EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EU Medicines Agencies Network Strategy to 2020

Presentation to the EMA Scientific Committees
May – June 2015

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Introduction

- Agreement between the EMA and the national medicines regulatory agencies to develop a joint strategy for the European Medicines Agencies Regulatory Network for the next five years (discussed at EMA MB and HMA meetings)
- Agreement that the joint Network strategy should provide a high level vision with a number of joint key strategic priorities where the highest benefit for human and animal health can be achieved
- Agreement that other less strategic aspects as well as implementation aspects should be undertaken through separate multi-annual work programmes/implementation plans

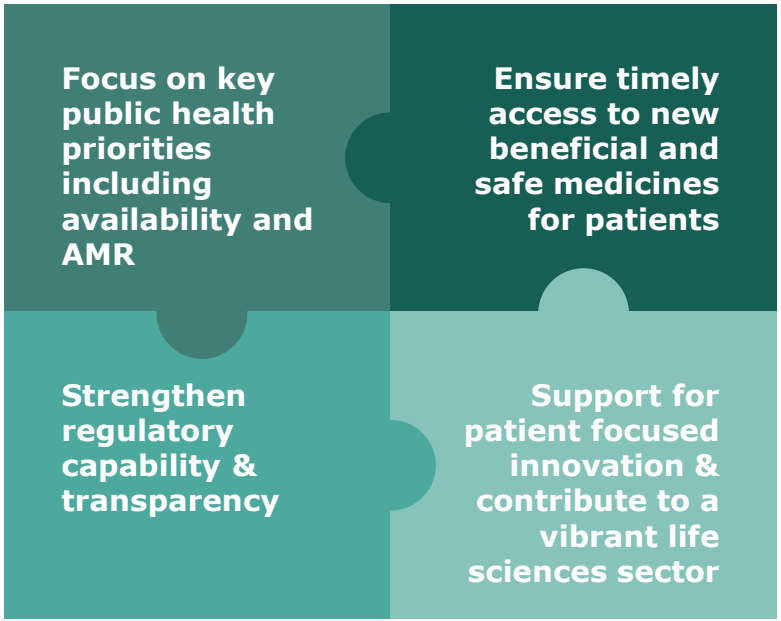
Approach and steps taken

- Joint EMA/HMA Strategy Group established in December 2014
- Leads (MHRA and EMA) and co-leads (HPRA, VMD, PEI, MEB) appointed for the different chapters of the Network Strategy
- Several drafts of the strategy discussed and reviewed at the EMA/HMA Steering Group
- Strategy subsequently discussed at a 5 February 2015 HMA strategic session in Riga
- Following HMA discussion, input from the EC and the EMA SciCoBo invited and implemented
- Network strategy endorsed by the MB at its March 2015 meeting, in view of a 3 months public consultation
- Network strategy published on 31 March inviting comments until 30 June 2015

Structure of the strategy

	Lead	Co-lead
Chapter 1: Introduction to the European medicines agencies regulatory network	MHRA	EMA
Chapter 2: Approach to the strategy	MHRA	EMA
Chapter 3: Strategy for the network		
Theme 1: Contributing to human health	MHRA	EMA
Theme 2: Contributing to animal health and human health in relation to veterinary medicines	EMA	HPRA, VMD
Theme 3: Optimising the operation of the network	EMA	PEI
Theme 4: Contributing to the global regulatory environment	EMA	MEB

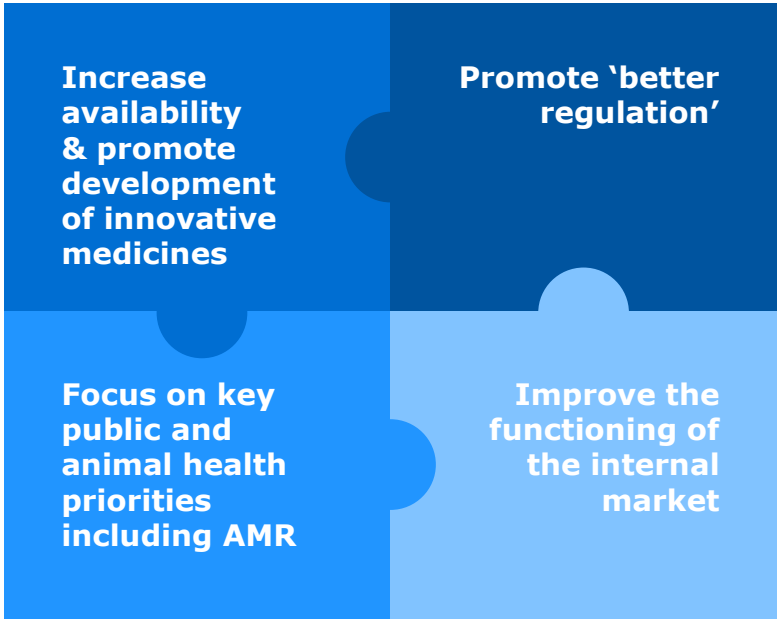
Theme 1: Contributing to human health



Theme 1: Main focus

- Address existing public health priorities (e.g. AMR) and new priority areas (e.g. Ebola), including special populations and rare diseases
- Tackle supply issues and potential shortages/lack of availability
- Facilitate access to new and innovative medicines (adaptive pathways, closer collaboration with HTA/pricing and reimbursement bodies)
- Provide support to innovation: European early stage innovative medicines designation?
- Make better use of the benefits real world databases and big data offer

Theme 2: Contributing to animal health and human health in relation to veterinary medicines



Theme 2: Main focus

- Revise MUMS guidelines
- Evaluate the success of measures put in place to facilitate access to market of new technologies
- Develop the Union database of veterinary medicines from which authorised products can be identified
- Improve the functioning of the existing legislation (optimisation of processes and increase in use of IT tools) whilst progressing the development of the new legislation
- Continue the European Surveillance of Veterinary Antimicrobial Consumption project
- Address continuity of supply/manage supply shortages

Theme 3: Optimising the operation of the network

Theme 3: Main focus

- Organise in a more optimal way the available expertise
- Continue efforts to strike the best balance between handling CoIs and securing the best possible expertise
- Review the scientific and operational procedures (capturing stakeholders' needs and expectations) to improve cost-effectiveness and operational efficiency
- Reduce the administrative burden whilst further strengthening the scientific quality
- Strive for an effective communication to maintain the trust of civil society in regulators
- Improve communication in case of health emergencies/crisis situations for authorised medicines
- Strive for a greater collaboration between regulators of medicines and regulators of medical devices
- Improve regular feedback from key stakeholders (on operation of activities and quality of output)

Theme 4: Contributing to the global regulatory environment

Theme 4: Main focus

- Strive for closer collaboration with global partners
- Work together with international partners where data are generated/used to ensure all suspicious data integrity problems are investigated
- Take a lead role in convergence of global standards
- Promote an integrated and consistent approach to collaboration with India, China, etc.
- Promote greater mutual reliance in inspection outcomes
- Strengthen promotion of international practices in developing countries

Next steps (1/2)

- Strategy is now subject to internal consultation (EMA staff and EMA scientific committees) in parallel with the external consultation
- Strategy has also been sent to partners (EU Institutions (EP, Commissioner, selected DGs, selected EU Agencies) and stakeholders (PCOs, HCPsOs, Academia, European Industry Associations, interested parties in the veterinary field))
- Face-to-face meetings will be organised with PCOs, HCPsOs, Academia (joint meeting on 4 June), European Industry Associations, interested parties in the veterinary field
- Comments have to be sent to EUnetworkstrategy@ema.europa.eu using a dedicated template
- EMA will prepare a consolidated document with all comments received to (1) facilitate the review and (2) be published later on to ensure transparency on the consultation process

Next steps (2/2)

- EMA and MHRA as leads, in close collaboration with the co-leads, will review the comments and make proposals for amendments to be discussed by the joint Steering Group
- A high level update on the comments made will be provided by EMA/MHRA at the July 2015 HMA and October 2015 MB meetings
- The revised strategy will be for decision at the October 2015 HMA and December 2015 MB meetings