- Such interaction can take place via liaison in Advisory Boards and more formal interactions with the EMA, namely systematic interaction with CHMP SAWP

- There are however limitations to the amount of engagement that the Agency can sustain

Conclusions

EMA is eager to support R&D efforts in the area of antibacterials and other options to tackle the issue of AMR

The level of engagement is limited by potential Conflict of Interest, resources and expected benefits for the agency

Targeted participation in key projects within advisory groups expected

More formal interaction via SAWP and BM Qualification expected