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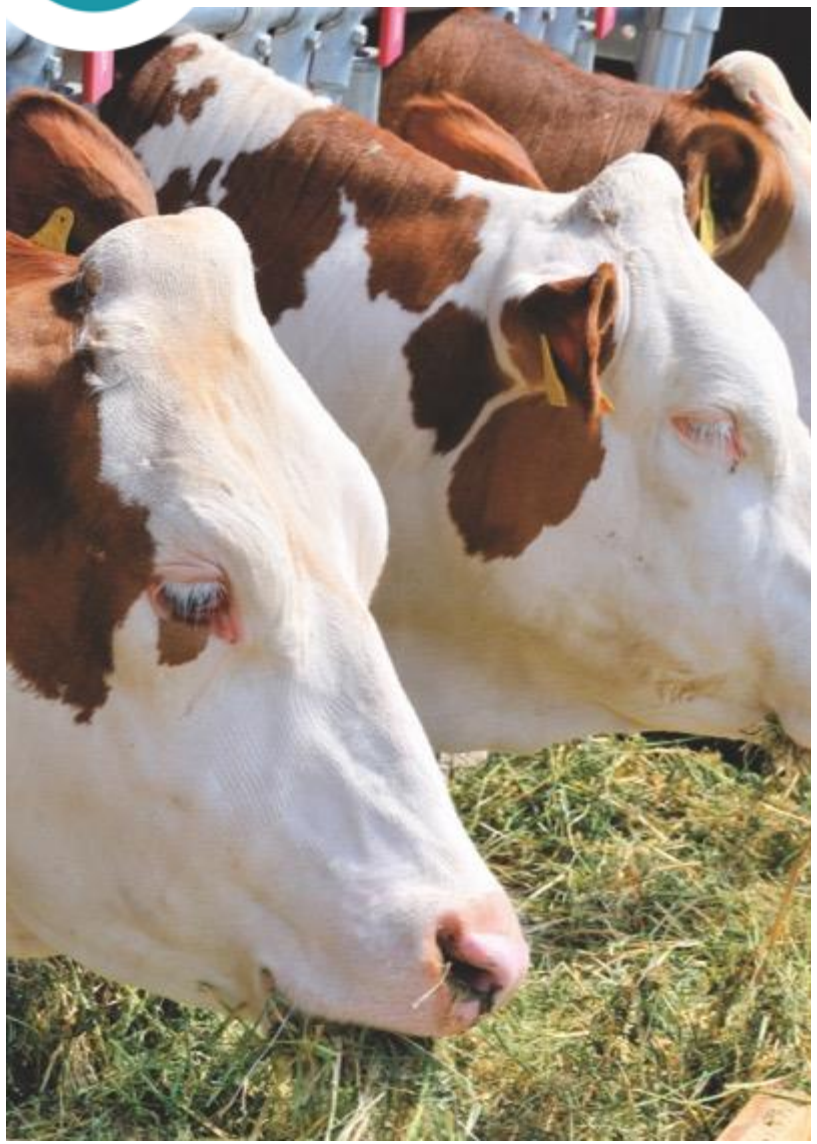
EMA/HMA workshop on medicines shortages

Veterinary breakout session:

Viewpoint of AnimalhealthEurope

R. Clayton
1 – 2 March 2023



Contents

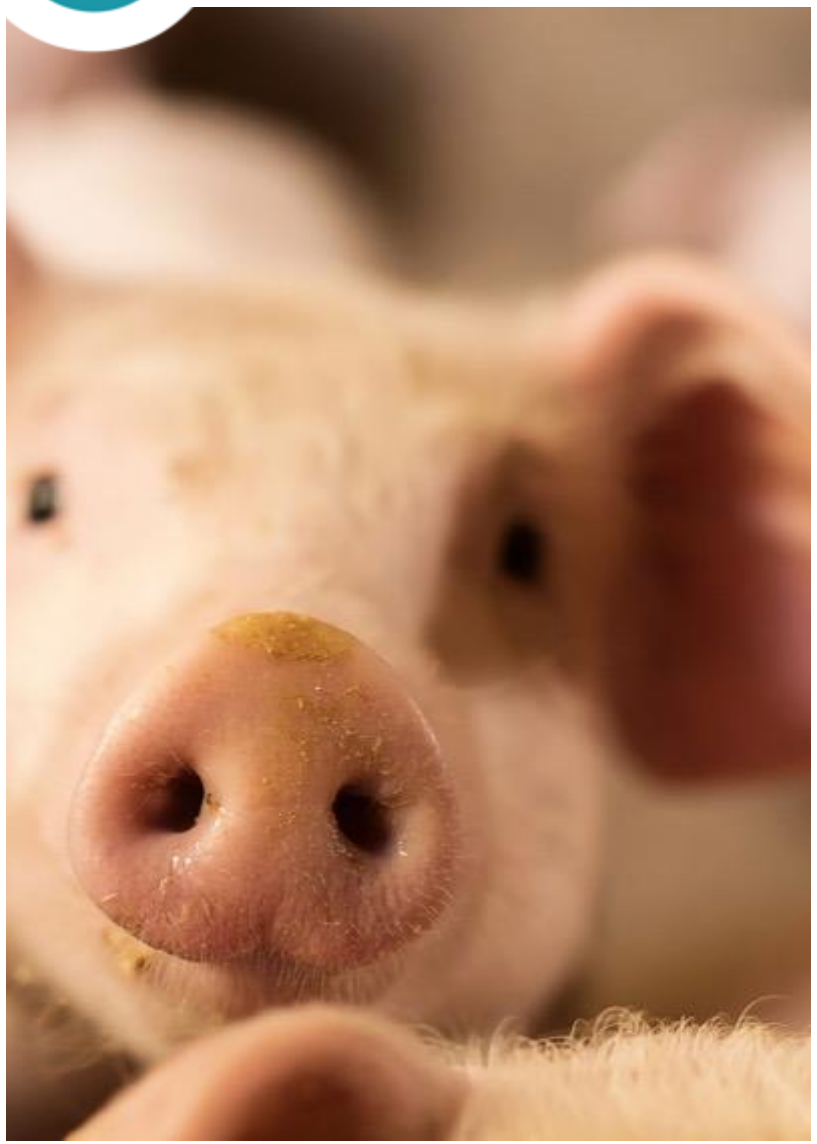
- Need to better understand the situation
- Need to understand the causes of any shortages
- Known potential reasons causing shortages
- Increasing pressures on “availability” (=MA) of VMPs
- What should and should not be done
- What should not be done

Need to better understand the situation

- **No major issues reported by manufacturers to AnimalhealthEurope**
  - ➢ note an increased lead time & pricing from suppliers
- **But, some MSs report issues**

  E.g. ANSES data:
  - ❖ 101 disruptions in supply declared in 2022
  - ❖ 24 new critical disruptions in 2022 (vs 6 in 2021)
  - ❖ Vaccines - the product category with most problems
- **Reports of shortages by veterinarians**
  - ▪ Shortages vs availability (no product authorised or product withdrawn)?
  - ▪ Local (one supplier) or widespread/national

Bottom line: need to know the true extent and severity of the problem



Need to understand the causes of any shortages

- All stakeholders to collaborate in defining the problem
- Need to survey current reported shortages and investigate the causes
    - Regulatory, market demand, manufacturing

Main reason reported is "stopped commercialisation"
This is an availability issue, not a shortages issue

Bottom line: need better data and problem definition before acting

Known potential reasons causing shortages are:

- **Increased regulatory pressure: compliance with new regulations in relatively short time period**
- **Sudden packaging changes; too short grace periods; regulatory bottle necks**
- Highly variable market demand >> a bullwhip effect in supply chain, especially for API suppliers.
- High demand can trigger general capacity issues and prioritisation decisions
- Increased lead-time in the overall supply chain generating backlog & short term shortages
- Manufacturing issues (batch failures, unplanned events at site impacting production etc)
- API or reagent, raw material supply (e.g. linked to high demand for human medicines due to COVID impacting supply for VMPs or other factors)

Bottom line : Some we can predict or have advance warning, but many we can't and some could be avoided

"availability"

Increasing pressures on marketing authorisations

Changing legislation impacting supply and availability

>> The costs to industry are constantly increasing

a) **High concern of impact on availability of 'horizontal' measures:**
   - PFAS, REACH, environmental labelling, impact of PPWD, TiO2 etc

b) More and more **REACH** encroachments on access to APIs >> more APIs and finished product not being manufactured in Europe; will impact manufacturing

c) Increased **packaging costs**; rationalisation of both markets supplied and pack sizes

d) Increased fees, MSs & EMA
   - new EMA Fee Regulation will increase fees by +/-50%; annual fees
   - Economical decision on product maintenance

Bottom line: availability is the bigger issue, and likely to get worse

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What should and should not be done

What should be done (1)

1. Improve collaboration and communication

- Industry and vet associations can collaborate to exchange information
- Vets to report ‘shortages’ to industry associations c.c. EMA
- Industry association to investigate cause and report back
- National follow-up is necessary
- Try case-by-case – no need for pan-EU reporting system ? (N.B. Size of the problem to be defined)

2. Improve the UPD – to be fully functional and user-friendly for vets

- UPD will provide basic information on availability status, including temporally unavailable (> 3 month disruption in manufacturing)
- UPD will not provide info on shortages at local level
- Report from individual vet does not always mean there is a shortage

What should be done (2)

3. EU wide action in pandemics/wars or other widespread high impact issues

- Continue to class VMPs as essential, same as HMPs; Green Lanes etc

4. Continue to improve the regulatory environment

- Make it easy to switch or add suppliers
- Do not create barriers to importing raw materials, especially APIs and/or reagents used in R&D and production
- Do not artificially create temporary shortage situations by imposing too short implementation time frames (in the absence of safety reason)
- Make use of digital tools to bring efficiencies, collect and exchange of info

5. Develop a list of critical medicines to monitor closely

What should not be done

- **Not required: guideline or BPG**
  - BPG is aimed at retailers/users
  - Vet market fundamentally different from human medicines market
  - GL not necessary (particularly as no major problem defined)
  - New tools being put in place – i.e. availability status reporting in UPD
    - Need to see how this works before implementing further tools

- **No additional reporting** (no pan-EU system needed in vet sector)
  - Avoid additional reporting and admin burden (*we are over-loaded*)
    - Currently reporting into some national systems
    - Will soon be reporting into UPD
    - Duplicate reporting (into national systems) must then stop (same for sales data)

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Thank you!