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SCIENCE MEDICINES HEALTH

Promoting innovation through the veterinary regulatory framework: Role of EMA

EMA veterinary medicines innovation day

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An agency of the European Union

Promoting innovation - overview

- EMA objectives that support innovation
- Regulatory framework: key elements that impact on innovation
- EMA contributions to promote innovation (current & future)
- Conclusions

EMA objectives that support innovation

- EMA recognises that **innovation is essential** to bring **new products** to market and thereby promote animal and public health through increased availability of veterinary medicines
- To "**Stimulate competitiveness and innovation**" is one of the primary objectives of the revision of legal framework for veterinary medicines
- EMA aims to create an environment that **encourages and supports innovation** in the veterinary domain

Regulatory framework: key elements that impact on innovation

Key legislation

- Directive 2001/82/EC
- Regulation(EC) 726/2004
- Commission Regulation (EC) No 37/2010

Annexes, delegated & implementing acts

- Annex 1 to Directive 2001/82
- Implementing acts for MRL regulation

Regulatory guidance

- NtA, EMA regulatory guidance and recommendations

Scientific guidance

- CVMP guidelines & reflection papers, VICH guidelines, European Pharmacopoeial monographs, scientific opinions of CVMP, scientific advice to applicants

Specific initiatives

- MUMS, ITF, ADVENT, SME scheme, international cooperation, availability initiatives, Network Strategy

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EMA contributions to promote innovation (current & future)

Key legislation

- Directive 2001/82/EC
- Regulation(EC) 726/2004
- Commission Regulation (EC) No 37/2010

New Veterinary Regulation
– advice on request to EC, EP and Council

Annexes, delegated & implementing acts

- Annex 1 to Directive 2001/82
- Implementing acts for MRL regulation

Advice to EC in preparing annexes, implementing delegated acts to the New Veterinary Regulation

Regulatory guidance

- NtA, EMA regulatory guidance and recommendations

Input to revision of NtA
Revision of EMA regulatory guidance & recommendations

Scientific guidance

- CVMP guidelines & reflection papers, VICH guidelines, European Pharmacopoeial monographs, scientific opinions of CVMP, scientific advice to applicants

New and revised CVMP guidelines, reflection papers etc.
Cooperation with EDQM to ensure alignment
(esp. biologicals)

Specific initiatives

- MUMS, ITF, ADVENT, SME scheme, international cooperation, availability initiatives, Network Strategy

Specific outputs from vet vaccine availability initiatives
Extrapolation of MRL data for existing antimicrobials
EMA Regulatory Science Strategy

Conclusions

- Coordinated activity at all levels of the regulatory framework will be necessary to achieve the objective in the New Veterinary Regulation of promoting innovation in the veterinary domain.
- Scientific input from EMA/CVMP will be key to ensuring that the particular needs of innovative veterinary medicines are addressed.
- The New Veterinary Regulation provides a unique opportunity to promote innovation in the veterinary domain and EMA intends to play a key role in realising these opportunities.
- Examples of areas which will be crucial for innovation include:
  - Defining the requirements for biologicals in the revised annex.
  - Striking an appropriate balance between availability and protecting public health in scientific advice to assist the European Commission in delegated and implementing acts for antimicrobials (i.e. creating the 'tools' in the 'Tool Box' for combatting AMR).
  - Developing an approach to harmonisation of SPCs that achieves the policy objectives whilst not diverting industry resources from innovation to defence of existing products.

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Any questions?

Further information

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