New Veterinary Regulation

Variations & Union Product Database

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Variations: current system

- Variation Regulation EC n°1234/2008
- Classification guideline ➔ categories
  - Conditions to be fullfilled
  - Documents needed
  - Type of variation: IA, IA_{in}, IB, II

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- Conditions - Documents	- Extensive list - Including purely administrative variations

Variations: future

- One of the EU Commission goals for NVR:

➔ decrease administrative burden

Variations NVR ➔ What's new?

- 2 categories left:
  - Variations requiring assessment
  - Variations not requiring assessment

- EU Commission ➔ implenting act: List of variations not requiring assessment

  To be established based on following criteria:
  - Need for scientific assessment ➔ Is there a risk for public & animal health + environment?
  - What is the impact on quality, safety & efficacy of the VMP?
  - Are the changes to the SPC minimal?
  - Are the changes purely administrative?

Variations not requiring assessment

According to the NVR text:

- If a variation is in the list
  - MAH will record the change in Union Product Database:
    - *Including if applicable changes to SPC/labeling/leaflet*
    - *Within 30 days after implementing the change*
  - NCA or Commission will amend MA where needed
  - NCA/RMS or Commission will inform relevant MS

The list: key to succes? (1)

- List to include:
  - Simple administrative changes
  - Changes of information outside the dossier
  - Changes to labeling or leaflet not related to SPC
  - Compendial Updates
  - Deletions
  - Other changes with no impact on quality, safety or efficacy
  - Changes already assessed under GMP or other compliance programs
  - Changes related to Pharmacovigilance
- List to be flexible
  - Allowing updates
  - Searchable
  - Prevent free interpretations

The list: key to succes? (2)

- Union Product Database
  - Full functionality needed

- Guidelines and constructive communication between industry and regulators

➔ Communication based on trust to ensure smooth and correct implementation in the future

Variations requiring assessment

- If not in the list ➔ assessment required
- Application:
  - Description of the variation
  - Data relevant to the variation
  - Details of the MA's affected by the application
  - Description of potential consequential variations
  - List of MS involved in case of MRP/DCP
- Grouping possible:
  - Several variations for 1 MA
  - One variation affecting multiple MA's
- Work-sharing encouraged:
  - Coordination group will agree on 1 MS to do the assessment

Variations requiring assessment: procedure (1)

- MS to acknowledge receipt of a valid application within 15 days
- In case of incomplete application ➔ additional information requested within reasonable time limit
- Assessment report within 60 days following receipt of a valid application
  - May be extended to 90 days in case of complex variations ➔ authority to inform applicant
- Clock-stop for additional information
- In case involved MS disagree with the assessment report made ➔ review procedure
  - RMS communicates to the coordination group
  - RMS has 90 days to seek agreement
  - Applicant will be provided the opportunity to clarify
  - If agreement ➔ approval or rejection
  - If no agreement ➔ to EU Commission
  - EU Commission will prepare draft decision within 30 days ➔ clock-stop possible

Variations requiring assessment: procedure (2)

- Assessment report / opinion
  - Written request for re-examination possible by the applicant within 15 days
  - Detailed grounds for re-examination to be submitted within 60 days
- Closing of the procedure:
  - Amended MA within 30 days after completion of the procedure + receipt complete translation SPC, labeling/leaflet
  - Authority will inform applicant
  - Authority will update UPD accordingly
  - Implementation by MA after receiving approval from authority

Union Product Database: current system

- NCA National databases
- No input from MAH's

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- ?	- Differences between MS - MAH's no access - Only for approvals

Union Product Database: future

- Different levels of access:
  - General public ➔ list of products, SPC, leaflet, assessment report
  - Regulators ➔ full access
  - MAH's ➔ only their products

- Links with many other databases and systems ➔ IT challenge
  - MRL database
  - NCA/EMA databases
  - Union Pharmacovigilance system
  - Sales and use data for antimicrobials
  - Union database on manufacturing and wholesale distribution
  - Electronic submissions
  - SPOR / CESP / EMA eSubmission Gateway ……

Impact UPD for industry

UPD is a resource intensive challenge for both regulators and industry, but in the long term bears the promise of significant simplification, transparency and reduction of admin burden.

Critical points:

- IT challenge – specificities vet business, in particular SMEs
  - Very limited (direct company) resource capacity, considerable effort
  - Scale of benefits not as obvious compared to big pharma sector

- If no full functionality by go-live:
  - Parallel submission/notification system for variations not requiring assessment?
  - What with the national databases?

- Questions:
  - Role of SPOR ➔ harmonisation of terminology ➔ uploaded in UPD

UPD: key to success

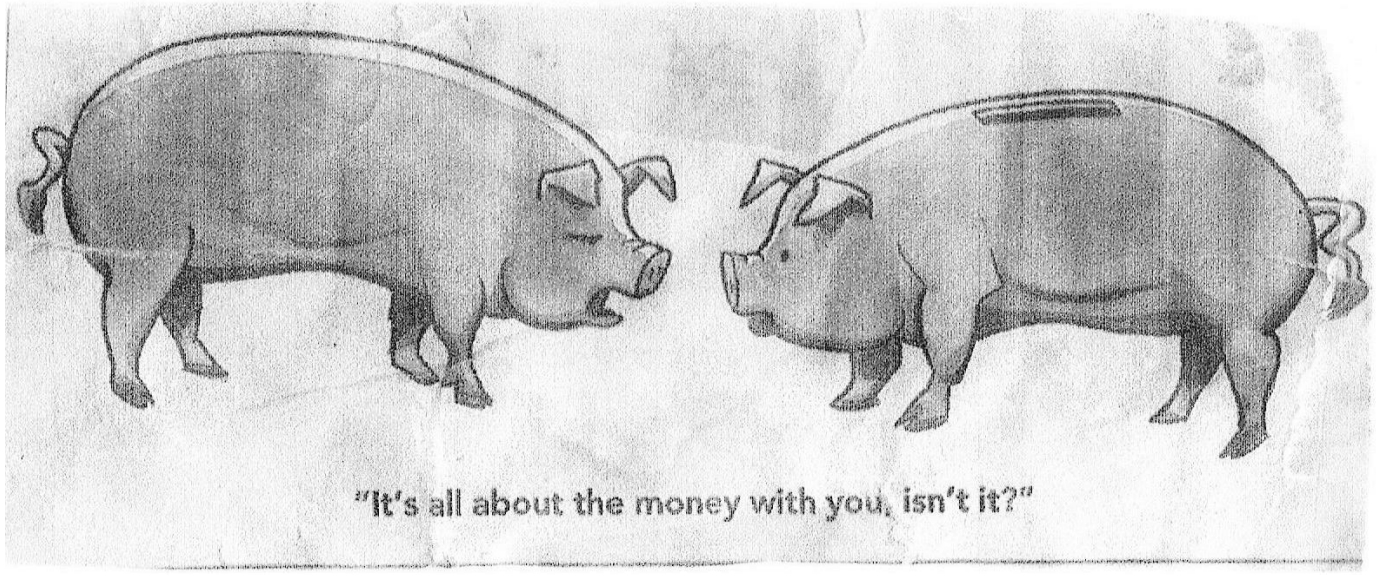
PARTNERSHIP	▪ Designed to work for all ▪ Interested Parties to participate in its functional design ▪ Partnership between all Agencies and MAHs is an essential success factor
USER-FRIENDLINESS	▪ Simple and cost effective IT solutions for the vet domain, adapted considering size and requirements ▪ Users can easily and effectively carry out the required tasks, while minimizing errors
EFFICIENCY	▪ Minimum data fields to allow **full functionality as required by NVR** ▪ Extensive use of existing legacy data ▪ Interconnectivity to ensure re-usability of entered data (guarantee one single level of reporting) ▪ UPD to synchronize with existing national DBs
PLACE IN IT LANDSCAPE	▪ Full compatibility of UPD with all relevant EU Telematics Projects ▪ Use of Master Data Services available at that time, at least RMS and OMS ▪ Possibility to use data to generate CESSP submissions

Timing UPD & ‘list not requiring assessment’

- January 2019 ➔ adoption of NVR
- January 2021 ➔ UPD specifications, list of variations not requiring assessment
- January 2022 ➔ Implementation: go-live UPD but also PV database, Manufacturers, importers & wholesalers database

Conclusion

In order to decrease the administrative burden related to **VARIATIONS** a fully functional **Union Product Database** is mandatory, however, reality will depend on **FUNDING**



Thank You!

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