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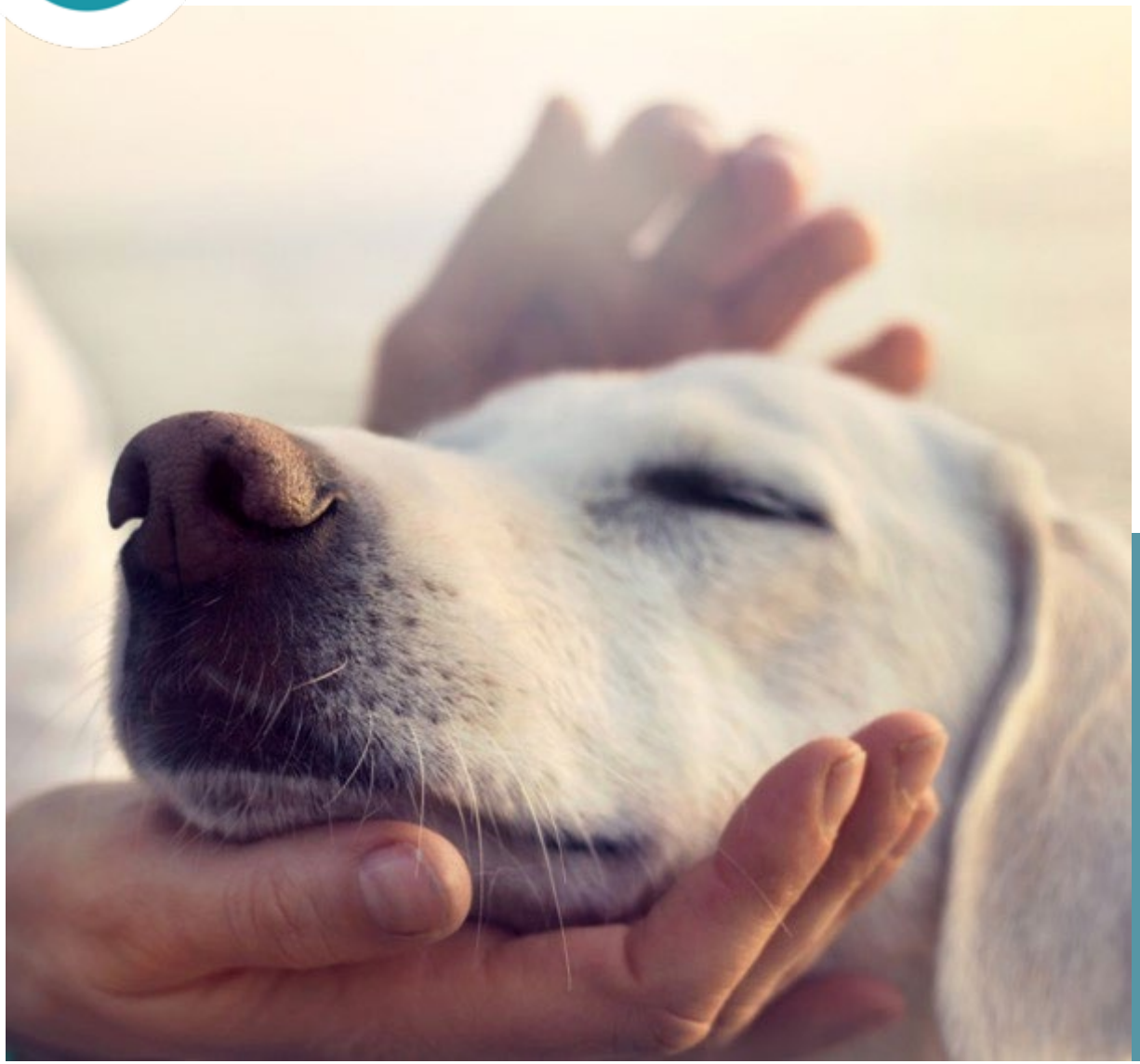

Veterinary Medicines Info day 2021

EU Regulation 2019/6 – towards 28 January 2022 - Industry perspective

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EU Regulation 2019/6

Implementation activities:

- Improvements expected & concerns
- Implementation phase – How does it look like from an industry perspective?
  - UPD, Variations, SPC harmonization, Type of applications & dossiers content (Annex II), new provisions (novel therapies, vaccine platform technology, multi-strain dossiers, VAMF), Packaging & VMP availabilities, opening of CP scope

Improvements expected & concerns:

Under the Directive 2001/82

- Many achievements to reach the current EU regulatory environment over the past decades.
- Improved predictability for new developments
- Opportunities to seek regulatory advice at national or European levels

Where further Improvements are expected

- Reduction of the administrative burden at all levels of the regulatory network (such as the five yearly renewals, the sunset clause, PSURS)
- Predictable benefit-risk assessment that encourages innovation
- Improvement of availability by encouraging multilingual packaging
- Incentives: balancing regulatory constraints and data protection
- GMP: more adapted measures to veterinary medicinal products particulars

Concerns over ageing products and hurdles to bring new products to the market

- Securing efficacious legacy products
- Predictability over regulatory constraints

Where we stand :

- **Under the Regulation 2019/6**
  - Providing advice and recommendations for the preparation of the Regulation and its implementing or delegated acts
  - Working with the EMA, CMDv and NCAs
- **2021 dedicated to ensure a smooth transition on the implementation date of 28/01/2022**
  - A lot still remains to be achieved…
- **Focus on preparedness**
  - Contributing recommendations on the drafting of guidelines and best practice guides
  - Contributing in dedicated workshops
  - Internal (company) awareness by training sessions and working sessions to anticipate the changes

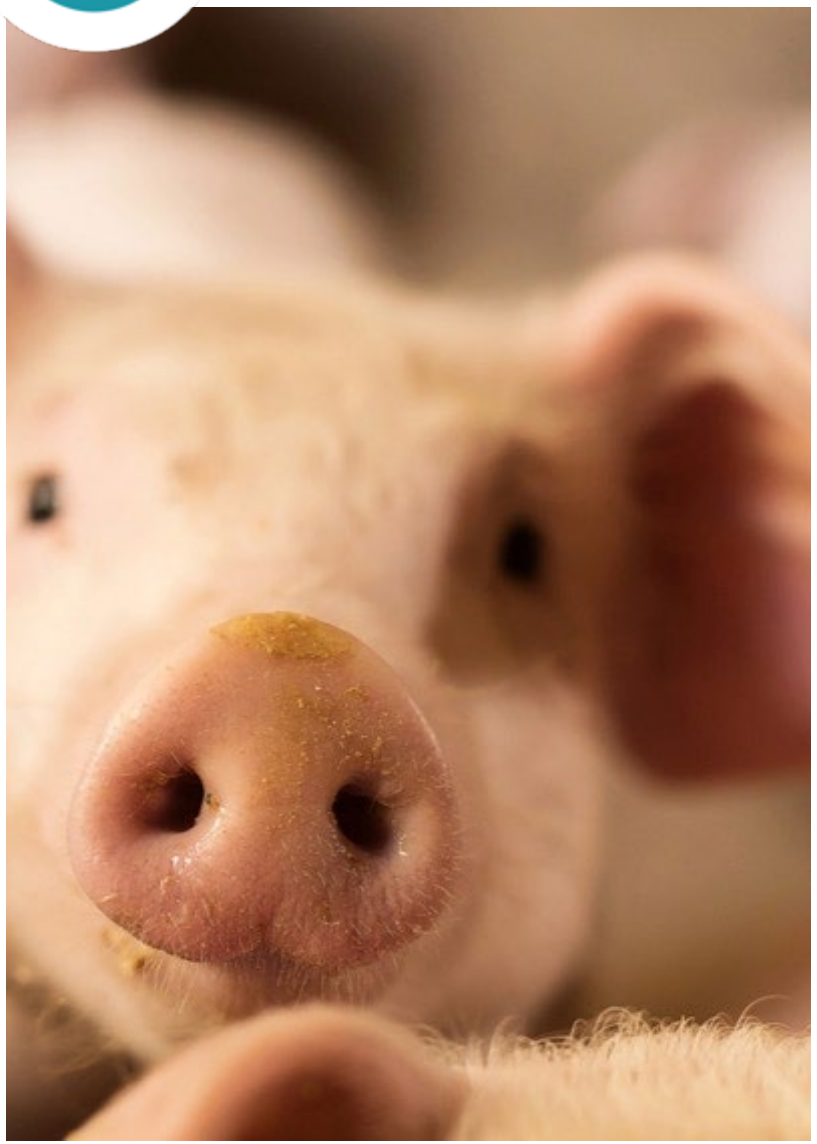
UPD – Union Product Database

- **Impact of UPD on Company's operations**

Preamble 84 - Information on veterinary medicinal products is essential in order to enable health professionals, authorities and companies make informed decisions. A key aspect is the creation of a Union database that should collate information on marketing authorisations granted in the Union. That database should enhance overall transparency, streamline and facilitate the flow of information between authorities, and prevent multiple reporting requirements.

- The UPD will impact the way we organise our operations for
  - Variations (not requiring assessment)
  - Reporting of sales volumes, status of authorisations, dates of placing on the market and availability of products

- On 28/01/2022, MVP version (minimum viable product)



UPD - Union Product Database

- **Internal preparedness sessions**
  - Raising awareness of coming changes to all departments
  - Identify critical areas where we may face difficulties :
    - Reporting of sales volumes…
    - Adapting internal tools and processes
    - Recording of variations not requiring assessment
    - How to manage the user interface and manage accesses
    - How to manage the submission of electronic data in the most efficient way

Many internal workshops still to organize in the remaining months

UPD - Union Product Database

Submissions and Reporting by MAHs into the UPD

- Recording dates of placing on the market
- Recording information on availability for each product
  - Defined at the packaging level not product level
- Recording the dates of suspension or revocation of the MA
- Recording the annual volume of sales for each product
- Recording the VNRAs within 30 days of implementation by MAH

UPD - Union Product Database

How to organise MAH responsibility for recording volume of sales for each product

- Initial “fear” of having to manually record each volume

  - Is dissipating as UPD development work progresses especially with the Product Owner working sessions

  - CSV formats or later API (application programming interface) developments to allow bulk

  - Still plenty of work to define how to organise the data and workflows within the company

- Define source of information and its formatting to agreed standards

- Importance of training and access to UPD mock ups prior to date of implementation

Variations

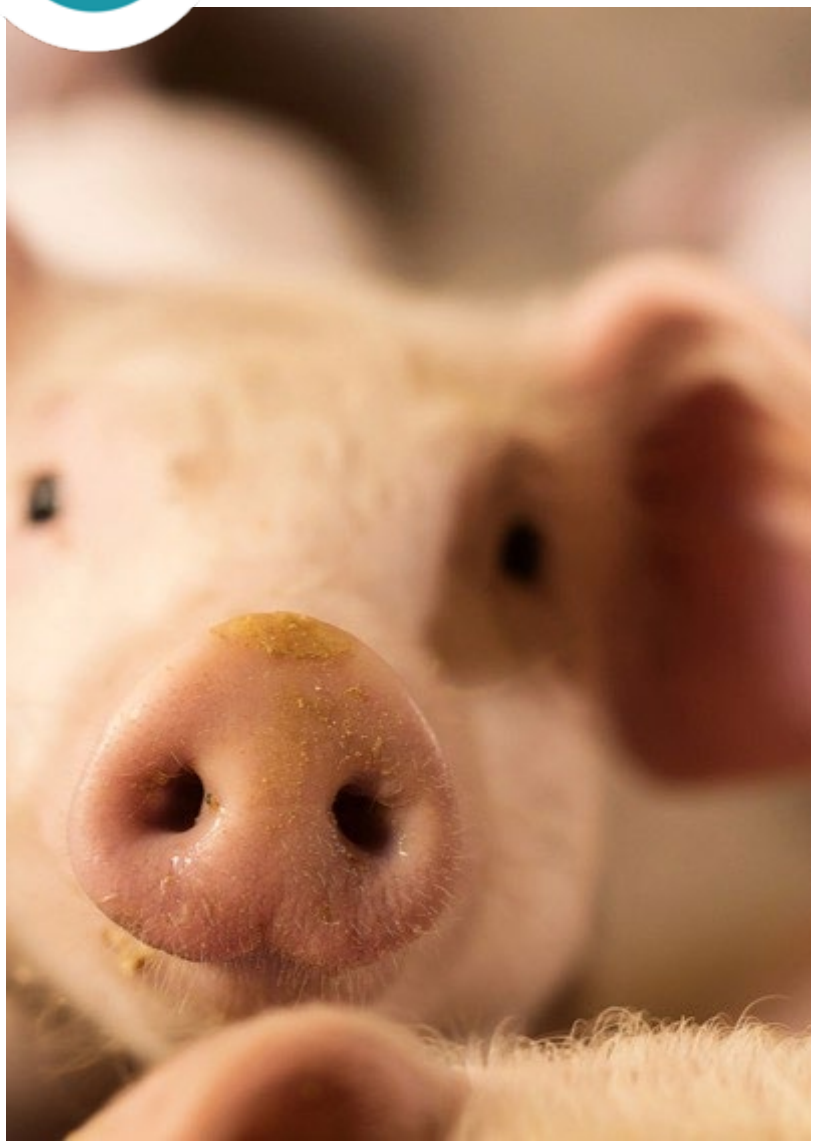
How to manage the transition between the current system defined under Regulation 1234/2008/EC

- Development of lifecycle projects run for many years, are defined by the type of variations (Type IA, IB, II, line extensions….)

and…

The new system with only 2 types of variations

- VNRAs, variations not requiring assessment (recording in the UPD)
  - Includes most current type IAs
  - Cover changes that are not limited to UPD entries
  - Can be supported by documentation
  - CMDv workshop expected later this year
- VRAs, variations requiring assessment



Variations

Impact on current lifecycle projects

- Annual declarations no longer possible after 28/01/2022
- VNRA: recorded within 30 days after implementation
- VRA: Implementation only after the final approval Decision

  → Major concern / impacts on how changes are implemented

  - Ex: usual practice under current system for most changes is to implement at the end of the variation procedure (favorable opinion)
- Compulsory Worksharing procedures
- Grouping possible for VRAs
- Facilitated grouped VNRA recording in the UPD expected
- Anticipate coming changes to avoid disrupting the company's project timelines and avoid availability disruption in case submissions need to be delayed for unforeseen reasons after 28/01/2022

SPC harmonisation

Scope and impact of this exercise on current products

- Potentially covers all products authorized nationally, most of the older products.
- Will concern reference products and subsequently all its generics/hybrids
- Concern over availability from loosing important characteristics of the product : target species, indications or worse
- Company preparedness to list the products concerned and assess possible impacts very early in the Regulation implementation process
- Exclusion of products authorised prior to 01/10/2005, identified as potentially harmful to the environment and not subject to an environmental risk assessment

  - update of environmental safety will be required

- 2 CMDv workshops in 2020 and 2021 were very helpful

SPC harmonisation

Impact on the company organisations resources

- The need to define the proposed common SPC and assemble all approved regulatory information (no new information should be used) will strain the often limited resources of SMEs.

- The transition to MRP at completion of the SPC harmonisation process requires the harmonisation of Part II as well.

  - 10 CPC (Critical Pharmaceutical Chars.) principle will apply

- The duration of the procedure that can last 1 year (from initial call to the end of the national phase) and strain human resource skills away from other projects

SPC harmonisation

There is room for opportunities

- Recognition by NCAs of SPC under the mutual trust principle
- An MAH can volunteer its own products for harmonisation
- Expected benefits :

  - increased availability: multilingual packaging, geographical extension,…

  - decreased industrial complexity with harmonised CMC dossiers

- Procedure open to all types of products, including immunologicals
- After the harmonisation procedure, the MAs will be part of a newly created MRP procedure

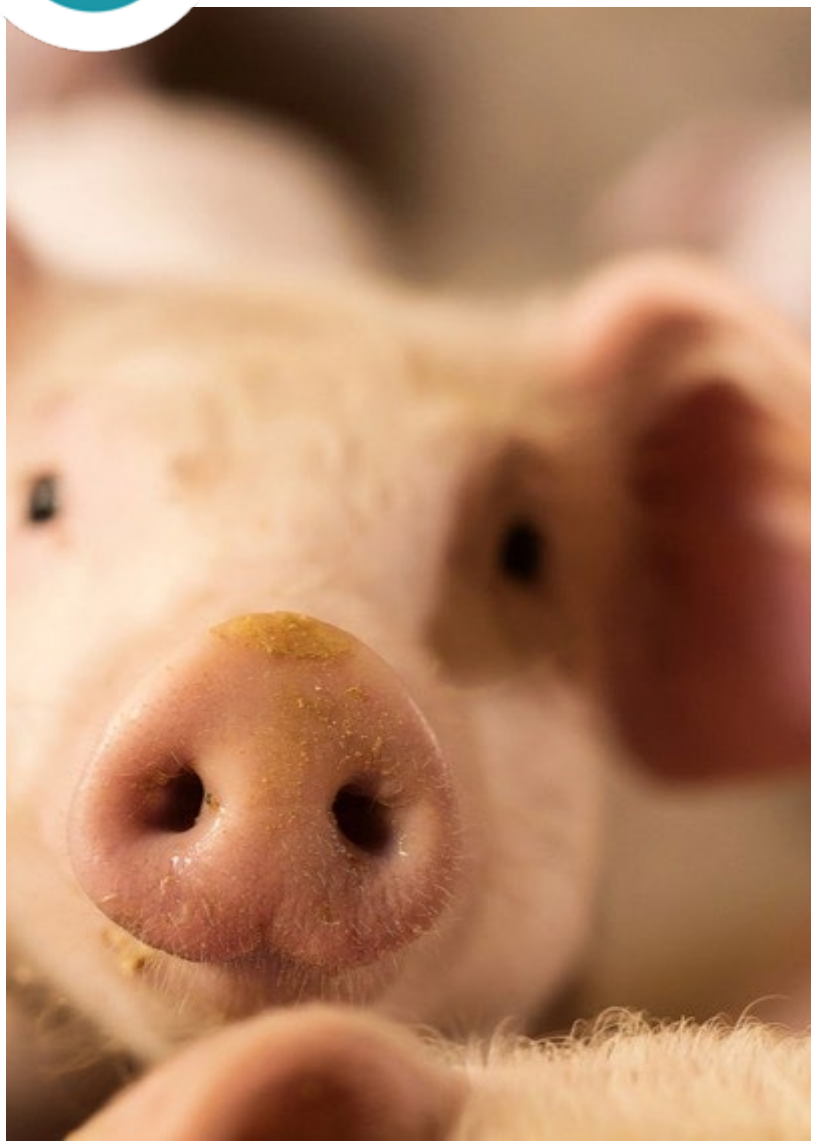
  - any future lifecycle activity will not disharmonise the SPC

  - expected simplification of product lifecycle

Dossiers

What impact from changes to the Annexes

- Article 8 defines the requirements for supporting evidence
  - includes a PSMF summary (Pharmacovigilance Summary Master File)
  - Antimicrobials: documentation on direct / indirect risk to public or animal health or the environment
  - Information on risk mitigation measures to limit antimicrobial resistance development
  - Where applicable, MRL and GMO requirements
- From annex 1 of Directive 2001/82/EC to annex 1 & 2 of Regulation 2019/6/EU
  - Annex I presents the administrative information
  - Annex II presents the technical information
    - (details in a delegated act)



Dossiers

Anticipating the changes on current developments

- Communication, training, identifying opportunities : internal workshops

- Areas of concern
  - Identify any new requirements that may be critical to product developments intended for submission soon after 28/01/2022
  - Risk assessments for developments that can either be submitted before or after 28/01/22.

Dossiers

New categories

- Dossier types: Biologicals (immunologicals or non-immunologicals) & Non biologicals
- Abridged applications
- Particular veterinary products
  - Novel therapies veterinary medicines (including gene therapy, regenerative medicine, tissue engineering, cell therapy, phage therapy, nanotechologies vet medicines)
  - Vaccine antigen master files
  - Multi-strain dossiers
  - Vaccine platform technology
  - Homeopathic veterinary medicinal products

Dossiers

Areas of concern

- If strict reference to monographs or guidelines are made
- If detailed CMC requirements are included in place of GMP
- If the requirement for immunological field studies is strict
- If multi strain dossiers cannot concern bacteria
- Limited impact on VNEEs structure expected

Registration procedures

The Regulation 2019/6/EU is rather conservative

- NP, MRP, DCP, CP procedures retained
- Timelines remain globally similar (pending release of the new best practice guides)
- CP eligibility opened to all new products
  - No indication that the constraints of Commission Communication 1998 will be lifted or amended
  - One MA per MAH and limited opportunity for duplicates
  - Limitations for parallel NP, MRP or DCP procedures

Packaging & medicines availability

Revised product literature rules

- New SPC, leaflet and labelling requirements
  - Facilitates multilingual packaging
    - more use of pictograms and abbreviations
    - limited room for national specifications
- Areas that can be improved or clarified
  - revised QRD expected to provide increased features to facilitate multilingual packaging
  - Call to facilitate approval of common trade names
  - opportunity for continued use of local distributors / local representatives (name address and logo)
- Article 152 defines a compliance date 29 Jan 2027
  - 5 years to review all packagings may be a challenging objective

Industry Perspective

THANK YOU