HMA/EMA multi-stakeholder workshop on shortages

Breakout session veterinary medicines

Access VetMed perspective

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- Founded in 2002 as the European Group for Generic Veterinary Products (EGGVP)
- Represents the generic and added-value veterinary medicines industry in Europe
- 26 members headquartered in Europe, largely SMEs
- 22 out of 26 members are “veterinary only” companies

We support animal health by

increasing access

to veterinary medicines,

many for **minor species** and

smaller markets in Europe.

Introduction

- It is important to address shortages through the veterinary medicines chain
- Vets increasing concerns on field about VMPs scarcity and unmet needs
- Issues also reported by some NCAs
- Perception of issues may differ. Availability problem or shortage?
  - Root cause not always determined / not relevant to user
  - Industry capacity to anticipate problems also differs depending on root cause

Thanks for organising this workshop to better understand issues at each side

- HMA-EMA TF on Availability of Authorised Medicines for Human and Vet Use:
  - BPG for prevention and management of shortages for HUMAN industry – in preparation
  - Equivalent needed at VETERINARY side? NO

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Shortages

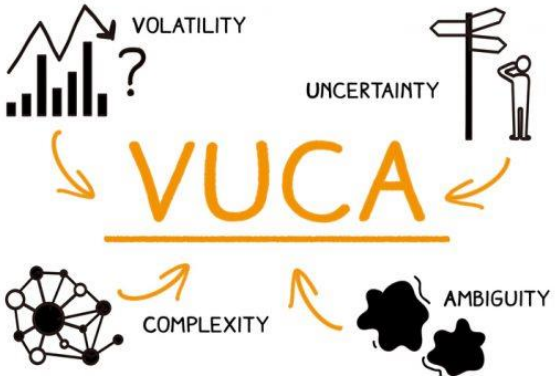
Report generic and added value VMPs in EU

Our industry segment not immune, but very resilient during uncertain & volatile times

Major supply problems avoided so far. Still, unexpected / minor issues / delays along the supply chain reported

Influencing factors different to human medicines industry; overall less complexity

Situation may change, unpredictable future



Shortages: main threats supply chain

> Compliance vs economics

> Increasing efforts to ensure continuous supply of critical VMPs

> Risk: old dossiers (lower return of investment)

Additional guidance for prevention and management of shortages vet sector?

Increasing burden, resources currently not justified ("overregulation" perception)

> Other: price increases, delays, energy supply

(Root cause manufacturing declared as not significant)

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Availability: impact Reg 2019/6

- Main objective new Regulation: increase availability of VMPs across Europe; Fully endorsed by Access VetMed
- Currently on implementation phase, objective not yet met – not yet visible
  - Important role from National Competent Authorities by using harmonised and pragmatic approaches
  - Implementing variations and new QRD template:
    - impact as substantial resources needed (cost package, fees, HHRR)
    - hinder rapid placing on the market
  - Focus on access to generics and added value VMPs
    - opening central procedure for generics (+)
    - new rules data protection / exclusivity periods (-)
    - predictability and transparency for timely access (-)

Suggestions moving forward (I)

- Avoid unnecessary reporting requirements and unnecessary burden on MAHs leverage (no additional guidance)
- Enhance collaboration to determine problems and better understand their causes
- Streamlined and efficient communication channels
  - AVAILABILITY: UPD
  - SHORTAGES
    - Case-by-case based on field information
    - Protocols vets / industry for a more agile handling of cases
    - List of essential and critical VMPs

Suggestions moving forward (II)

- Flexible and agile regulatory framework in order to be more efficient in the life cycle management of changes
- Active listening to industry; pragmatic approaches
- VMPs recognised and regulated as essential goods and services
  - Any measures applied to human meds to alleviate pressure and prevent shortages → immediate application to veterinary medicines sector too

Thank you

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