

Session 1 - View from European Medicines Regulatory Network

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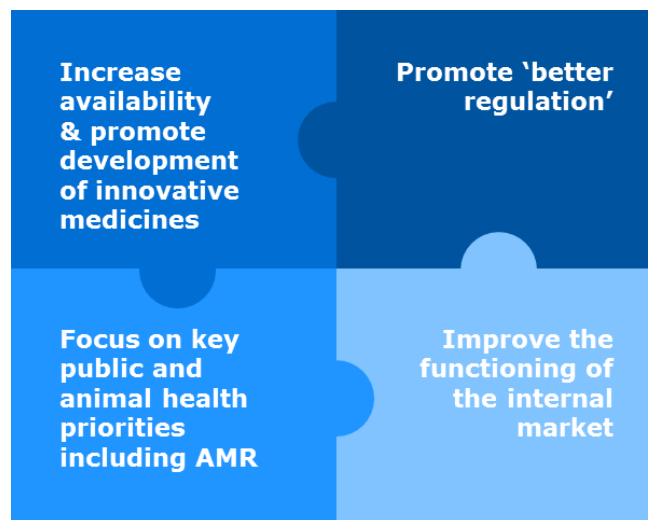
Background: *EU Agencies Network Strategy to 2020*

- **HMA network:** more than 50 national competent authorities from EU/EEA
 Close cooperation - complementary approaches - common mission:
 - *Securing efficient and effective operation of both the EMRS and the Network*
 - *Ensuring that available resources are sufficient to support the work of the network*
 - *Ensuring that the Network is aware of and responds appropriately to the challenges it faces due to the ever-changing nature of the environment in which it operates*
- **EMA and HMA:** close cooperation - common strategy to 2020 outlining:
 - *Common challenges and opportunities*
 - *Setting out joint key priorities & a high-level roadmap to achieve these*



Background: *EU Agencies Network Strategy to 2020*

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



Background: *EU Agencies Network Strategy to 2020*



- Theme 1: Contributing to human health
 - Objective 4: Strengthen regulatory capability and transparency

The network will ensure that it has the capability to regulate novel products of the future, develop regulatory science, consider greater use of real world databases and increase transparency about the data that underpin regulatory decisions



- Theme 3: Optimising the operation of the network
 - Objective 1: Reinforce the scientific and regulatory capacity and capability of the network

The network will adapt the available scientific and regulatory expertise both in terms of capacity and capability to cope with changing demands

HMA - Multi Annual Work Plan (MAWP)

- After finalisation of the joint HMA/EMA strategy, the HMA developed a MAWP to bring the joint overarching strategy into operation on the HMA level with the involvement of all NCAs:
 - o 11 Priorities: e.g. **Innovation** & access to new medicines, Availability of good quality appropriately authorized medicines, Responding to public and animal health emergencies, Competence development programme...
 - o Mid-term review 2018
 - o Discussion started for building up common strategy to 2025



Needs in animal health sector - context

- **Globalisation:** increase of circulation of goods, Impact on trade, impact on animal and public health

« The 5 Ts »

Trade

Travel

Transport

Tourism

Terrorism



- **One World – One Health approach**

- ✓ AMR
- ✓ Antiparasitic resistance

- **Climate change**

- ✓ Vector-borne disease

Outbreaks :

- Blue tongue
- Foot and Mouth disease
- Avian Influenza
- Lumpy skin disease
- African Swine fever
- West Nile fever
- ...

Problem encountered for veterinary medicines

- Less resources than in human sector, different economical context, need for return on investment



- Regulation

- ✓ MRL
- ✓ Environmental risk assessment
- ✓ Difficulties to constitute a full dossier, lot of GLs



- Therapeutic gaps - MUMS

- ✓ Specificities of minor species : Goats, fish, bees...

- Shortages in vaccines production



- Major health concerns :

- ✓ AMR
- ✓ Climate change : vector-borne disease, insecticides to treat animals...

Regulatory Science in veterinary medicines

Regulatory science shall take into account the problem encountered:

- Facilitation for registration : review of GLs
 - ✓ E.g. field trials for registration of vaccines
- Consideration of major health concerns
- Answer to therapeutic gaps - MUMS
 - ✓ (extension to minors species: goat, fish...)
- Consideration of economic context
- Social research leading to studies organised by Academia



Regulatory science shall promote innovation

- New technologies



National Experience: the French Animal Health Network

- RFSA is the mirror group in France of the European technology platform for animal health created in 2007, bringing together representatives from the veterinary medicinal product industry, researchers in the field of animal health and European regulatory authorities.



Example of cooperation in medicine availability



<http://www.reseau-francais-sante-animale.net>



- **WG1:** A first group seeks out **practical solutions to field problems such as the availability** of veterinary products for minor species
- **WG2:** A second group is in charge of identifying **needs arising from emerging trends**
- **WG3:** A third group undertakes forward-looking analyses **to identify research requirements** in order to submit them to the supervisory authorities who will pass this information on to the European Commission
- **WG4:** A fourth group identifies public/private scientific cooperation projects

The benefit for Animal Health and Public Health

- Successful partnership for animal health
 - Consultation (eg. AMR research program)
 - Coordination (mapping of scientific studies available)
 - Cooperation (eg. interaction with human research org.)
- Diagnostics and Veterinary Medicines are « Public goods » and Industry have special responsibilities regarding:
 - Availability of Veterinary Medicines
 - o ex: VMP therapeutic gap' mapping
 - Reactivity during emergencies
 - o e.g. coordination between vaccines producers for an urgent answer in case of outbreaks
- Open innovation (academics- companies)
 - Development of new medicines
 - Public – Private cooperation