EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Clarifications on actions for industry in 2023 and beyond

Veterinary Medicines Info Day 2023

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An agency of the European Union

UPD – volume of sales

- Submission of 2022 volume of sales for veterinary medicinal products **by end of June 2023**
- Guidance available in Chapter 7 of the EU Vet Implementation Guide: https://www.ema.europa.eu/documents/other/eu-implementation-guide-ig-veterinary-medicines-product-data-union-product-database-chapter-7_en.pdf
- Recording of webinar held in September 2021 available on EMA website https://www.ema.europa.eu/en/events/union-product-database-webinar-marketing-authorisation-holders
- Further clarifications in Chapter 7 to be published shortly

1 Clarifications on actions for industry in 2023 and beyond

UPD – volume of sales
Why is this important?

- Legal obligation: **MAHs to submit *annual* volume of sales**; Regulation (EU) 2019/6 became applicable on 28 January 2022; first submission due early 2023 (extended deadline to June 2023 as functionality only became fully available in January)
- Integration to achieve administrative simplification (no duplication of effort):
  - Data exchange between systems, and subsequent legislative requirements such as **publication of incidence of adverse events from 2024**; system development for adrreports.eu will start in Q3 2023; information from volume of sales submissions is needed both for testing and to be able to publish from 2024 as legally required
  - Some NCAs intend to use the UPD volume of sales as a basis for preparing their antimicrobial sales submissions; first submission due in 2024

UPD – volume of sales
Quality of pack information in UPD

- Recent reports indicate that some packs in UPD (which MAHs need to map against) had been changed (deletion of packs and re-entering same information under a different identifier)
- Investigation ongoing; does not seem to affect many Member States/many products
- NCAs have been previously informed (communications, trainings) that changes to pack information should be entered under the same pack ID, not a new one
  - Message will be reinforced
  - Applying data analytics to extract some information that could be shared with MAHs from the change logs

UPD – availability status

- Updates to availability status of products/packages per country in UPD: no specific legal deadline, but listed as an MAH obligation & information is **essential** to veterinarians / general public using the public UPD portal
- Final issues with functionality are being resolved and it should be available/fully functional in the next release (2 March 2023)
- Guidance available in Chapter 7 of the EU Vet Implementation Guide: https://www.ema.europa.eu/documents/other/eu-implementation-guide-ig-veterinary-medicines-product-data-union-product-database-chapter-7_en.pdf
- Recording of webinar held in January 2022 available on EMA website https://www.ema.europa.eu/en/events/union-product-database-follow-webinar-marketing-authorisation-holders

VNRA – QPPV & PSMF information in UPD

- MAHs requested to enrich UPD especially in relation to the QPPV and PSMF information for their products; asap
- Technical grouping possible per Member States (ie. per responsible authority for national authorisations & RMS in MRP/DCP products)
- No fee for VNRAs for CAPs
- Rationale: Information required for regulatory procedures, especially where the location of the QPPV or the PSMF is essential for planning purposes

VRA - G.I.18 variation

- Reminder that QRD V9 has to be applied by 2027
- Guidance has been communicated by email
- Recommendation to plan the coverage of product portfolio carefully

Positive example: one company has already shared their plans for when they will submit G.I.18 for which products over the next few years with NCAs & EMA!

UPD – data quality

- approx. 45.000 products in UPD (99.5% *completeness* rate)
- Small number of outstanding products per MS, some related to bugs/issues that are being resolved; additional support continuously provided to MS to reach completion
- Shifting focus to **data quality:**
  - Visualisation through data analytics (scope limited);
  - Dashboards on focus areas (e. g. strength, package information, product names);
  - Identification of quality issues to relevant NCAs (e.g. by providing access to the dashboards)
  - Ongoing monitoring

UPD – data quality

- Commission Implementing Regulation (EU) 2021/16; Article 18:

> 8. Marketing authorisation holders shall be responsible for ensuring that the data and documents they record in datasets existing in the Union product database for their veterinary medicinal products are correct and up to date.
>
> 9. Where holders of a marketing authorisation granted in accordance with Chapter III of Regulation (EU) 2019/6, of a registration for homeopathic veterinary medicinal products granted in accordance with Chapter V of Regulation (EU) 2019/6, of veterinary medicinal products referred to in Article 5(6) of Regulation (EU) 2019/6 or of an approval to parallel trade veterinary medicinal products in accordance with Article 102 of Regulation (EU) 2019/6 identify data or document quality issues in the entries created for their veterinary medicinal products in accordance with paragraph (1), or updated in accordance paragraph (4), they shall immediately notify the relevant competent authorities or the Commission, as applicable, which shall correct the data without delay upon verification that the requests are justified.

- In case of data quality issues affecting your products, please contact the NCAs with ***specific*** requests to update product data (see CMDv list of contact points published on HMA website)
- *Functionality coming up in Q2: it will be possible to connect to the UPD via API (read-only) and you can download the product information (e. g. by connecting via an API tool to retrieve a .csv file containing the fields you are interested in)*

Contacts

Please use the applicable route for any questions or support needs that arise:

- UPD user support still active for ***technical*** questions: https://servicedesk.ema.europa.eu/jira/servicedesk/customer/portal/283
- ***Regulatory*** questions: please use AskEMA https://www.ema.europa.eu/en/about-us/contacts/send-question-european-medicines-agency
- Contact the NCAs for questions/***quality*** issues in relation to the ***product data*** in UPD (EMA for CAPs)
- ***Anything else***: vetchange.programme@ema.europa.eu is still active; but:
  - Many messages are merely being forwarded/redirected to the appropriate services already
  - Mailbox will be discontinued later this year (closure will be communicated)

Any questions?

Further information

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