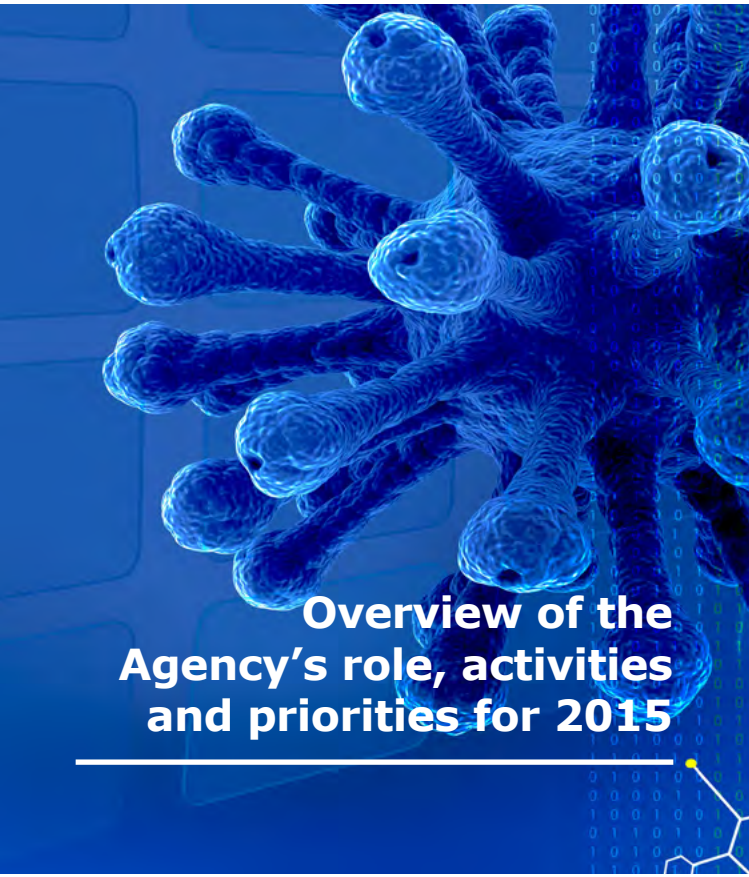
EUROPEAN MEDICINES AGENCY

SCIENCE MEDICINES HEALTH



Overview of the Agency's role, activities and priorities for 2015

An agency of the European Union

The Agency's prioroties for 2015

In light of the above influences and other business-environment factors, the Agency has set out the following priorities for 2015:

- Deliver business activities to a high level of quality, efficiency and consistency in both the human and veterinary areas.
- Facilitate early stages of medicines development in both the human and veterinary areas.
- Enhance cooperation within the network, as well as with European and international partners.
- Implement pharmacovigilance legislation and the clinical-trials legislation.
- Provide technical support to the European Commission during the co-decision process for the proposal on revision of the veterinary medicines legislation in the Council and the European Parliament.
- Ensure efficient crisis management and responsiveness to public-health threats, including addressing antimicrobial resistance and the availability of anti-infective treatments.
- Further increase transparency and implement stakeholder and communication strategies.
- Improve quality, integration and accessibility of data held by the Agency.

Mission statement

The mission of the European Medicines Agency is to foster scientific excellence in the evaluation and supervision of medicines, for the benefit of public and animal health.

Legal role

The European Medicines Agency is the European Union (EU) body responsible for coordinating the existing scientific resources put at its disposal by Member States for the evaluation, supervision and pharmacovigilance of medicinal products.

The Agency provides the Member States and the institutions of the EU the best-possible scientific advice on any question relating to the evaluation of the quality, safety and efficacy of medicinal products for human or veterinary use referred to it in accordance with the provisions of EU legislation relating to medicinal products.

The founding legislation of the Agency is Regulation (EC) No 726/2004.

Principal activities

Working with the Member States and the European Commission as partners in a European medicines network, the Agency:

- provides independent, science-based recommendations on the quality, safety and efficacy of medicines, and on more general

issues relevant to public and animal health that involve medicines;

- applies efficient and transparent evaluation procedures to help bring new medicines to the market by means of a single, EU-wide marketing authorisation granted by the European Commission;
- implements measures for continuously supervising the quality, safety and efficacy of authorised medicines to ensure that their benefits outweigh their risks;
- provides scientific advice and incentives to stimulate the development and improve the availability of innovative new medicines;
- recommends safe limits for residues of veterinary medicines used in food-producing animals, for the establishment of maximum residue limits by the European Commission;
- involves representatives of patients, healthcare professionals and other stakeholders in its work, to facilitate dialogue on issues of common interest;
- publishes impartial and comprehensible information about medicines and their use;
- develops best practice for medicines evaluation and supervision in Europe, and contributes alongside the Member States and the European Commission to the harmonisation of regulatory standards at the international level.

Guiding principles

- We are strongly committed to public and animal health.

- We make independent recommendations based on scientific evidence, using state-of-the-art knowledge and expertise in our field.
- We support research and innovation to stimulate the development of better medicines.
- We assure continual improvement of our processes and procedures, in accordance with recognised quality standards.
- We adhere to high standards of professional and personal integrity.
- We communicate in an open, transparent manner with all of our partners, stakeholders and colleagues.
- We promote the well-being, motivation and ongoing professional development of every member of the Agency.

Legal Role

The three pillars on which all of the Agency's work is based:

- *Science*, representing the scientific expertise that guides the Agency in all of its regulatory decision-making.
- *Medicines*, representing the Agency's focus on assessing and monitoring medicines to ensure their quality, safety and efficacy.
- *Health*, representing the purpose for which the Agency was created, namely to protect and improve public and animal health.

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Further information

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