EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Actions for industry until January 2022 and beyond

EMA Info Day II 2021

Presented by Jana Schalansky on 30 November 2021
Head of Veterinary Strategic Support

An agency of the European Union

By 28th January 2022

- Stay up to date with developments: newsletter
- Attend training sessions

Classified as internal/staff & contractors by the European Medicines Agency

By 28th January 2022 – Pharmacovigilance (EVVet)

- Ensure you have a **VICH to DEG converter** available if you will not be ready to receive VICH standard messages in your pharmacovigilance database

  a) If you are implementing VICH standard by 28 January: no further action

  b) If not: deploy a VICH to DEG converter; as the messages obtained from EVVet will be in the format they came into the database and all EVWEB submissions are in VICH standard

  c) If neither is possible: use EVWEB and the EVVet DWH to perform your pharmacovigilance obligations until you are ready

- In case of option b): New business rules for **DEG** to ensure compatibility with the VICH format

  - Species (DEG R.17.02 (species name)): Must exist in the VICH species list
  - Breed (DEG R.17.03.02 (breed name)): Must exist in the VICH breeds list
  - AER ID (DEG R.05 (case number)): Must comply with VICH format (e.g. PRT-PRTDGVFV-…)

Classified as internal/staff & contractors by the European Medicines Agency

In January 2022

- UPD super user to register; once approved:
  - All other users to register for UPD roles, super user approves
- EVVet super users and users to reset their password (super users will be notified when to do this, please forward information to all other users to do the same)
- Marketing authorisation holders: check your organisation/locations data in OMS and submit change requests, if necessary

Classified as internal/staff & contractors by the European Medicines Agency

After 28 January 2022: EVVet AERs and signal management

- VICH to DEG converter required if you have not upgraded to VICH standard in your local database
- Check EVWEB regularly to obtain the new cases submitted
- You will only be able to see the full cases (incl. narrative) for the products that are in UPD, where recoding has completed (approx. 2-3 months after the product was entered in UPD); for the others, level 1 access (Product 'as reported') without case narratives is possible
- Signal detection/management: same constraints apply as above; stay in touch with NCAs and EMA on progress

Classified as internal/staff & contractors by the European Medicines Agency

After 28 January 2022: UPD data quality and availability

- Check **product data** entries in UPD; notify any data quality issues to responsible NCA; except:
  - QPPV name and location: if contains placeholder data and NCA wishes to resolve via variation not requiring assessment, agree approach with them and if possible, wait until May/June when the next release of VNRA functionality will go live (reduces administrative burden on NCAs and potential for errors in product updates)
  - PSMF-related information (slide 11)
- Consider updating **availability status** of packages in Member States as soon as possible: important information for veterinary healthcare professionals/general public

Classified as internal/staff & contractors by the European Medicines Agency

After 28 January 2022: OMS entries of manufacturers

- EMA currently exporting and cleansing organisation data from EudraGMDP into OMS
- After 28 January 2022, check organisation/locations data for EU and non-EU manufacturers in OMS and agree who submits change requests, if necessary
- Up to date information required for any document requests and applications

Classified as internal/staff & contractors by the European Medicines Agency

After 28 January 2022: UPD volume of sales

- Familiarize yourself with **volume of sales** submission and choose your approach: monthly/quarterly/annual submission
  - Data in monthly increments (1 line per month) in any case
  - Legal requirement: 28 January 2022 – 31 December 2022; consider including full January 2022 data voluntarily
  - Completed submission of 2022 data expected in Q1 2023 (dates to be clarified); ie. by this time the full data for 2022 should be completed, whether choosing monthly, quarterly or annual submissions

Classified as internal/staff & contractors by the European Medicines Agency

After 28 January 2022: UPD – third country product names

- MAHs do not have to provide any information for the UPD MVP
- EMA will treat them as ‘misspellings’ of the relevant EU products
- EMA may contact MAHs should clarifications on specific cases be needed

Classified as internal/staff & contractors by the European Medicines Agency

Initial applications/variations requiring assessment

- Those validated before 28 January will be completed under the old legislative framework
- For any applications planned after 28 January:
  - new electronic application forms, plan some additional time in preparing submissions (e. g. in case OMS or RMS updates are required)
  - Familiarise yourself with new legislative framework and guidance provided on EMA website
  - Use **version 9** of the QRD template for your product information

Classified as internal/staff & contractors by the European Medicines Agency

Variations not requiring assessment (1/2)

- Outstanding Type IA variations can be submitted within 12 months (ie. changes that have been implemented before 28 January 2022)
- VNRA functionality will be gradually improved in 2022; consider timing of changes that need to be submitted within 30 days
- If you have to submit a VNRA and the product is not in the UPD yet (e. g. in February); contact responsible NCA as early as possible to find an agreement how to proceed

Classified as internal/staff & contractors by the European Medicines Agency

Variations not requiring assessment (2/2)

Confidentiality of data for submission of VNRAs against a product approved under DCP/MRP/SRP and owned by different MAHs in different Member States:

→ UPD MVP – one representative for all involved MAHs to ensure that only one submission is sent to UPD

Classified as internal/staff & contractors by the European Medicines Agency

DDPS to PSMF

- You must have a PSMF for all authorised VMPs (new and existing)
- PSMF reference and location: to be included in UPD, e.g. via VNRA (in which case, should be postponed to May/June – see slide 4)
- PSMF summary inclusion in dossier (e.g via VNRA): no obligation to include the PSMF summary in the dossier for existing/legacy products (clarification previously provided by DG Sante); no additional requirements from Commission Implementing Regulation (EU) 2021/1281
- Updates to PSMF summary after 28 January 2022 to be handled via VNRA; at that point, included in the dossier

Classified as internal/staff & contractors by the European Medicines Agency

Submission of new substances

- VMPs will be available in the UPD only after authorization
- At the time of initial application, if the substance is not yet in SMS and you need it for the application form:

→ Fill the substance registration form with the '**Restricted**' value

Classified as internal/staff & contractors by the European Medicines Agency

Irish language derogation

EC decisions for CAPs for MAHs established in Ireland:

- EMA will engage with MAHs in Ireland – will they require EC decisions in Irish or request a language waiver?
- To request a waiver, MAHs/applicants established in Ireland should submit to the EMA a language waiver requesting to use English as authentic language
- 3-year validity, automatically renewed for 3 additional years
- Deadline: submit waiver to IrishWaiver@ema.europa.eu by 31 January 2022 (unless opinion scheduled for December 2021 –> submit no later than the adoption of the opinion at CVMP)
- Guidance and waiver published here.

Classified as internal/staff & contractors by the European Medicines Agency

Any questions?

Further information

vetchange.programme@ema.europa.eu

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Telephone +31 (0)88 781 6000
Send us a question Go to www.ema.europa.eu/contact

Follow us on **@EMA_News**

Classified as internal/staff & contractors by the European Medicines Agency