

# EMA HMA/EMA multi-stakeholder workshop on shortages

Session 3: Prevention of shortage

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#### The FVE network



- >45 national associations
- >38 European countries
- >4 FVE Sections
  - UEVP (Practitioners)
  - UEVH (Hygienists Public Health Officers)
  - EASVO (Veterinary State Officers)
  - EVERI (Education, Research, Industry)





## We are similar, but we are not the same: veterinary medicines versus human medicine

#### Number of species:

Human Sector: one species Veterinary Sector: 7 major species and many minor

#### Market size and who pays:

Human Sector: ~97%, social security

Veterinary Sector: ~3 %, owner

pays

(and paying for the medicine)

**Ensuring food and environmental safety:** 

Extra tests are done to ensure food, consumer and environmental safety.





#### Lack of Availability versus Shortages



I am short of...'



FVE survey on lack of medicine/vaccines in Europe

Country	-	Important medicines/vaccines shortages you are aware of currently
Croatia		Anthrax vaccine, horse influenza and tetanus vaccine, then for the other medicines bovine PPD and avin PPD for tuberculosis testing
Cyprus		Feline vaccines, some canine vaccines, caninsulin, some antibiotics, cytopoint and xylazine. In large animal medicine there is shortage on Ovipast vaccine for pneumonia in lambs and Enzovac for chlamydial abortion. There are also medicines that were never marketed in Cyprus but are widely used in other EU countries (e.g. DepoMedrol).
FEEVA		Equine Influenza Vaccine has been in sort supply in recent months to the point that FEI have adjusted the vaccination requirements for competition horses. Historically Equine Herpes Virus vaccine has been unavilable. Some local anaesthetic have also been unavailable.
Finland		lokivetmab (Cytopoint ®), bedinvetmab (Librela ®), oclacitinib (Apoquel ®). At the time of writing this answer Fimea has also announced problems in availability of some vaccines (Eurican DAPPI®, Eurican Herpes®).

#### **Critical shortages**

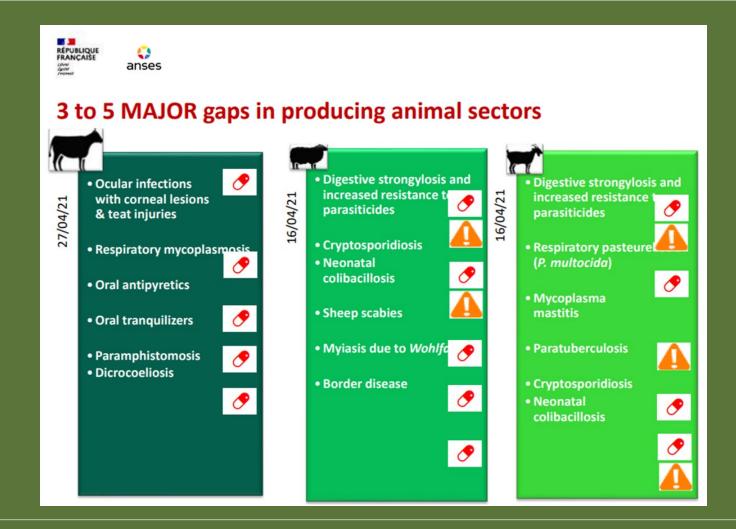
- Vaccines, observed for several species
- Antibiotics, especially narrow spectrum or lower classes antibiotics— *i.e. penicillin, amoxycillin, tetracyclines, etc.*

7708	Greece - reports issues with live salmonella and Gumboro vaccines in recent months. Portugal -Some current issues with availability of mycoplasma, Pox and AE are reported. France - shortages are not unusual, but vary from week to week, month to month. A wide range of live vaccines and some inactivated vaccines have been experienced this year and some continue for many months
Romania	No problems related to the important medicines/vaccines shortages
Slovenia	Rabies vaccine from time to time and infectious disease polyvalent vaccine and dermatophytosis vaccine (Rabisin, Eurican, Purevax, Vanguard, Insol Trichophyton). Currently there is a substantial shortage of tetracyclines on market
Sweden	Equine influenza vaccine, atropine eyedrops, meloxicam, and (for laboratory animals): Hypnorm (needed for diabetes research) and Buprenorphine.
Switzerland	Almost permanent with intramammary Penicilline-Products, other first-line Antibiotics. This spring we hadn't any vaccine against Enterotoxemia/pulpy kidney disease in lambs, a lot died.
United Kingdom	Cat vaccines ( which is now improving), equine influenza vaccines, intravenous fluids, particularly large 5 litre bags for equine practice





To conclude: lack of availability of veterinary medicines is a huge problem



Aims new veterinary medicines legislation:

- Address the public health risk of antimicrobial resistance (AMR)
- Increase availability of veterinary
   medicinal products; and improve the
   functioning of the internal market
- Reduce administrative burden
- Stimulate competitiveness and innovation





### New regulation has potential to increase availability



Veterinary medicines = many species/subspecies →needs flexibility



Increased flexibility of prescription cascade



Stimulate innovation incl. new medicines



Union Product
Database & easier
import of medicines
from other EU MSs;
prescriptions valid
throughout the EU



Extension centralized authorization procedure





## We need to ensure that this potential is used to increase availability

- Shortages, lack of incentives for investment, national restrictions, more stringent regulatory requirements, etc all influence availability.
- Important for regulators to use flexibility (riskbenefit)
- Important to monitor availability on EU and national level, especially for essential medicines



# How to prevent shortages?

- Shortages worsen lack of availability
- We can prevent/rectify them by:
  - Facilitating the single market
  - Empowering the Union Product Database
  - Increasing communication and collaboration

NOT by adding extra red tape....



#### THANK YOU FOR YOUR ATTENTION

