EMA
EUROPEAN MEDICINES AGENCY

# Implementation status of Pharmacovigilance processes

## EMA Veterinary Medicines Info Day 2026

Presented by James Mount on 12 March 2026

Chair of CVMP Pharmacovigilance Working Party

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# Signal management process

"the signal management process is the '**gold standard**'"

*Source: Recital 63 of Regulation (EU) 2019/6*

"*'signal management process' means a process for performing **active surveillance** of pharmacovigilance data for veterinary medicinal products in order to assess the pharmacovigilance data and determine whether there is any change to the **benefit-risk balance** of those veterinary medicinal products, with a view to **detecting risks** to animal or public health or protection of the environment.*"

*Source: Article 4 of Regulation (EU) 2019/6*

# A signal

> “‘signal’ means information that arises from one or multiple sources, including observations and experiments, which suggests a potentially **new causal association**, or a **new aspect of a known causal association** between an intervention and an adverse event or a set of related adverse events, that is **judged** likely to justify further investigation of possible causality.”

*Source: Article 1 of IR (EU) 2021/1281*

# The four principal obligations of MAHs

1. Continuously monitor the benefit-risk balance of their products.
2. Carry out a signal management process, including sales data and scientific literature.
3. Notify within 30 days of change to the benefit-risk balance or a new risk, take necessary action. [Emerging Safety Issue = 3 days]
4. Annually record all results and outcomes of the signal management process, including a conclusion on the benefit-risk balance.

*Source: Regulation (EU) 2019/6 and IR (EU) 2021/1281*

# Implementation in IT systems (IRIS)

3 Notify within 30 days of change to the benefit-risk balance or a new risk, take necessary action. *[Emerging Safety Issue = 3 days]*

**'Signal management submission' in IRIS**

- Including assessment report.
- Selection of action: refute, close monitoring or amendment to product information.
- Recommended to use signal assessment report template.

4 Annually record all results and outcomes of the signal management process, including a conclusion on the benefit-risk balance.

**'Annual statements submission' in IRIS**

- MAH to confirm compliance with Regulation (EU) 2019/6 and relevant guidelines.
- Benefit-risk balance remains unchanged.

# VGVP Module: Signal Management

- Obligations clarified further in Guideline on veterinary good pharmacovigilance practices (VGVP) Module: Signal Management
    - Signal detection, prioritisation, validation, assessment and documentation of outcome.

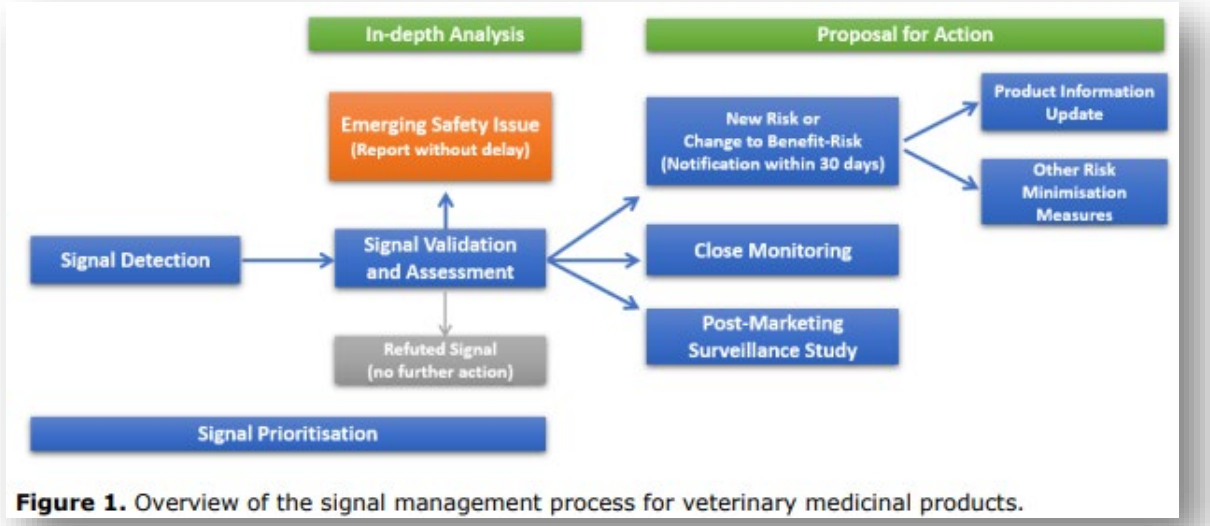



**Figure 1.** Overview of the signal management process for veterinary medicinal products.

**Revision of VGVP Module in progress!**

- Union Pharmacovigilance Database – Best Practice Guide [formerly EVV-BPG] includes practical guidance on signal detection in UPhD (EVV Datawarehouse) – published 13 November 2025.

# Responsibilities of regulators

1. Evaluate the results and outcomes of the signal management process recorded in the Union pharmacovigilance database.

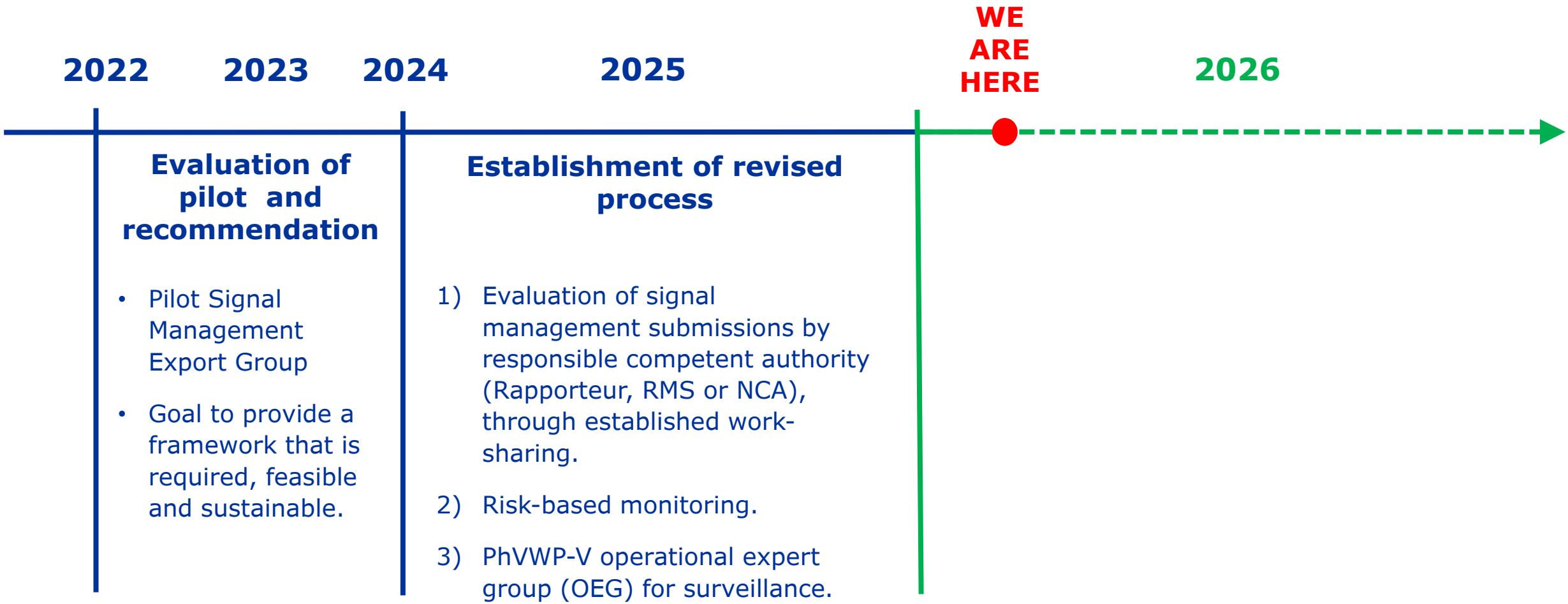
2. Verify, by means of controls and inspections, that MAHs comply with the requirements.

3. Perform, when needed, a targeted signal management process for a given VMP or a group of VMPs.

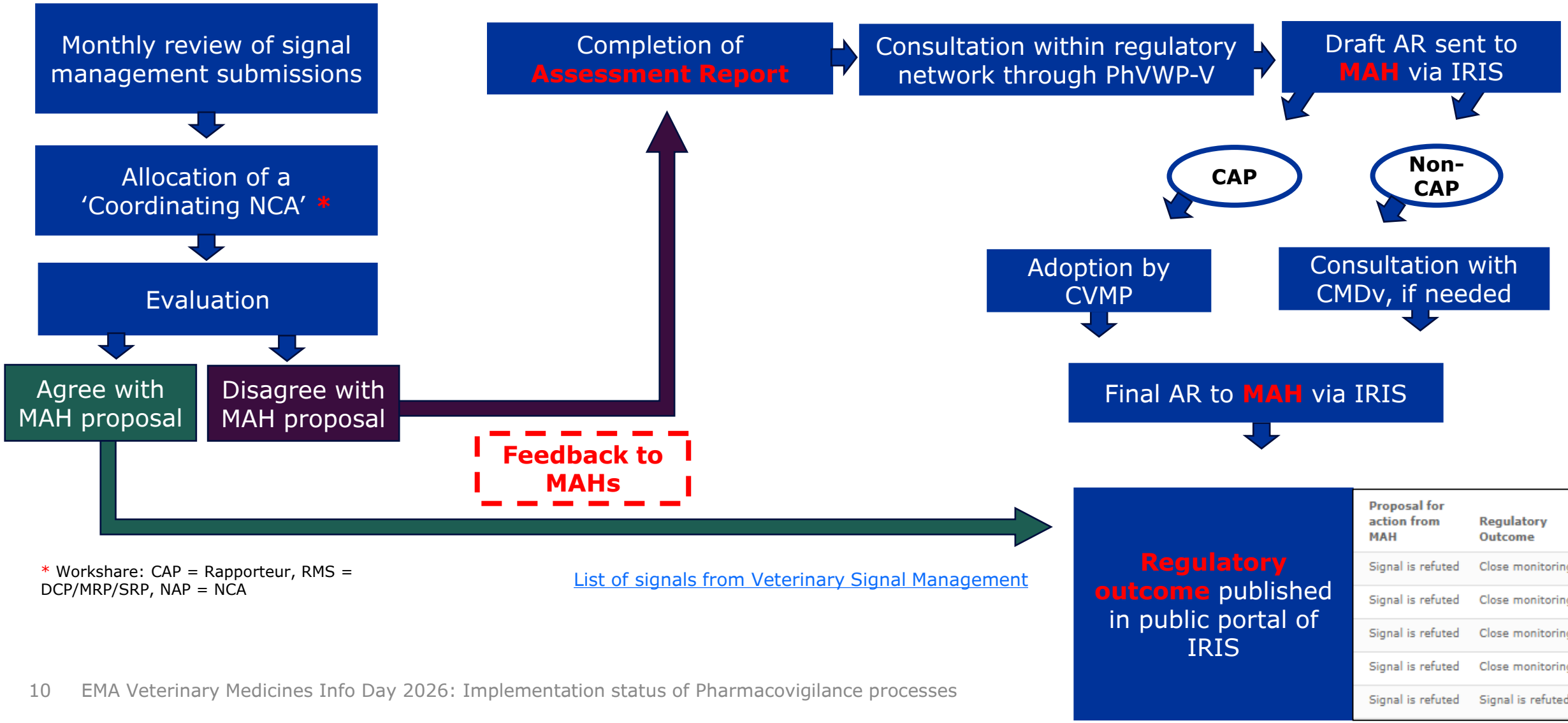
*Source: Regulation (EU) 2019/6 and IR (EU) 2021/1281*

Opens for an **interplay** between MAHs and regulators in the signal management process.

# Timeline of implementation of the signal management process in EU



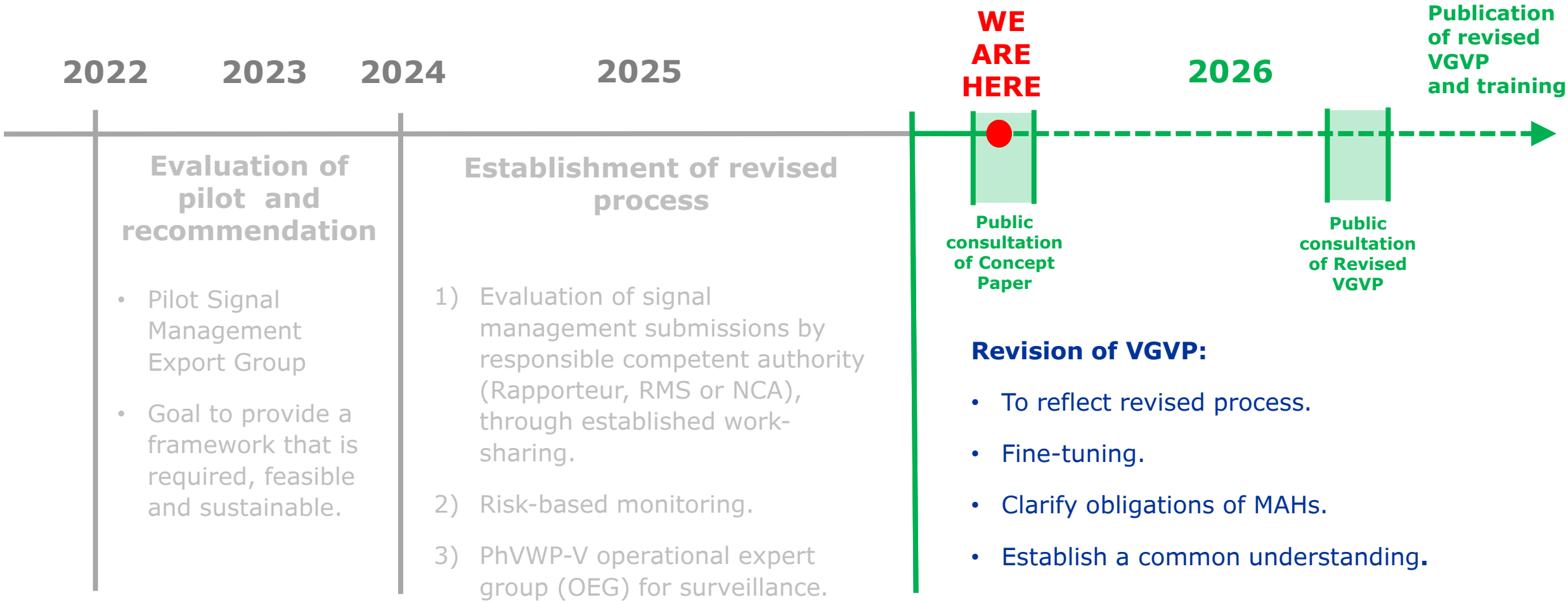
# Revised Process: Signal Evaluation by regulators




* Workshare: CAP = Rapporteur, RMS = DCP/MRP/SRP, NAP = NCA

List of signals from Veterinary Signal Management

# Timeline of implementation of the signal management process in EU



# Revision of VGVP Signal Management Module

- **Establish a common understanding**
  - Signal detection, evaluation and validation; reporting obligations.
  - Progress made through Union Pharmacovigilance Database – Best Practice Guide [formerly EVV-BPG].
  - Aim to refine key process steps (prioritization, validation, assessment) and supply definitions (safety observation, valid signal, 'confirmed' and refuted signal).
- **Optimises signal management procedures**
  - Fine-tuning, although ensuring minimal impact on MAHs and regulators but ensuring sustainability.
  - Modification to systems, if warranted.
- **Concept paper out now!**
  - Opportunity for stakeholders to provide input and feedback.
  - Published on 13 February 2026. Deadline for comments on 15 March 2026.

# Improvements to public portals

- Public portal of EudraVigilance Veterinary (EVV) – full transparency in line with the Regulation.
- EMA consulted (survey) with Stakeholders (Industry and NCAs).
- Initially, updates to guidance and disclaimers on the platform, including translation by the Centre de traduction des organes de l'Union européenne (CdT).
- Further consultation planned with FVE.
- Additional improvements are envisaged, including dashboards.


adrreports.eu

# Vet Medicine Safety Day 2026

- First launched by EMA, EU Member States and the Federation of Veterinarians of Europe in 2025.
- Theme for 2026: '*Encourage animal owners, veterinarians, and farmers to report lack of expected efficacy of antiparasitic products*'.
- Initial key messages drafted jointly by members from CVMP Efficacy and Pharmacovigilance Working Parties.
- Launch on **8th April 2026.**
- Stakeholders encouraged to facilitate the spread of messages.

#VetMedSafetyDay

**Join us in 8th April 2026!**

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# Thank you

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**Safer medicines, healthy animals.**

**Report adverse events!**

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