EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Road Map to 2015

High-level Overview of the Outcome of the Public Consultation

Outcomes of the Evaluation of the European Medicines Agency – the Future Sustainability of the System

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An agency of the European Union

In This Presentation

- The European Medicines Agency's Road Map to 2015 – How the Agency envisages to contribute to science, medicines, health – A high-level overview of the Agency's proposals
- The outcome of the public consultation – An overview of the main comments made
- Selected areas for discussion

Objectives and Priorities 2010-2015 (1/5)

- Stocktaking of the implementation of the Road Map to 2010: very good progress, but further work is still needed
- Focus for the next 5 years:
  - First priority: successful delivery of the Agency's core business
  - In addition, three strategic areas for the future have been identified:
    - Addressing public health needs
    - Facilitating access to medicines
    - Optimising the safe use of medicines

Objectives and Priorities 2010-2015 (2/5)

- Core activities:
  - 1st priority
  - In line with current and upcoming Community legislation
  - Further strengthen efficiency
  - Focus on increasing the quality of the outcome of the work
  - Details in “From Vision to Reality” document

Objectives and Priorities 2010-2015 (3/5)

- Strategic area 1: Addressing public health needs, with focus on:
  - Gaps in medicine development
  - New and emerging science
  - Public health threats

Objectives and Priorities 2010-2015 (4/5)

- Strategic area 2: Facilitating access to medicines, with focus on:
  - Medicine development process, early assessment and continuing dialogue
  - B/R assessment and communication
  - Facilitation of the relative effectiveness assessment

Objectives and Priorities 2010-2015 (5/5)

- Strategic area 3: Optimising the safe use of medicines, with focus on:
  - Post-authorisation follow-up
  - Patient safety
  - Authoritative source of information
  - Outcome research

Outcome of Public Consultation (1/2)

- 71 contributions have been received:
  - EU Institutions
  - Member States' Competent Authorities
  - European Industry Associations
  - European Patients/Consumers Organisations, European HCP Organisations
  - International Organisations
  - Academia / Learned Societies
  - HTA Bodies
  - Individual pharmaceutical companies, etc.

Outcome of Public Consultation (2/2)

- Feedback is very positive:
  - Overall support for the Agency's vision for the next 5 years
  - Overall agreement with the proposed objectives and priorities as well as the choice of the strategic areas

Overview of Main Comments (1/10)

- Objectives and priorities for the next 5 years:
  - Clarify that the Agency's role in public health is in the context of medicines regulation
  - Focus the Agency's vision to foster scientific excellence so that there is always a direct link / added value to the evaluation / supervision of medicinal products
  - Questioning the Agency's financial and intellectual independence from pharmaceutical industry
  - Request to widen the role and responsibilities of the Agency: e.g. medical devices evaluation, involvement in clinical trials
  - Include transparency and openness of operation as a specific objective and priority

Overview of Main Comments (2/10)

- Implementation of the Road Map / organisational and operational aspects:
  - Fundamental and potentially far-reaching consequences on drug development, licensing and life cycle management require
    - Careful consideration of the impact on resources and costs
    - Architecture of the system to be looked at (e.g. integrated process between the Agency and the Network, better coordination between the various Scientific Committees)
    - Stable funding to be ensured for those providing the scientific expertise
  - When new roles/responsibilities have been assigned strengths of both the Agency and the Network to be considered when solutions to concrete challenges have to be found

Overview of Main Comments (3/10)

- Specific veterinary issues:
  - One world one health concept to be emphasised
  - Divergent views about the appropriateness of a separation of the legal framework between human and veterinary medicines
  - Not yet completed issues from Road Map to 2010 to be addressed:
    - Ensuring adequate provision of medicinal products for minor species
    - Application of pharmacovigilance in the veterinary sector remains heterogeneous

Overview of Main Comments (4/10)

- Core business:
  - To remain 1st priority and not to be affected by the other proposed activities
  - How to ensure maintenance of the current well-balanced operating environment for innovative and generic pharmaceutical business
  - Further efficiency gains to be explored and administrative burden (including for SMEs) to be further reduced
  - Agency's involvement in areas such as non-prescription medicines, generic/biosimilar medicines, herbal medicines to be emphasised as part of its core business and specific activities for the next 5 years to be included
  - Request for alternative medicines and contrast agents to be part of the core business

Overview of Main Comments (5/10)

- Interaction with partners and stakeholders:
  - Better recognition of the role of pharmaceutical industry, EDQM, OMCL, wholesalers
  - Request for the Agency to act as a facilitator to promote discussions with all stakeholders (civil society, academia / learned societies, pharmaceutical industry)
    - Better understanding of the needs, expectations, constraints
    - Facilitate collaborative awareness

Overview of Main Comments (6/10)

- Scientific review process:
  - Divergent views on the use of the conditional marketing authorisation concept, either asking for a widening of the scope or for it to remain a tool to be used exceptionally
  - Concept of “staggered” approval seems to be unclear and requires clarification
  - Support for focus on risks and benefits post-authorisation but caution that the proposed B/R management plan should not result in systematic requests for efficacy assessment after licensing
  - Continuous dialogue during drug development is supported but to remain optional (*cave* control of R&D by regulators)
  - Importance of scientific advice in the overall approval process is recognised but there is a need to introduce further (process) improvements

Overview of Main Comments (7/10)

- Interaction with HTA Bodies:
  - Wide variety of comments received:
    - Agency's vision to be better explained
    - Not to become the 4th hurdle in licensing
    - Extent of interaction may lead to acceptance of validated surrogate parameters being pushed back
    - Interaction with HTA Bodies to be strengthened
    - Alternative clinical trials designs that meet the needs of both regulators and HTA Bodies need to be explored and agreed upon

Overview of Main Comments (8/10)

- Addressing specific population needs:
  - Needs of elderly people to be taken into account (specific scientific forum at the Agency, mandatory pharmacokinetic / clinical studies in elderly for medicines in this population)
  - Underrepresentation of women in clinical trials, biological groups which are more prone to certain disorders also need to be looked at

Overview of Main Comments (9/10)

- Patient safety:
  - Need for pharmacoepidemiology of the highest quality (e.g. in terms of strengthening the methodology, resources and network of the core pharmacoepidemiology discipline)
  - More emphasis to be put on preventing medication errors

Overview of Main Comments (10/10)

- Authoritative source of information:
  - Need to reinforce communication strategies, especially in case of major public health threats
  - E-Health aspects:
    - Vision to include eSPC as an important tool to improve the healthcare system
    - Emphasis to be put on the use of electronic health records, national databases, registries to foster post-marketing surveillance systems for the monitoring of medicines

Selected Areas for Discussion

- The Agency's vision on an improved regulatory model for the licensing of medicines: do the concepts proposed achieve this aim?
- Interaction with HTA bodies: *quo vadis*?