1 YEAR IMPLEMENTING REG 2019/6

INDUSTRY PERSPECTIVE

EMA InfoDay

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SPEAKERS

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

III. AREAS THAT IMPACT AVAILABILITY MOST

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

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National requirements and continued disharmonisation

EU regulatory network made efforts to simplify the transition process, but

> National requirements are retained by the different NCAs

- National laws not aligned. More expected and when?
- Some burdensome procedures still retained

> Differences between NCAs in the interpretation of the Regulation

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

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

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

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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

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

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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

Critical industry to be involved in the update of such Guidance at an early stage

Impact availability

- Additional national requirements and MSs disharmonisation increase workload
- Implementing variations and QRD updates: substantial resources needed
- Clarity, guidance and transparent rules expected for a timely access to all VMPs and a pragmatic approach is needed

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

+ increased fees

Unpredictability and costs/resources to keep licenses on the market

Cost of compliance may lead to rationalisation of portfolios

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The way forward

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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 user-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

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?

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'?

Acronyms

- AE – Adverse Event
- AVS – Availability Status
- CAs – Competent Authority
- CSV – 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

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

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