EU Network Strategy
Vision for Veterinary Medicines

European Medicines Agency/IFAH Europe Info Day 2016

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Introduction

- The first joint strategy for the European Medicines Agencies Regulatory Network for the next five years
- The result of close cooperation between the partners in the Network and consultation with stakeholders
- Provides a high level vision of joint key strategic priorities where the highest benefit for human and animal health can be achieved
- Implementation undertaken through separate multi-annual work programmes of EMA and HMA
- Specific theme recognising the particular nature of the veterinary domain and actions required to address the needs of animal health
# Structure of the strategy

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Theme 1: Contributing to human health

Focus on key public health priorities including availability and AMR

Ensure timely access to new beneficial and safe medicines for patients

Strengthen regulatory capability & transparency

Support for patient focused innovation & contribute to a vibrant life sciences sector
Focus on key public health priorities including availability and antimicrobial resistance (AMR)

- AMR a high priority for the Network tackled by a ‘One Health’ approach
- Selected key activities with respect to veterinary medicines
  - Contribution to the next European Commission Action Plan on AMR
  - Active engagement in the Trans-Atlantic Task Force on AMR (TATFAR)
    - Cooperate in filling knowledge gaps on the link between use of antimicrobials in veterinary medicines and risks to human health from AMR
  - Contribution to the WHO Global Action Plan and other global initiatives such as G8
  - Fostering implementation of the CVMP Strategy on antimicrobial 2016-2020
    - Specific activities listed in the theme on veterinary medicines
  - Update on advice on veterinary use of colistin
Theme 2: Contributing to animal health and human health in relation to veterinary medicines

- Increase availability & promote development of innovative medicines
- Promote ‘better regulation’
- Focus on key public and animal health priorities including AMR
- Improve the functioning of the internal market
Increase availability of veterinary medicines and promote development of innovative medicines and new technologies

- Activities to promote availability in advance of the revision of the veterinary legislation
- Minor Use/Minor Species/Limited Markets (MUMS)
  - Finalise review of the MUMS guidelines
- Focus on availability of vaccines, particularly those against transboundary diseases
  - Implement a joint EMA/HMA Action Plan on Availability of Veterinary Vaccines
- Assist access to market of novel technologies (ADVENT, Innovation Task Force, Scientific Advice etc)
- Support the HMA with measures to reduce attrition of existing products, particularly antimicrobials
Theme 2: Contributing to animal health and human health in relation to veterinary medicines

Increase availability & promote development of innovative medicines

Promote ‘better regulation’

Focus on key public and animal health priorities including AMR

Improve the functioning of the internal market
Promote ‘Better regulation’

- Optimise existing processes and prepare business and IT systems for the revised legislation
- EU Telematics
  - Develop existing ‘Eudrapharm Veterinary’ database of veterinary medicinal products
  - Implement a VICH compliant Eudravigilance Veterinary pharmacovigilance system (EVVet 3)
  - Plan integration of veterinary products within the SPOR (Substances, Products, Organisations and Referentials) Master Data Management System
- Optimise processes for veterinary pharmacovigilance
Theme 2: Contributing to animal health and human health in relation to veterinary medicines

- Increase availability & promote development of innovative medicines
- Promote ‘better regulation’
- Focus on key public and animal health priorities including AMR
- Improve the functioning of the internal market
Improve the functioning of the single market

- Promote harmonisation of existing products
  - Referrals of antimicrobials through the CVMP to achieve harmonised SPCs in line with prudent and responsible use
  - CVMP reflecting on how best to promote responsible use of anthelmintics to minimise the risks of resistance
Theme 2: Contributing to animal health and human health in relation to veterinary medicines

- Increase availability & promote development of innovative medicines
- Promote ‘better regulation’
- Focus on key public and animal health priorities including AMR
- Improve the functioning of the internal market
Focus on key public and animal health priorities including antimicrobial resistance

- Foster implementation of the CVMP Strategy on Antimicrobials 2016-2020
- Develop further the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC)
  - Annual reports on consumption
  - Develop methods for estimating and measuring consumption per species
  - Publish defined units of measurement (DDDvet/DCDvet)
- Publish CVMP opinions together with CHMP and other agencies e.g.
  - RONAFA (Reduction Of the Need to use Antimicrobials in Food-producing Animals)
  - JIACRA (joint report on the integrated analysis of the consumption of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from humans and food-producing animals)
Theme 3: Optimising the operation of the network

- Reinforce the scientific and regulatory capacity and capability of the network
- Strengthen the links with other authorities and with stakeholders
- Strive for operational excellence
- Ensure effective communication of and within the network
Optimising the operation of the Network

• Key actions in the veterinary domain
  – Promote harmonised assessment and scientific excellence through the EU Network Training Centre
    • Veterinary competence frameworks and curricula
    • Possibility of developing joint training with industry, where appropriate
  – Continuous improvement through the BEMA exercise (Benchmarking of European Medicine Agencies)
  – Optimal use of information management systems through the EU Telematics programme
  – Improved communication with veterinary stakeholders
  – Improved handling of animal health threats and product shortages through the revised Incident Management Plan
Theme 4: Contributing to the global regulatory environment

- Assure product supply chain and data integrity
- Convergence of global standards and contribute to international fora
- Support training and capacity building and promote the EU regulatory model
- Ensure best use of resources through promoting mutual reliance & work sharing
Contributing to the global regulatory environment

• Key actions in the veterinary domain
  – Participate in initiatives to secure the product supply chain and data integrity through working with global partners
  – Promote harmonised standards through EU input into VICH and its Outreach Forum and Codex Alimentarius
  – Promote uptake of best practice in the 3Rs (replacement, reduction and refinement of use of animals in authorisation of medicines)
    • VICH
    • Joint Expert Group on 3Rs
  – Global initiatives on regulatory convergence and capacity building through VICH Outreach Forum, OIE, FAO, and NGOs
Conclusions

- The Network Strategy to 2020
  - Defines ambitious objectives for the Network over the next 5 years
  - Aims to optimise operation of existing legislation whilst preparing for the new legislation
  - Places enhanced emphasis on working jointly as a Network to achieve shared objectives
  - Represents a real opportunity to achieve the objectives set out by the Commission for the new legislation to the benefit of animal and public health
Thank you for your attention

Further information

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