

Medicines for veterinary use Breakout Session: HMA-EMA Multi-stakeholder workshop on shortages

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Content

- Setting the scene
- Shortages/availability issues presentations from
 - the veterinarians' perspective / FVE
 - the industry's perspective / Access VetMed and AnimalhealthEurope
 - the regulators' perspective / DE-BVL and FR-ANSES
- Discussion
- Conclusions and actions

Session objectives

- Define lack of availability versus shortage of VMPs
- Identify the root causes of lack of availability and shortage of VMPs
- Discuss specific issues with lack of availability/shortages of VMPs e.g. small markets
- How does Regulation (EU) 2019/6 support availability of VMPs?
- In order to manage availability/shortage of VMPs to identify actions that are needed/need to be avoided

Lack of availability versus shortage

- Lack of availability: lack of products that are authorised **but** are not marketed or no longer marketed
- Shortage: lack of products that are authorised **and** marketed (*supply chain disruptions directly prevent the availability of authorised and marketed products*)

How does Regulation (EU) 2019/6 support availability of VMPs?

Art. 58(2)

"The marketing authorisation holder shall, within the limits of its responsibilities, ensure appropriate and continued supplies of its veterinary medicinal products."

Art. 101(4)

"Wholesale distributors shall, within the limits of their responsibility, ensure appropriate and continued supply of veterinary medicinal product to persons authorised to supply it in accordance with Article 103(1), so that the needs for animal health in the relevant Member State are covered."

Outcome

- Veterinarians experience shortage issues to an extent which is currently unknown
- It appears that mainly vaccines and antibiotics are affected
- The topic needs further investigation on a multi-stakeholder level to quantify the actual problem
- Develop list of critical VMPs –(criticality may differ in individual Member States)
- Some MS report on shortages. France has developed the most comprehensive system (reporting shortages is mandatory in France since 2022)
- Voluntary reporting of shortages (Germany) did not deliver useful data
- Use of UPD data (availability, sales) has been discussed as possible option for monitoring shortages (avoid setting up a separate system)

Outcome

- VMPs should be regarded as 'essential goods' like HMPs
- Same level of regulatory flexibility should apply for VMPs as for HMPs
- To look into the missing quantitative data and root cause regarding shortages of vaccines and antibiotics
- Current H & V guidance documents can only be considered for VMPs when we know the full scale of the problem on the veterinary side
- No additional guidance was deemed necessary

Thank you for listening

Further information

See websites for contact details

Heads of Medicines Agencies www.hma.eu
European Medicines Agency www.ema.europa.eu

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