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Press release

Shaping the future of human and animal health in the EU

EMA Management Board and Heads of Medicines Agencies adopt network strategy to 2020

The European Medicines Agency (EMA) Management Board and the Heads of Medicines Agencies (HMA) have adopted a common strategy to 2020 for the European medicines regulatory network.

This is the first time that a single strategy for the whole network has been developed. It outlines common challenges and opportunities and sets out joint key priorities and a high-level roadmap to achieve these over the next five years. The strategy also supports the strategic priorities of the European Commission and the European Union (EU) agenda on human and animal health.

By joining forces and following the same strategy, the network will be able to tackle current and future challenges more effectively and better advance and protect public and animal health in the EU. The agreement of the strategy follows a public consultation during which stakeholders had the opportunity to send their comments and feedback to EMA and HMA.

The European medicines regulatory network is unique in the global regulatory environment. It includes all national medicines regulatory authorities for both human and veterinary medicines from EU Member States and the European Economic Area (EEA), and EMA. By working closely together, the network can draw on the resources and expertise available across the EU, avoid duplication and share workloads.

The strategy focuses on areas where collaboration within the network can make a real difference to human and animal health in the EU over the next five years and is built around four key themes:

Contribution to human health

The strategy sets out a comprehensive approach to encourage and support the development of new medicines addressing real public health needs, so that patients have timely access to new effective and safe medicines. It also highlights the importance of ensuring that patients in the EU continue to have access to existing medicines by safeguarding a robust supply chain and by supporting the development of generics and biosimilars.

Contribution to animal health and human health in relation to veterinary medicines

While the revised legal framework for veterinary medicines is being discussed at the level of the European Council and European Parliament, the strategy ensures that priority is given to activities that increase the availability of veterinary medicines, reduce administrative burden for veterinary medicines

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developers, improve the functioning of the EU's internal market for veterinary medicines and minimise the risks to human and animal health that may arise from the use of antimicrobials in veterinary medicine.

Optimising the operation of the network

The strategy aims to ensure that the right scientific expertise is available within the network to respond effectively to new public health challenges, including health emergencies and crises. It emphasises the need to strive for operational excellence whilst also strengthening collaboration, cooperation and communication within the network and with the network's stakeholders.

Contributing to the global regulatory environment

The strategy progresses a strong international role for the network in enhancing oversight of global supply chains, contributing to global convergence of regulatory standards, promoting reliance and work-sharing with other regulators and strengthening capacity building.

The strategy builds on the EMA roadmap to 2015 and the HMA strategy for 2011-2015 and will form the basis for separate multi-annual work programmes/implementation plans for EMA, HMA, and the coordination groups for mutual recognition and decentralised procedures, human and veterinary (CMDh and CMDv). These will give detailed information on the work of each component of the network, and will also describe how the joint network strategy will be taken forward in terms of detailed activities.

Notes

- 1. This press release, together with all related documents, is available on the Agency's website and on HMA's website.
- 2. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu
- 3. More information on the work of the Heads of Medicines Agencies is available at http://www.hma.eu/

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