1 YEAR IMPLEMENTING REG 2019/6

INDUSTRY PERSPECTIVE

EMA InfoDay

16 February 2023

Access VETMED
Committed to animal well-being in Europe

animalhealth europe
THE VOICE OF THE ANIMAL MEDICINES INDUSTRY

AVC
Association of Veterinary Consultants

CONTENTS

SPEAKERS

> Heidi Schwer, Vetmedico (AVC)

> Aafke Huizenga, Dechra (Access VetMed)

On behalf of

Association of Veterinary Consultants

Access VETMED
Committed to animal well-being in Europe

animalhealth europe
THE VOICE OF THE ANIMAL MEDICINES INDUSTRY

Presentation addressed to EU regulatory network (including NCAs) and MAHs

Classified as public by the European Medicines Agency

I. REG 2019/6

MEETING THE OBJECTIVES?

Association of Veterinary Consultants

Classified as public by the European Medicines Agency

Implementing the Regulation

- Enormous effort has been made by all parties and progress has been achieved
- Implementation of new systems within 3 years was very ambitious
- Some immediate positives from the Regulation
  - Deletion of renewals and sunset clause; pictograms
- Some potential positives yet to be delivered or used
  - Removal of PSUR submission, extended AE reporting deadlines, but replaced by new requirements
  - UPD – high expectations but at present still in the "forming and storming" phase
  - Novel therapies, VAMF, platform technologies
- POSITIVE – joint collaboration between EMA/NCAs/industry
  - EMA staff very responsive – highly appreciated
- Many challenges remain

Association of Veterinary Consultants

Classified as public by the European Medicines Agency

VMR objectives: where we stand Feb 2023

(5) This Regulation aims to reduce the administrative burden, enhance the internal market and increase the availability of veterinary medicinal products, while guaranteeing the highest level of public and animal health and environmental protection.

1. Burden higher than before, both industry and regulators

2. Further harmonisation / optimisation of regulatory environment needed

3. Improvements not foreseen (due to 1. and 2.)

Association of Veterinary Consultants

Classified as public by the European Medicines Agency

Since proposals were made….

permanent support from industry to new approach establishing central EU databases, aiming at more efficient

- regulatory procedures
- exchange of information with regulators and the general public

It was expected that…

it would be a resource intensive challenge for both regulators and industry, but the extent of this work was underestimated. However, we must remain optimistic that, **in the long-term, it will deliver the promise of significant simplification, transparency and reduction of administrative burden.**

VMR: a future proof regulation?

We are not yet there

> Industry would welcome visibilisation of progress against the objectives of the Regulation

  - Progress report?

> Industry willing to collaborate in identifying concrete areas, parameters and metrics to evaluate future proof regulation.

Association of Veterinary Consultants

Classified as public by the European Medicines Agency

II. NEW IT SYSTEMS

ADAPTING TO CHANGE

1. Status quo 1 year underway
2. UPD – data and functionality efforts
3. UPD - experiences and expectations

Association of Veterinary Consultants

Classified as public by the European Medicines Agency

1. New IT systems; status quo 1 year underway

Three **MAJOR** databases

UPD

EVVET3

IRIS

+ SUBSETS of these databases

DWH

OPAD(VOS)

WHOLESALER DB

OPAD (AVS)

+ other platforms, such as SPOR/OMS, to be used

New to MAHs, must deal with these on a daily basis since Jan 2022

Heavy impact on dedicated resources for implementation, company reorganisation

WORKLOAD SIGNIFICANTLY INCREASED

Aggravated by difficulties to work with the databases (next slide)

Association of Veterinary Consultants

Classified as public by the European Medicines Agency

2. UPD - data and functionality efforts

UPD has been one of the biggest efforts for all to set up during the last 12 months

NCAs, EMA and MAHs aligned to feed and improve the UPD, mainly on

- Data uploads and quality: having all products in UPD (not 100% yet) + data is lacking quality
- Certain features/desired functionalities are still missing
- Bug fixing > resulting in creation of other bugs, guidance documents very technical & late publication

Last year (ongoing): highly burdensome MAHs activity checking data and communicating with NCAs to enhance it

Heavy impact on day-to-day business operations

- Will still take some time until MAHs are fully confident in new databases so as to fulfill their legal obligations

Association of Veterinary Consultants

Classified as public by the European Medicines Agency

3. UPD - experiences and expectations

Submissions for Variations Not Requiring Assessment (VRNA)

- Good progress reported by MAHs (when no supporting documentation involved). Still,
- Some submissions not possible yet due to the current state of the UPD
- Email communication MAH - NCA still needed i.e. issues VNRAs reception (NCAs); notification system not functional yet

Volume of Sales (VOS) and Availability Status (AVS) submissions

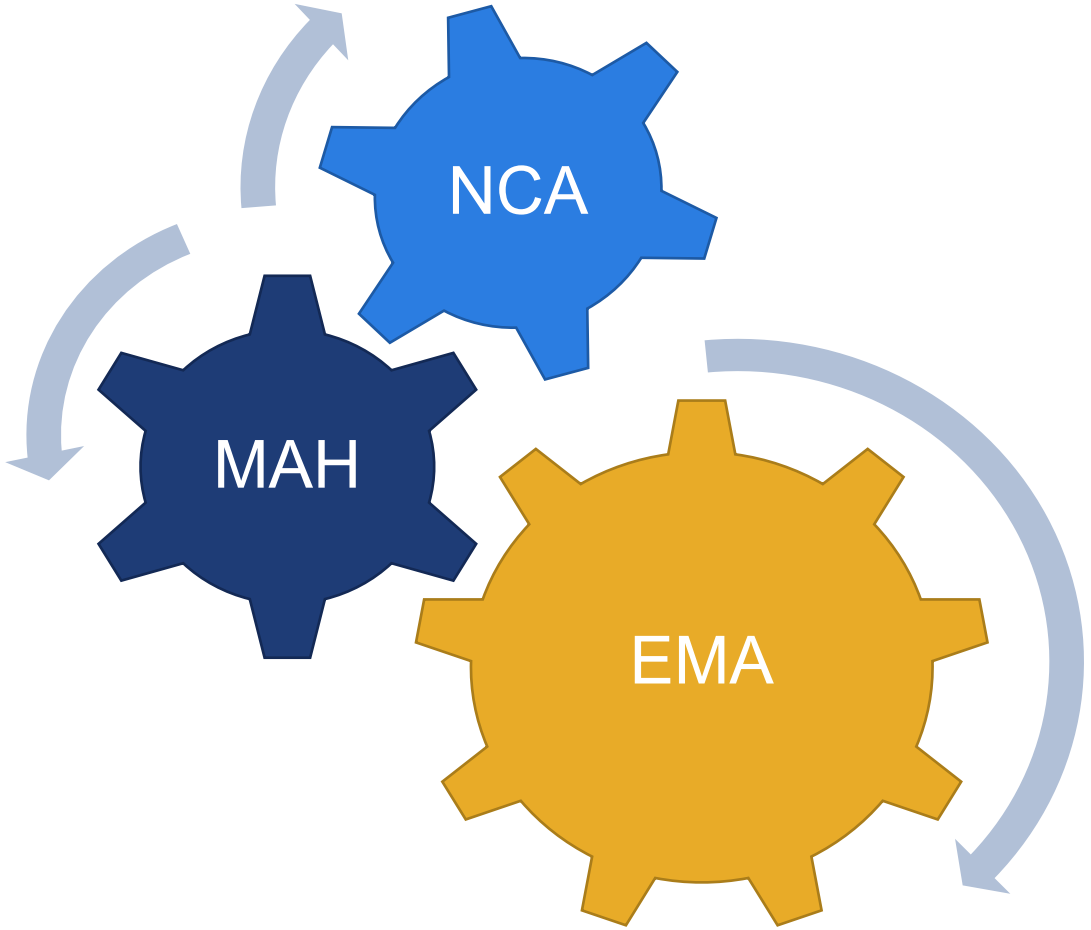
- Mapping of UPD products packages highly complex and a prerequisite before MAHs can fully submit data. This work can only start once UPD product data is stable.
- Deadlines to submit VOS data and record AVS, although marginally extended, still represent an incredible challenge
- The support from EMA to help NCAs and MAHs has been very helpful, but additional training (i.e. how to complete CSV files) would be very useful

Association of Veterinary Consultants

Classified as public by the European Medicines Agency

Huge reliance on ALL players to make this work

Closer interactions & teamwork



CONTINUED GOOD COLLABORATION NEEDED!

Association of Veterinary Consultants

Classified as public by the European Medicines Agency

III. AREAS THAT IMPACT AVAILABILITY MOST

1. National requirements and continued disharmonisation
2. Variations
3. SPC, labeling and package leaflet
4. Transparency and predictability

Access VETMED

Classified as public by the European Medicines Agency

National requirements and continued disharmonisation

EMA / CMDv efforts to simplify the transition process, but

> National requirements are retained by the different NCAs

- National laws not aligned. More expected?
- Some burdensome procedures still retained (i.e. routine mock-up checks, samples check up…)

> Differences between NCAs in the interpretation of the Regulation

- "Representatives for Pharmacovigilance" and/or "Representative of the MAH"
- Parallel import
- Different implementation dates

> Duplication of efforts – national "on top of" EU

- Why national reporting on top of UPD, i.e. availability or sales data

Access VETMED

Classified as public by the European Medicines Agency

Variations

- The shortening of the notification period from 12 months to 30 days for a VNRA, following implementation
  - Unnecessarily increases the time pressure with already stretched resources
  - Severely limits ability to group variations

- A yearly review and amendment of the list of VNRAs would improve the quality of the implementing regulation (R2021/17). Flexibility during this process will be essential
- Call to allow presenting VNRAs that are consequential or related to a VRA in a single grouped package
- Overall rules for implementation of VRAs need more clarity and flexibility

Classified as public by the European Medicines Agency

SPC, labeling and package leaflet (QRD V9)

- A common implementation of decisions throughout the regulatory network is needed, especially with implementation of revised packaging
- The information on the national reporting system needs considerable simplification
- Section 16, the contact details for reporting suspected adverse events needs clarification and alignment
- Local representative rules for naming, location, responsibilities / obligations and labeling is open for interpretation

- Avoid the requirement of national non-harmonised pictograms for the recycling of packaging waste materials

Access VETMED

Classified as public by the European Medicines Agency

Level playing field; transparency and predictability

- New rules for Protection of Technical Documentation: substantial change both for new MAs and existing MAs
- How will these impact innovation, competition, access to VMPs/generics and availability? Will promises deliver? Monitoring plans?
- Concerns transparency, legal uncertainty and predictability: unclear how information on extensions, non-cumulative and overall exclusivity periods in the market be made available

These and other provisions currently developed in updated Guidance to Applicants

It is critical that industry is involved in the update of such Guidance at an early stage

Access VETMED

Classified as public by the European Medicines Agency

Impact availability

- Additional national requirements and MSs disharmonisation increase burden and workload
- Implementing variations and QRD updates: substantial resources needed, need clarification and improvement. Pragmatic approaches needed
- Clarity, guidance and transparent rules expected for a timely access to all VMPs

+ Impact cross sectorial legislation
(TiO2, PFAS, waste labeling)

+ increased fees

} Further unpredictability and costs/resources to keep licences on the market

Cost of compliance may lead to rationalisation of portfolios

Classified as public by the European Medicines Agency

The way forward

Classified as public by the European Medicines Agency

The way forward new IT systems

- Over the past year since the UPD was introduced, it has not yet yielded its expected benefits, but on the contrary has created significant administrative burden to all

- Industry is highly concerned by this situation and calls for rapid resolution for:
  - achieving product data completeness, in quality and quantity
  - developing all remaining functionalities to operate
  - further prioritisation of bug fixing

- Continue the good interactions and quality training provided by the EMA, with a few suggestions and points for consideration (next slides)

Access VETMED

Classified as public by the European Medicines Agency

The way forward IT systems: Training & Communication

The work, resources and efforts of EMA to support MAHs

for the implementation of the new systems is highly appreciated

Suggestions

- A flowchart to navigate the Helpdesk would be of great help
- Ensure published training materials on the EMA website are kept up-to-date
- Simpler, shorter, more focused communication. Release notes difficult to understand by non-IT people; more friendly description would be useful
- New volume of sales reporting system: instructions for use and/or additional training are necessary for the completion of the CSV files

Access VETMED

Classified as public by the European Medicines Agency

The way forward IT systems: interactions & collaboration

- Industry highly appreciates the opportunity that has been given over the years to be involved in the new IT systems developments
- Now shifting to Agile methodology through the establishment of dedicated SME groups for the VMP-Reg project
- The change to Agile development will be too resource-demanding for smaller (and not so small) MAHs to be able to participate and contribute
- Alternative forum for dialogue EMA / industry associations?

Access VETMED

Classified as public by the European Medicines Agency

The way forward - availability

National requirements

> Harmonisation: procedures, requirements, implementation deadlines

> National laws under development as aligned as possible

> Eliminate national requirements

> Eliminate duplicate national reporting i.e. sales data and availability status

Collaborations CMDv IP meetings much useful and appreciated

New regulatory procedures

> Flexibility and pragmatism, review areas for improvement (i.e. QRD updates, procedures variations)

> Ensure transparency, predictability and level playing field for all MAHs

Access VETMED

Classified as public by the European Medicines Agency

Final remarks

Access VETMED

Classified as public by the European Medicines Agency

Final remarks

Overall, the stated objectives key benefits of the regulation were not experienced during 2022

- It has been a year for adaptation to the Regulation 2019/6 where several difficulties have arisen.
- The training provided by EMA has helped industry to get used to the new systems.
- It will be still some time until we can say with confidence that we trust the databases and that we have well established procedures to fulfil our legal obligations.
- Not all the issues have been solved and we would appreciate a continued pragmatic and flexible approach.

Should 2023 be another 'transition year'?

Access VETMED

Classified as public by the European Medicines Agency

Acronyms

- AE – Adverse Event
- AVS – Availability Status
- CAs – Competent Authority
- CVS – Comma separated values
- DWH – Data Warehouse
- EVVet3 – Union Pharmacovigilance Database
- MAH – Marketing Authorisation Holder
- NCA – National Competent Authority
- OMS – Organisation Management Services
- OPAD – Other Post Authorisation Data
- PFAS - Per-and polyfluoroalkyl substances
- PSUR – Periodic Safety Update Report
- QRD – Quality Review of Documents
- SME – Subject Matter Expert
- SPOR – Substances, Products, Organisations, Referentials
- UPD – Union Product Database
- VAMF – Vaccine Antigen Master File
- VNRA – Variation Not Requiring Assessment
- VRA – Variations Requiring Assessment
- VOS – Volume of Sales

Classified as public by the European Medicines Agency

In the past year, the implementation of the new legislation has brought industry and authorities closer together, which has helped to understand each other's perspective.

There is still a long way to go, but we remain hopeful that we are getting on the right track.

Thank you for listening

animalhealth europe THE VOICE OF THE ANIMAL MEDICINES INDUSTRY

Access VETMED Committed to animal well-being in Europe

AVC Association of Veterinary Consultants

Classified as public by the European Medicines Agency