

EU Medicines Agencies Network Strategy to 2020

“Working together to improve health”

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Chapter 1 : Introduction to the network

IFAH-Europe welcomes:

- ✓ agencies working closely together as the network can draw on the resources and expertise available across the EU, **avoid duplication and share workloads;**
- ✓ The acknowledgement of the **small size** of the veterinary network and the **entirely commercial nature of the VMP** and, as a consequence;
- ✓ the approach adopted to ensure **sustainability** of both the animal health industry and the regulatory network.

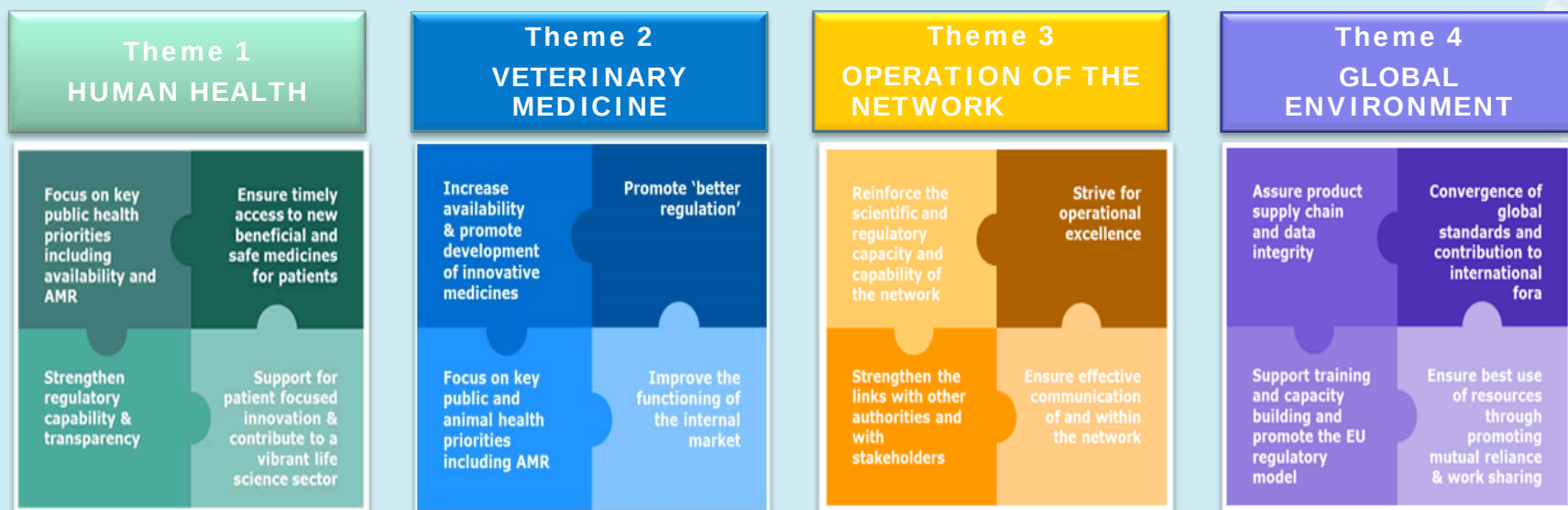
Chapter 2: Approach to the strategy

IFAH-Europe welcomes the objective :

- ✓ To adopt for the first time a **single strategy** for the entire network
- ✓ To set key **strategic priorities for the next five years**
- ✓ For the Network to support **new and innovative developments**
- ✓ **To have identified the following drivers**
 - increase efficiency and optimise the operation of the network
 - address new and emerging **threats**
 - work **globally** with more global collaboration



Chapter 3: Strategy for the network



Theme 1: *Contributing to human health*



IFAH-Europe will keep a close eye on this theme as it may serve/influence the animal health sector :

- Explore flexible licensing pathways

Objective 4: Strengthen regulatory capability and transparency

- Capability to regulate novel products



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



Objective 1: Increase availability and promote innovation

- Focus on: minor species, smaller national markets and technologies that are new to the veterinary domain

*“Experience has shown that reducing the data required at the time of authorisation can act as a strong incentive to the pharmaceutical industry to market products for MUMS.” (Quite rare situation - **Bluetongue is the exception – Need to revisit the guidelines on MUMS)***

- Lack of availability for smaller national markets (**What will be done?**)
- Ensuring preparedness for new emerging animal diseases (**How?**)
- New technologies are being developed : Network will evaluate the success of measures recently put in place to accommodate these (**Needs to be proportionate to the size of market**)
- Develop a Union Database of veterinary products (**How is this going to increase availability?**)

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



Objective 2: Promote better regulation

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- Complexity of the VMP market creates a high admin burden ***(Recognition welcomed - What about the small market size? need greater efficiencies)***
 - Initiatives within CMDv involving industry ***(Welcomed)***
 - Optimise processes for veterinary pharmacovigilance and increase use of IT tools ***(Welcomed)***
 - Extensive projects for revised processes and IT systems in new Network will follow developments on effect of chemicals on groundwater ***(Ensure that the human sector is involved and covered)***
 - Network will work with the European Commission and stakeholders to enrich the debate on the new legislation ***(Welcomed)***

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



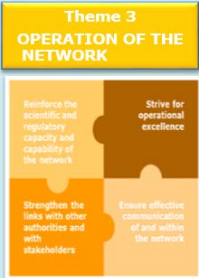
Objective 3: Improve functioning Single Market

- Effective single market = availability across the network of a wide range of products with harmonised conditions of use (**Welcomed**)
- Continued high workload of referrals of antimicrobials and other classes of products is expected. (**Noted**)
- Network will develop a strategy aimed at providing incentives and tools to increase availability in smaller national markets (**When?**)

Objective 4: Focus on key public and animal health priorities

- Continue to define prudent and responsible use (**Epruma**)
- Collection of data on the consumption of antimicrobials (**Data on use - ESVAC**)
- Will address emerging environmental concerns (**Noted**)
- Review how best to ensure continuity of supply, including vaccines (**Welcomed**)

Theme 3: Optimising the operation of the Network



IFAH-Europe welcomes:

- Strengthening the collaboration and cooperation between all parties in the network
- Critical success factor: sustainable high-quality scientific and regulatory expertise (***State of the art***)
- Taking into account that the network encompasses human, veterinary and joint NCAs
- Allowing the veterinary domain to benefit from the economies of scale that arise from being part of a wider network

Theme 3: Optimising the operation of the Network

Theme 3 OPERATION OF THE NETWORK



Objective 1: Optimising the operation of the Network

- Identification of any gaps in scientific and regulatory expertise
- Future needs include innovative therapies and new methodologies

Objective 2: Operational excellence

- Objective to reduce regulatory burden on stakeholders, administrative burden on NCAs (*stakeholders believe there is still further room for optimising the regulatory operations*)
- A common EU Telematics Strategy and inter-operable IT systems play a major role

Theme 3: Optimising the operation of the Network



Objective 3: Ensure effective communication

- Five year communication plan (*welcomed*)

Objective 4: Strengthen links with other authorities and stakeholders

- Network will put in place more streamlined mechanisms to obtain regular feedback from relevant stakeholders (*welcomed*)



Theme 4: Contributing to the global regulatory environment



Objective 1: Assure product supply chain and data integrity

- Mechanisms to facilitate greater information sharing (*Welcomed*)

Objective 2: Convergence of global standards and contribution to international fora

- Int'l cooperation facilitates better use of collective resources, avoiding duplication; sharing of best practices
 - Equivalence of standards: VICH;
 - VICH has embarked on a global outreach initiative

Objective 4: Support training and capacity building + promote the EU regulatory model

- Promote international best practices
- VICH training