EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Regulatory and procedural developments

EMA Veterinary Medicines Info Day March 2024

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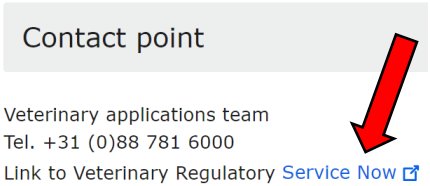
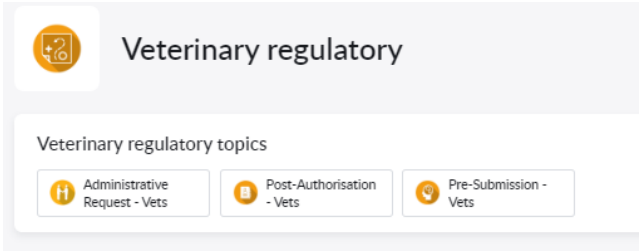
Vet applications mailbox discontinued

From 1 January 2024, MAHs should use EMA Service Now **to initiate** specific veterinary procedures:

- **Administrative** – notification of change of contact person for product.
- **Pre-submission** - requests for eligibility, pre-submission meetings, notifying change of intended submission date or contact person, accelerated assessment, withdrawal requests, mock-up submission*.
- **Post-authorisation** – intent to submit VRAs, queries on VRAs/VNRAs/ marketing authorisation transfers, and withdrawal requests*.

(*coming soon)





Invented names

- From 1 Jan 2024, invented name requests limited to two per MA application.
- No impact on already submitted or already accepted invented names.
- In case neither invented name is accepted by CVMP, the applicant may submit a new request with up to two further proposed invented names. The number of finally accepted invented names cannot exceed two per marketing authorisation application.
- EMA analysis (also involving human medicines) is that this reduction from 4 to 2 names per request does not significantly impact probability of achieving invented names. Procedure will be more efficient and allow for better tracking of unused invented names.

Variations – Commission Decisions

In May 2023, the process changed for EC Decisions:

For VRAs:

- If no changes to product information (incl. Annex II) → no EC Decision, only CVMP opinion. VRA can be implemented immediately after notification of opinion by EMA.
- If there are changes to product information → EC Decision required. VRA can only be implemented after adoption of Decision. Implementation date for VRA included in Decision.

For VNRAs:

- Same concept – if no changes to product information → no EC Decision.
- If changes to product information → will be reflected with EC Decision on next VRA.
- In exceptional cases, a dedicated EC Decision can reflect a VNRA.

Commission Notice – Guidance to Applicants (C/2024/1443)

Published February 2024

Effectively replaces Volume 6A, Chapter 1 of the Notice to Applicants

New sections compared to NtA e.g. definition of veterinary medicinal products (including zootechnical products)

Extensive section on limited markets

Clarifications on cumulative criteria of Article 23(1)(a))

CVMP reflection paper on LM classification needs revision

Clarifications on scenarios for generic applications with examples

Extensive section on data protection, introduces concept of 'same marketing authorisation' which replaces previous term 'global MA'

Section on environment:

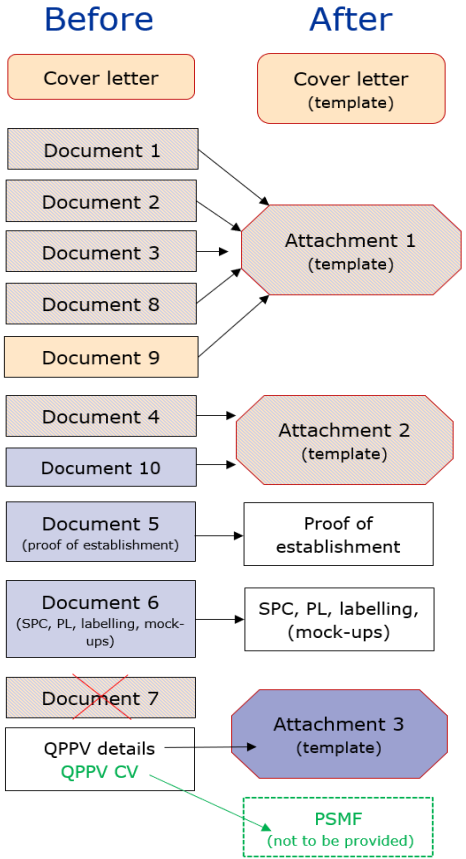
- ERA general principles
- Risk mitigation measures in product information
- PBTs/vPvBs (incl. existing MAs)

Regulation (EU) 2024/568 of the European Parliament and of the Council on fees and charges payable to the European Medicines Agency

- The Regulation has been published in the EU Official Journal following final adoption by the European Parliament and the Council.
- The Regulation will become applicable as of 1 January 2025.
- Marketing Authorisation Holders are advised to familiarise themselves with the Regulation (new fees, including for non-CAPs e.g. referrals or annual PhV fee also for NAPs); Fees Payable to the European Medicines Agency.
- EMA is currently working on the implementation of the Regulation, including guidance and setting up all the necessary systems.
- The Agency will hold dedicated events for industry to help manage this major change.

Q&As on MA transfer procedure

- Q&As updated to align with Regulation (EU) 2019/6 and other recently updated vet guidance documents.
- Q&As aligned with human Q&A, when relevant.
- Templates provided to ease the preparation of transfer applications.
- Reduced number of attachments to provide.
- Possibility change to QPPV as part of the transfer.
- Other changes to PSMF to be notified via VNRAs in UPD.
- Publication of the revised Q&As expected around 14/03/2024.



Regulatory Procedure Management for PLM in IRIS

- **1st roll-out** of Variations Requiring Assessment and Marketing Authorisation Transfers on IRIS took place on **23 January 2024**.
- For the first transition to IRIS, EMA has selected a **subset of 44 veterinary medicinal products**.
- This impacts the industry users from Marketing Authorisation Holders (MAHs) with selected products, as they **need to access IRIS** to:
  - view procedure status
  - withdraw a procedure
  - update procedure contacts/ contributors/ managers
  - retrieve documents sent by EMA and submit non-VNeeS documents

Next Steps:

- **Additional functionalities** will be incrementally released.
- Development of other **post-authorisation processes (e.g. post-authorisation measures & studies)** and onboarding **more CAPs**.

QR code guidance

- Inclusion of QR code on pack cannot substitute for inclusion of a package leaflet unless a Member State has explicitly allowed this possibility under Article 14(3).
- Info linked via QR code (e.g. videos) should be available in all official languages of MSs where pack is authorised.
- Pay attention that background images e.g. in videos, do not inadvertently contradict clinical info in the SPC or best practice for administering medicines.
- Guidance contains clearer info (with flow charts) on procedural aspects e.g. timing of submission of draft versus final content linked via QR code, and translations.
- Consider how new product developments affect the content linked via existing QR codes and the timing of submitting revised QR code content.

QRD template – new implementing and delegated acts

- QRD **v.9.1** is on the horizon in mid-2024
- Delegated act on oral administration expected mid-2024
- 2 x implementing acts imminent on pictograms/abbreviations and size of small immediate packaging units
- Transitional periods for each act for existing MAs
- New, dedicated VNRAs to implement changes to product information/packs, where applicable

- Delegated act: anticipate standard sentences on individual feeding, interactions, major incompatibilities.
- Implementing acts: anticipate changing non-standard pictograms/abbreviations that are replacing text and checking if packs > 50 ml meet derogation criteria to stay as small immediate labelling

Batch release after 29 January 2027 (QRD v.9)

- According to Reg. (EU) 2022/839, batches compliant with previous packaging and labelling requirements (QRD v.8.2) can continue to be released until **29 January 2027**.

- Batches released thereafter would have to be compliant with the labelling and packaging requirements under Regulation (EU) 2019/6, i.e. QRD v.9 or later versions.

Any questions?

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