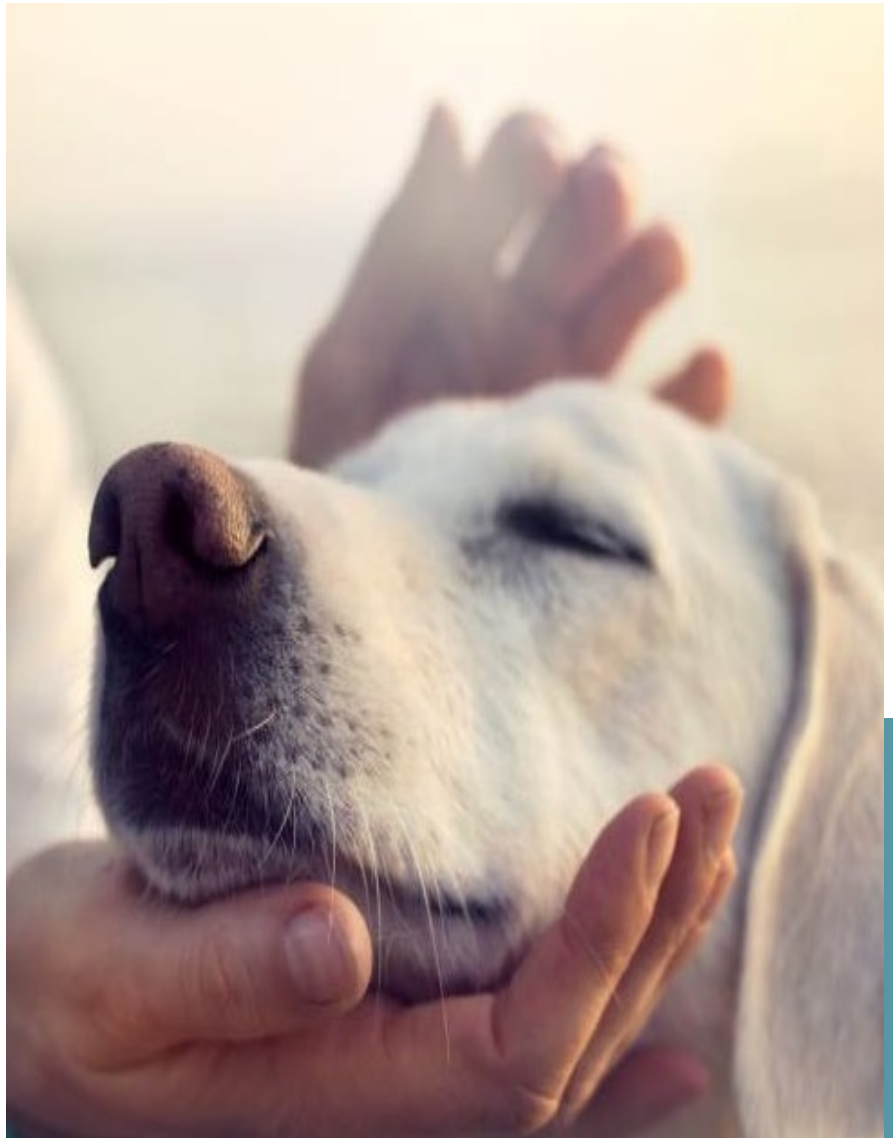
EMA Vet Meds Info Day 2022



Regulatory Policy - Industry perspective

12th May 2022

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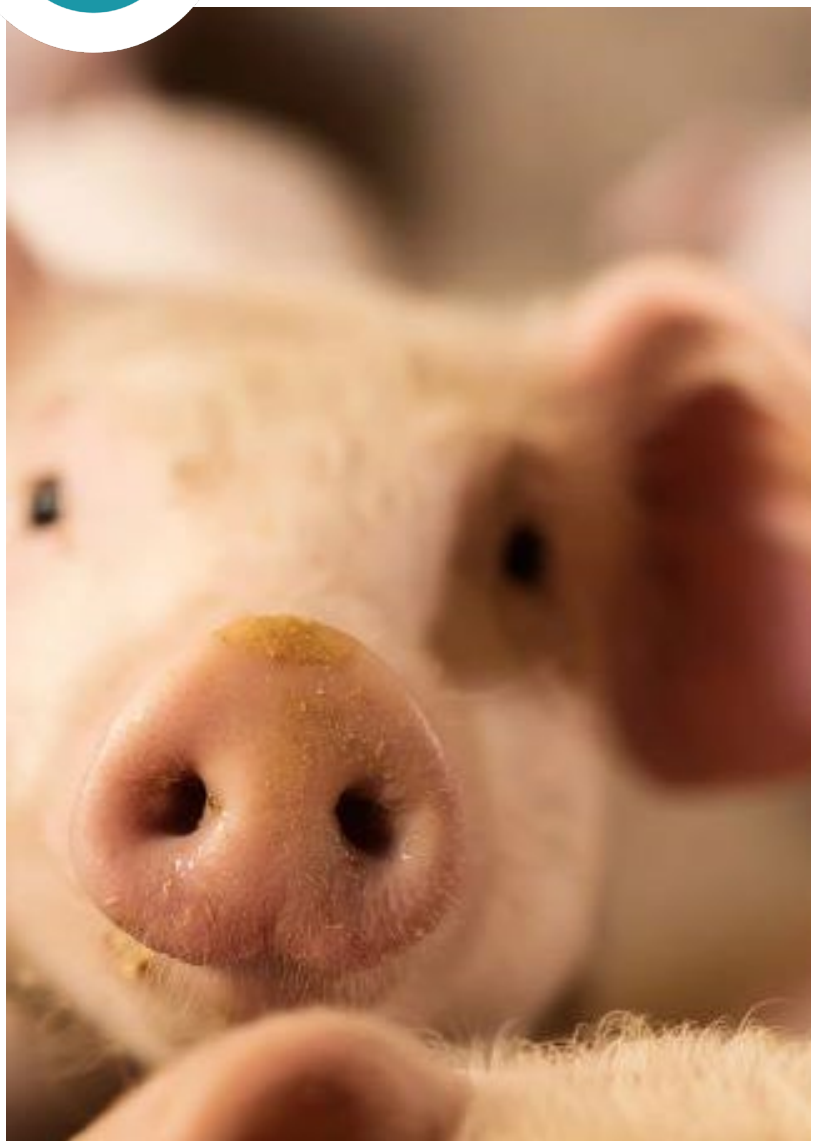

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- The road to compliance
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First feedback post implementation

- Enormous achievements within transition period
- Increased communication from EMA and CMDv, including stakeholder interactions, demonstrations and trainings
- But high admin burden during this bedding-in period = increased resource requirements
- All parties doing their best to manage the current situation with immature (not fully functional) databases

  - UPD data completeness still an issue
  - UPD data quality an issue
  - Pharmacovigilance – learning by doing
  - Not all database functionalities required to run the VMR regulatory business processes are available yet

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Huge amount of work on GLs/RPs etc

AnimalhealthEurope has provided comments on 52 documents from CVMP and CMDv

The chance to comment and feedback on comments is highly appreciated by Industry

Many key GLs still to come and the work of the EMA, CVMP and NCAs

Is critical for the aims of the regulation to be achieved

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Art.152/QRDv9 updates

The update of the QRD texts for all products is a big task for industry and Regulatory authorities

- A flexible and pragmatic approach is needed to ensure these do not result in requests for additional data
- Options for extended implementation time for revised artwork will help ensure medicines availability and management of costs
- Option to include Article 107.3 revisions of prophylaxis claims as part of QRD update and not a separate VRA would reduce admin burden and be a positive for industry

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TELEMATICS

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The road to compliance (1)

- **Union Product Database**
  - Flexibility needed: due to product data gaps or data inconsistencies/errors
    - 30-day deadline for Vnra* only possible if product is visible in UPD
    - Potential business impact if changes are delayed
    - Companies should not delay making changes that qualify as Vnra
    - Notify the RMS/NCA by email and update UPD when possible

*Vnra – Variation not requiring assessment

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The road to compliance (2)

- **Pharmacovigilance & EVVET**

To be covered in Infoday session 2

Key points

- Again, flexibility needed during year 1, including PhV inspections
- MAHs and NCAs are learning on the job - many uncertainties
- MAH processes and systems need to be significantly changed
- Need time to implement and test/optimise new systems in light of complexity and late publication of the guidance
- MAHs not yet fully confident in the EVVET systems and the reliability of the data
- Human PhV experience: the changes to MAH systems took several years to be embedded
- Positive step - JIG meeting reconvened

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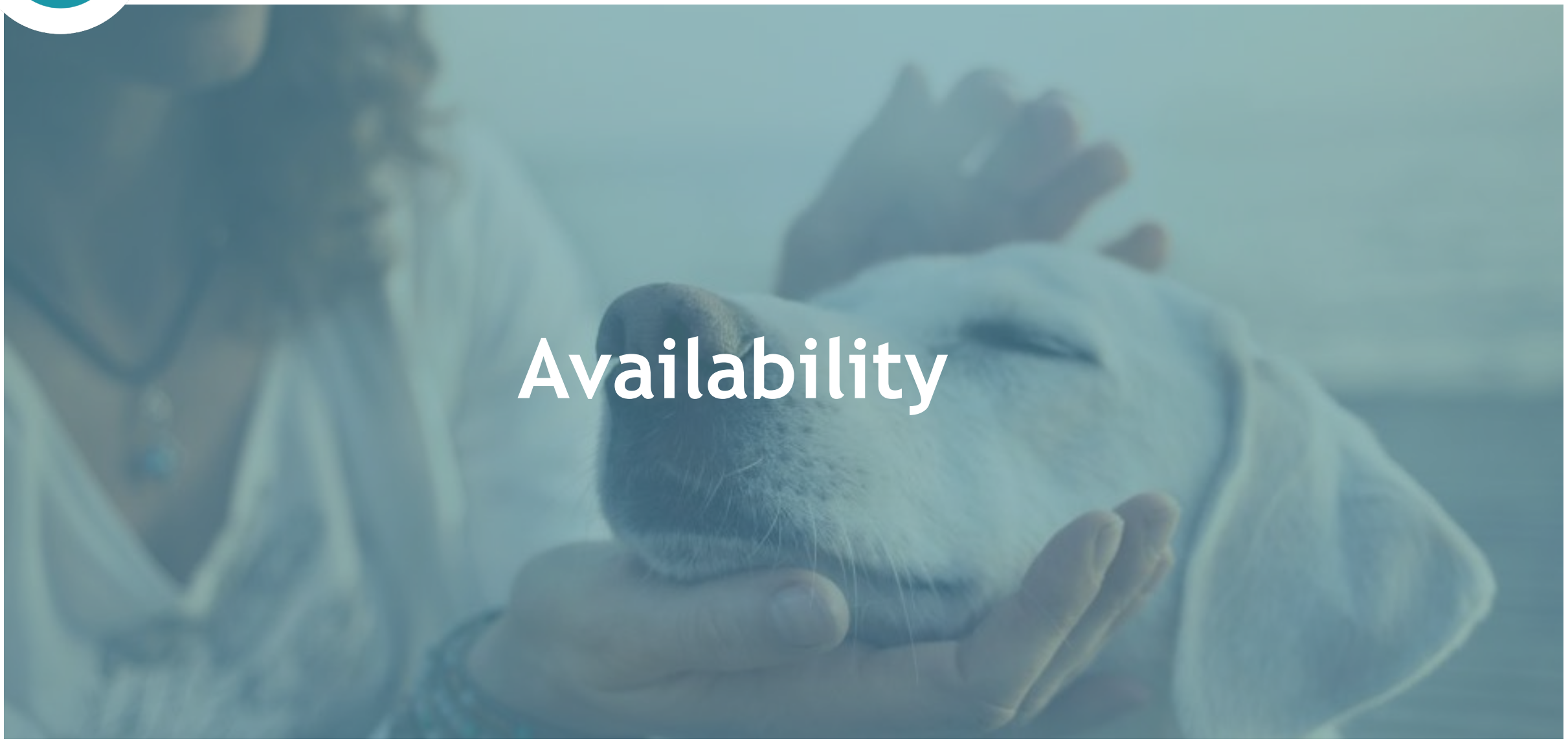

Availability

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Limited markets

- Limited market guidance documents are a key first step
- Early experience of the classification process is positive
- Too early to tell what impact this will have on availability
- Important next steps
  - MUMS style policy/guidance for those products that meet minor species (or limited market) requirements but not classified as limited market (i.e. do not meet both Art 23. requirements)
    - The above to include extrapolation of MRLs
  - MUMS style guidance for quality aspects of limited market products

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Emerging threats to availability

- **New national (different) ID requirements: EAN codes, QR codes**
  - Industry requests a harmonised approach for a European ID code (as foreseen in 2019/6)
  - "Shall, when appropriate" develop harmonised rules (article 17,1 of VMR)
  - Impact on joint labelling and cost
  - Examples:
    - NL requirement for an EAN barcode (or QR code) on labels
    - BE national code number (CNK pharmacy distribution codes)
    - PL - EAN code mandatory
    - IT - Data Matrix mandatory

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Emerging threats

- To availability
- To innovation
- Increased admin burden (joint issue)

- **Wholesaler licenses**

  - Despite being valid throughout the Union, wholesalers can be prevented from supplying retailers established in other MSs
  - Inconsistency between MS in issuing vWDAs (common position needed)

- **Double reporting –** EU vs national databases

  e.g. sales data and availability status

- **Cost of variations requiring assessment (VRA) -** Disproportionate in some cases i.e.

  e.g. cost of a VRA eligible for a reduced timetable; reduced fee advised.
  e.g. cost of a VRA for revising product information to QRD 9 template; reduced fee also advised

- **Divergent national legislation and requirements**

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Divergent national legislation and requirements (I)

Can new disharmonisation be avoided??

Can additional national requirements be eliminated??

Where can EMA help???

Maintaining harmonisation is important

especially when the Regulation 2019/6 (EU) foresees local decisions by individual MSs

Examples

- New national (different) ID requirements: EAN codes, QR codes. Industry requests a harmonised approach (as in 2019/6) → Impact on joint labelling and cost
- Electronic leaflets: a common specification for the implementation of electronic leaflets would be beneficial – easier and faster implementation of changes with e-leaflets
- Local representatives, rules regarding their establishment in each country.
- PPWD and labelling/packaging – engage with EC on impact of PPWD revision

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Divergent national legislation and requirements (II)

Transparency, communication and access to information are key for the industry

Examples:

- Understanding expectations and requirements for GDP (especially biological API) and approach to risk based GMP inspection of active substance sites – common approach and understanding needed
- Diverging **labelling and packaging** requirements driven by local regulation i.e. environmental requirements (link to PPWD revision)

This is more critical for nationally registered products but also impacts CAP: please increase transparency-communication -information

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Priorities looking forward

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Priorities looking forward

- **Top priority**
  - Finish data upload and data clean-up
  - Fix the first-use issues and bugs
- **Reduce the admin burden -** focus now on delivering this objective
  - A shared objective - need to continue to work together to achieve this
  - Current experience shows the need for this to be kept in mind when implementing new rules/processes for the benefit of all (incl. Industry)
  - Small details can have a major impact on the teams doing the work
- Identify **priorities** for functional improvements to UPD (via VSIAG)
- **Flexibility** during 'year 1' (and beyond) to adapt business processes (all, NCAs and MAHs)

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Key Guidance and Priorities looking forward

- Revised B/R guideline – important for many aspects
- Reflection paper on criteria for the application of Article 40(5) including the issue of PoTD for new species added to established products
- Clarification of PoTD for new indications (global MA context)
- Revision/update of NtA to align with Regulation 2019/6 and associated GLs
- Understanding status of Dose Optimisation project, and relationship to the process of SPC harmonisation
- Continued dialogue and communication as we all navigate the new regulatory environment

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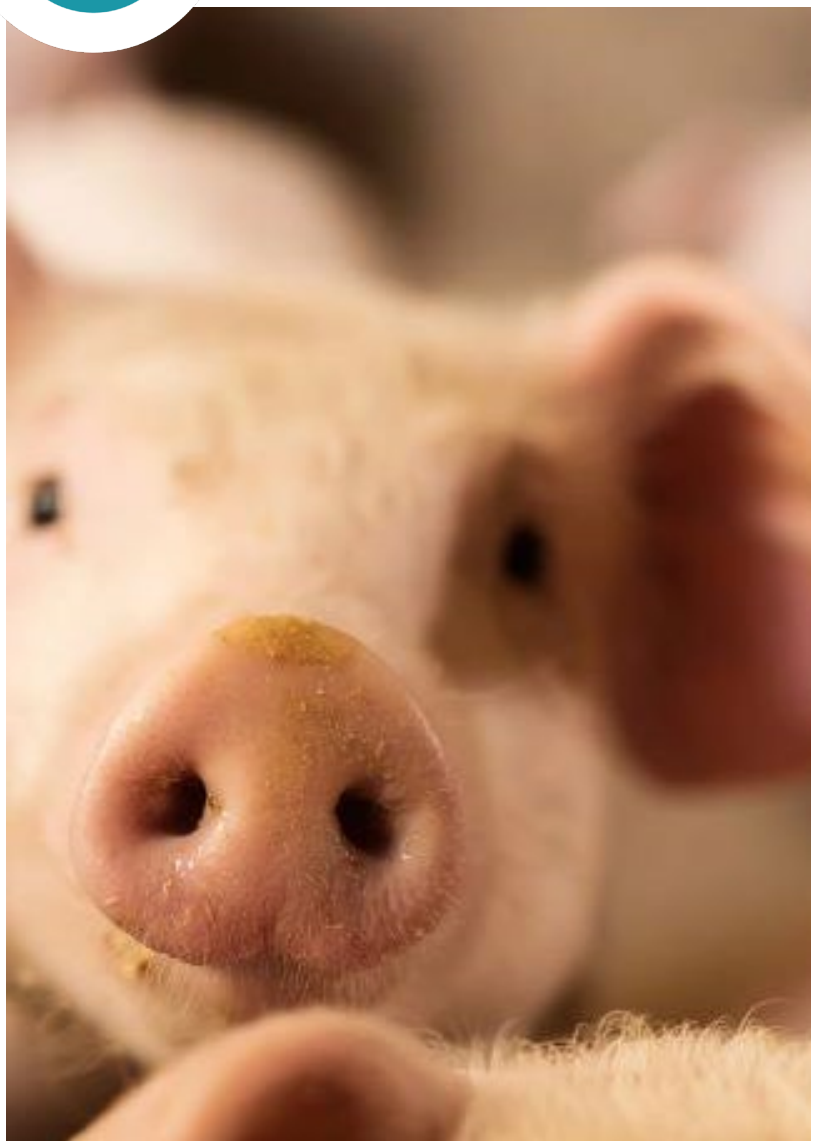

Agile governance

Potential impact of Agile Network Portfolio IT environment on veterinary regulatory environment

- Agile governance & environment is adapted to Human sector needs and structure
- Aim: human/vet - same platform but different configuration
- Vet sector is represented in the different or dedicated bodies
- Vet sector (MAH and vet CAs) should collaborate to ensure vet voice is heard and Vet sector needs and constraints are accommodated (limited resources, different legislative drivers)

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Thank you!

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