Pilot project on dose optimisation of established veterinary antibiotics in the context of SPC harmonisation

12 October 2018, EMA, London

1. Context

2. Principles

3. Key success factors

4. Methodology – Reflection paper

5. Implementation

CONTEXT

- **Posology old ABs** not always adequate, **field** evidence (efficacy, context **AMR**)
- Update **current requirements** → **Not viable** approach; concern **availability**
- **Security of supply** and incentive to maintain some **older ABs** on the market essential.

  → Remote likelihood new vet ABs developed

  → Pave the way for **sustainable regulatory environment** existing ones

  → Exploring **scientific approach** + options offered by existing **legal tools**

PRINCIPLES

Social shared responsibility **Regulators + Industry**

PILOT PROJECT: Feasibility mathematical **modelling**

1. Update and harmonise dose – PK/PD
2. Address consequences –WPs, **ERA**, Safety

Non-experimental approach; Use of **existing data in dossiers** and literature to the most extent possible

- Efforts from all players; limitations, constraints and market consequences acknowledged
- "Must-do"; any other alternative too costly and would impact availability (-).

KEY SUCCESS FACTORS

1

Modelling applied to every product ("hour glass approach")

Essential hybrid authorisations i.e. if there were differences with the WPs, those would be maintained

Product harmonisation, not class harmonisation

2

Pragmatic approach

- Existing data in dossiers
- Existing data in literature

3

When strictly necessary based on **evidence of risk**

- Field experience, Substances underdose would lead AMR
- Prioritization.

METHDOLOGY – REFLECTION PAPER

At present reviewing and compiling comments (31.01.2019)

Basically we think, that this is a **scientific** based, **well designed**, **logically and intelligibly** described draft proposal.

This draft is very long and deeply **professional**

This very extensive reflection paper is **well written** and uses **scientifically sound** methods

We are **extremely enthusiastic** about this document. We have many **old products** that could benefit if this paper was finalized in a guideline. We would be able to **update** some of our our products making them **safer for animals and people**

IMPLEMENTATION

Agreed scheme Regulators/Industry supported & preferred.

Would allow better management of

- Timings, **planning** and anticipation
- Selection of molecules (**priorities**)
- Monitoring **implementation** and follow-up

In line with **PPHOVA principles and spirit:** commitment, open dialogue, joint responsibility, effective implementation

Cooperation for a **COMMON KEY COMMON OBJECTIVE:**
to **guarantee** the range of **treatment options**

IMPLEMENTATION (II)

CONCERN REFERRALS, not aligned with PPHOVA principles

1. **SCOPE?**

   Broader scope (not only dose). Loss of indications, species, pharmaceutical forms…? -> availability **(-)**

2. **METHODOLOGY?**

   Class harmonisation, conflict with “hour glass approach” **(-)**

   Disincentive innovate and improve old products **(-)**

1. **PRAGMATISM?**

   Cost and burden for industry and regulators **(-)**

RECAP

1. Context - agreed ✓
2. Principles - endorsed ✓
3. Key success factors - supported ✓
4. Methodology / Reflection paper – welcome! ✓
5. Implementation – proposals TBD ✓

Balanced and pragmatic approaches to maintain a broad arsenal of safe and effective therapeutic options.