Minor Use / Minor Species Policy
Industry Feedback

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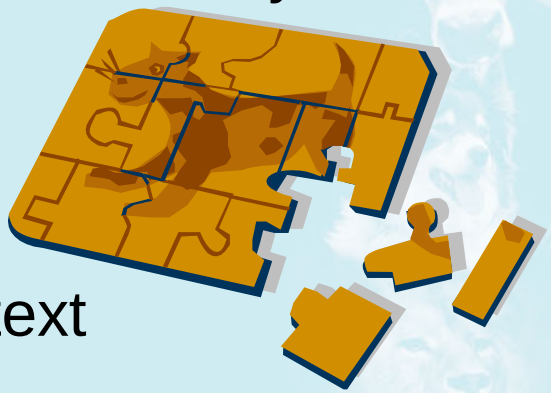
Contents

- Introduction
- Problem statement
- Causes
- MUMS Policy
- Perspectives
- Outlook

Introduction

- Minor Use / Minor Species policy has been introduced to improve / maintain medicines availability
- The MUMS policy is very important and can be very beneficial
- MUMS is only one piece of the puzzle
- MUMS has to be seen in the greater context
- IFAH-Europe firmly supports MUMS



Problem statement

- We have major medicines gaps especially prevalent in food-producing species
- “Old products" will be more restricted and will disappear
- New products are, if at all, developed only for certain major species and main indications
- New products not marketed in all countries

The problem has been known for a long time !

Implications

The lack of suitable veterinary medicines can have a direct impact on:

- Animal Welfare
- Target animal safety
- Consumer safety
- Environmental protection

Causes

- The veterinary pharmaceutical market is rather small (4% of HH) and highly fragmented
- Regulatory requirements for veterinary medicinal products have steadily increased over time and still do
- Development and maintenance costs for veterinary medicinal products have significantly increased (e.g. variation fees, PV, country specific packaging etc.)
- Insufficient data protection is the “innovation stopper”

Causes – examples

- Excessive quality requirements: purified water for pour on products
- Excessive costs: product specific changes to the DDPS
- Excessive regulatory requirements: draft antibiotic efficacy guideline
- Excessive……
- Excessive…….

MUMS Policy

- Application of the policy is unpredictable and inconsistent *(examples on file)*
- Clinical data requirements are “major” and not a “minor” *(examples on file)*
- Overall feasibility to develop for minor use in a major species appears to be most affected (*examples on file)*
- Overall incentive / benefit is simply not attractive enough

➡ **Paradigm shift is needed**

MUMS Perspectives

- MUMS policy has to be revised in its entirety
- Apply risk management for label-use
- MUMS labelling
- Conditional approval (clinical efficacy)
- Turn pharmacovigilance into a more value-added tool
- MUMS to be the rule for all veterinary medicines and exceptions to be defined!

Outlook

- Industry / Stakeholder / Regulator to challenge Legislator
- HMA (Heads of Medicinal Agencies) medicines availability initiative to be strengthened & continued
- National funding projects (US National Research Support Project No.7) to be considered
- “Old drug product” policy to be established

Thank you for your attention

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