

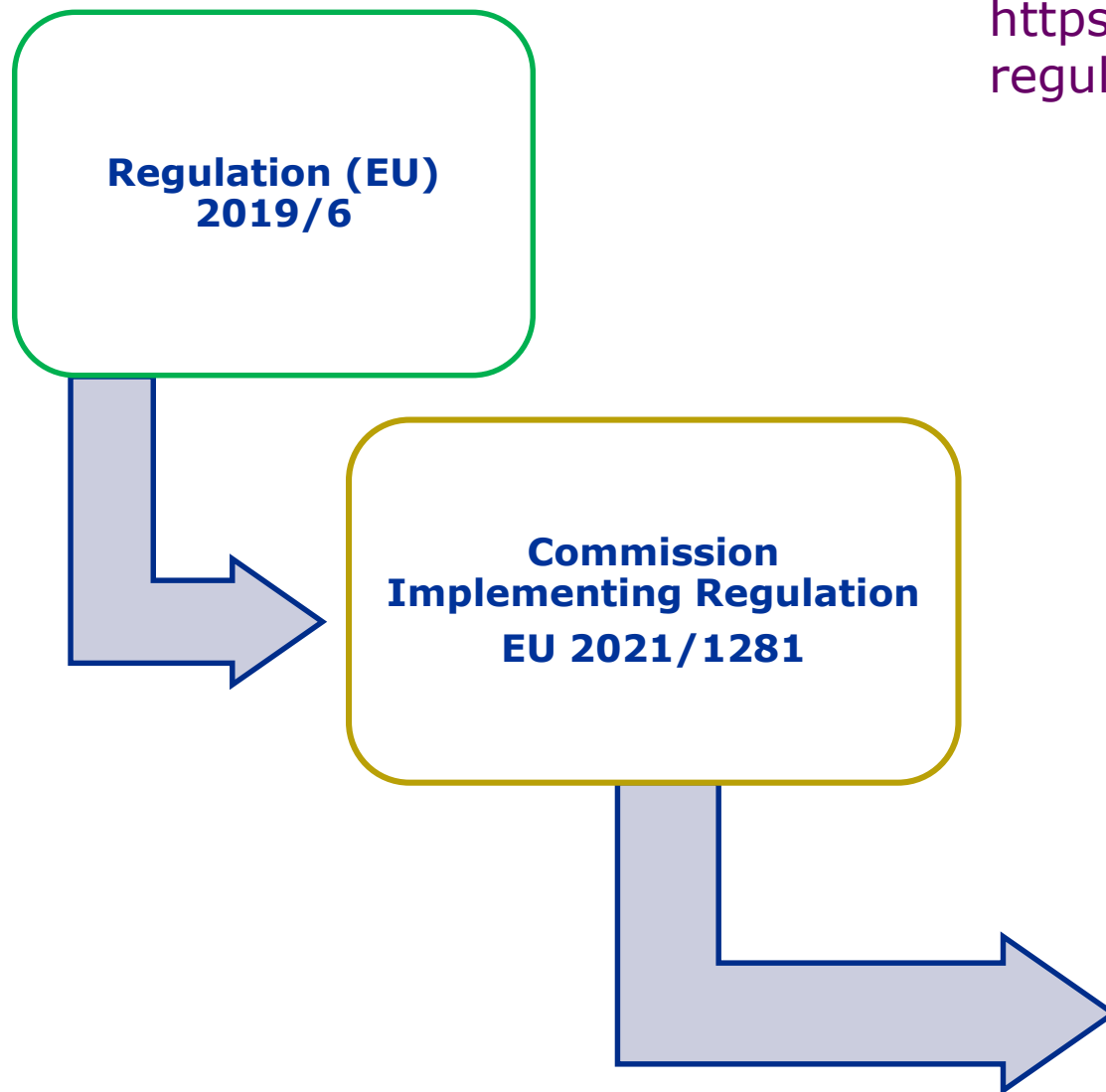
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Pharmacovigilance, signal detection and surveillance

Presented by Jos Olaerts 30 November 2021
Head of Veterinary Risk and Surveillance Service



<https://www.ema.europa.eu/en/veterinary-regulatory/post-authorisation/pharmacovigilance>

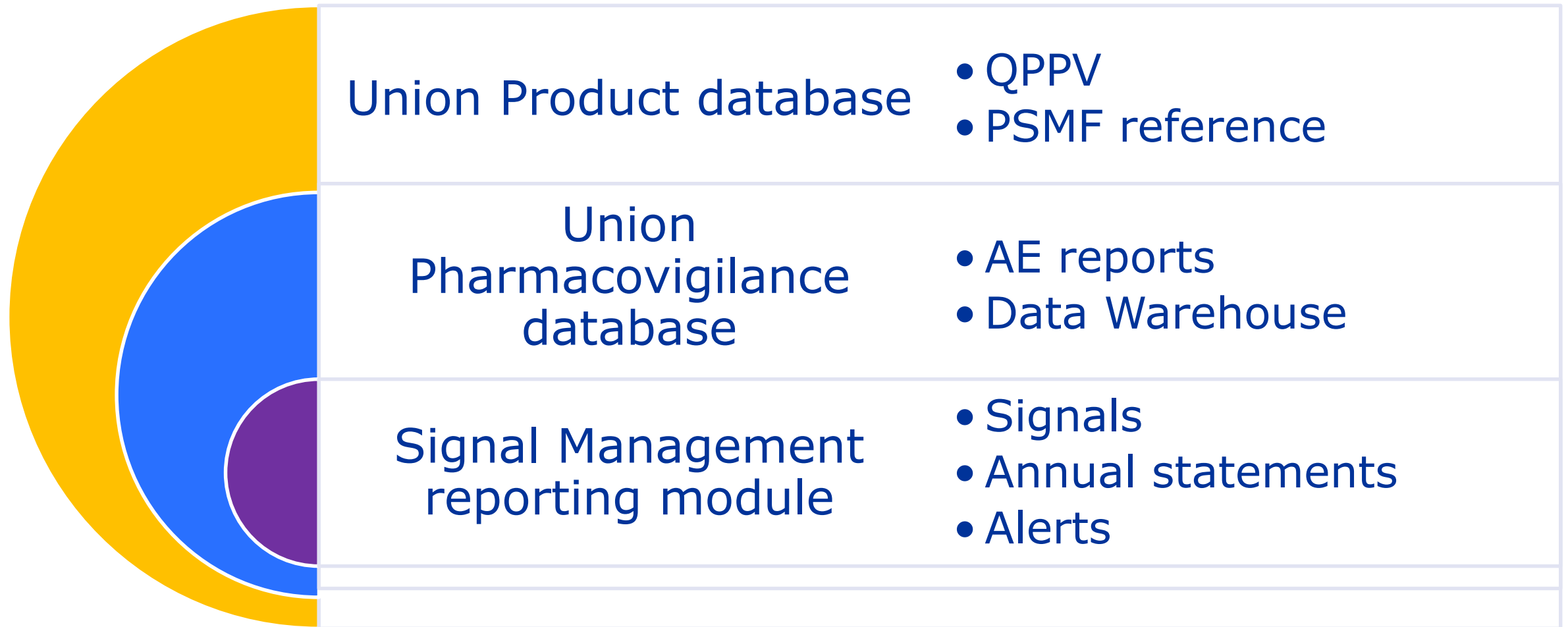


Final VGVP modules

- [Guideline on veterinary good pharmacovigilance practices \(VGVP\) - Module: Collection and recording of suspected adverse events for veterinary medicinal products \(PDF/281.93 KB\) \(new\)](#)
Adopted
First published: 18/11/2021
Legal effective date: 28/01/2022
EMA/306663/2021
- [Guideline on veterinary good pharmacovigilance practices \(VGVP\) - Module: Signal Management \(PDF/366.74 KB\) \(new\)](#)
Adopted
First published: 18/11/2021
Legal effective date: 28/01/2022
EMA/522332/2020
- [Guideline on veterinary good pharmacovigilance practices \(VGVP\) - Module: Veterinary pharmacovigilance communication \(PDF/320.27 KB\) \(new\)](#)
Adopted
First published: 18/11/2021
Legal effective date: 28/01/2022
EMA/63454/2021
- [Guideline on veterinary good pharmacovigilance practices \(VGVP\) - Module: Pharmacovigilance systems, their quality management systems and pharmacovigilance system master files \(PDF/245.28 KB\) \(new\)](#)
Adopted
First published: 18/11/2021
Legal effective date: 28/01/2022
EMA/595115/2021
- [Guideline on veterinary good pharmacovigilance practices \(VGVP\) - Module: Controls and pharmacovigilance Inspections \(PDF/262.58 KB\) \(new\)](#)
Adopted
First published: 18/11/2021
Legal effective date: 28/01/2022
EMA/328998/2021
- [Guideline on veterinary good pharmacovigilance practices \(VGVP\) - Module: Glossary \(PDF/135.23 KB\) \(new\)](#)
Adopted
First published: 18/11/2021
Legal effective date: 28/01/2022
EMA/118227/2021



Essential DATA systems





Trainings

- **Adverse Event collection and recording**
 - 10 November 2021 (500+)
 - 13 January 2022
- **Continuous Adverse Event analysis by MAH (signal management)**
 - 23 and 24 November 2021 (signal analysis) (500+)
 - 18 and 19 January 2022 (yearly statements and signal submission)
- **Pharmacovigilance Inspections and Pharmacovigilance Master File**
 - 8 December 2021



Key messages on signal management

- Signal management is a **continuous** process throughout the product life-cycle
- **Risk-based** approach
- **Flexibility** and sound **scientific** and **clinical judgement** should always be applied
- **Trust** (& inspections)



Annual submission statements

| | Benefit-risk balance |
|----------|---|
| X | I confirm that the benefit-risk balance remains unchanged |
| | A procedure is ongoing concerning the benefit-risk assessment |

| | Adherence to VGVP guidelines |
|----------|---|
| X | I confirm that the signal management process has been conducted in compliance with the pharmacovigilance guidelines published by the Agency (VGVP) and all assessed signals have been submitted |



Due dates for Signal Management

| | A | B | C | D | E | F | G | H | I | J | K | L |
|----|--|---|---|---|---|---|---|---|--------|-------------------|---------------------|-------------------|
| 1 | Category | | | | | | | | | target spp | CAP | Rapporteur |
| 2 | QI02AB Inactivated bacterial vaccines (including mycoplasma, toxoid and chlamydia) | | | | | | | | 31-May | cattle | Startvac | DE |
| 3 | | | | | | | | | | | Coxevac | FR |
| 4 | | | | | | | | | | | Ubac | DE |
| 5 | QI02AC Inactivated bacterial vaccines and antisera | | | | | | | | 31-May | cattle | | |
| 6 | QI02AE Live bacterial vaccines | | | | | | | | 31-May | cattle | | |
| 7 | QI02AF Live bacterial and viral vaccines | | | | | | | | 31-May | cattle | | |
| 8 | QI02AG Live and inactivated bacterial vaccines | | | | | | | | 31-May | cattle | | |
| 9 | QI04AB Inactivated bacterial vaccines (including mycoplasma, toxoid and chlamydia) | | | | | | | | 31-May | sheep | | |
| 10 | QI04AC Inactivated bacterial vaccines and antisera | | | | | | | | 31-May | sheep | | |
| 11 | QI04AE Live bacterial vaccines | | | | | | | | 31-May | sheep | | |
| 12 | QI04AF Live bacterial and viral vaccines | | | | | | | | 31-May | sheep | | |
| 13 | QI04AG Live and inactivated bacterial vaccines | | | | | | | | 31-May | sheep | | |
| 14 | QI03AB Inactivated bacterial vaccines (including mycoplasma, toxoid and chlamydia) | | | | | | | | 31-May | goat | | |
| 15 | QI03AC Inactivated bacterial vaccines and antisera | | | | | | | | 31-May | goat | | |
| 16 | QI03AE Live bacterial vaccines | | | | | | | | 31-May | goat | | |
| 17 | QI03AF Live bacterial and viral | | | | | | | | 31-May | goat | | |
| 18 | QI03AG Live and inactivated bacterial vaccines | | | | | | | | 31-May | goat | | |
| 19 | QI07AI Live viral and inactivated bacterial vaccines | | | | | | | | 31-May | dog | Versican Plus Pi/L4 | DE |
| 20 | QI07BI Live viral and inactivated bacterial vaccines | | | | | | | | 31-May | fox | | |
| 21 | QI07XI Live viral and inactivated bacterial vaccines | | | | | | | | 31-May | other canidae | | |
| 22 | | | | | | | | | | | | |

| | A | B | C | D |
|----|--|------------------------|---|--------------------|
| 1 | ATCvet Codes | category | Product (CAP) | NCA Country |
| 2 | QJ01M QUINOLONE AND QUINOXALINE ANTIBACTERIALS | systemic use | Veriflox | DE (BVL) |
| 3 | QJ04 ANTIMYCOBACTERIALS | systemic use | n/a | n/a |
| 4 | QJ54 ANTIMYCOBACTERIALS FOR INTRAMAMMARY USE | intramammary | n/a | n/a |
| 5 | QP53AC08 cypermethrin | pyrethrins/pyrethroids | n/a | n/a |
| 6 | QP53AC10 fluvalinate | pyrethrins/pyrethroids | n/a | n/a |
| 7 | QP53AC11 deltamethrin | pyrethrins/pyrethroids | n/a | n/a |
| 8 | QP53AC12 cyfluthrin | pyrethrins/pyrethroids | n/a | n/a |
| 9 | QP53AC13 tetramethrin | pyrethrins/pyrethroids | n/a | n/a |
| 10 | QP53AC14 fenvalerate | pyrethrins/pyrethroids | n/a | n/a |
| 11 | QP53AC15 acrinathrin | pyrethrins/pyrethroids | n/a | n/a |
| 12 | QP53AC30 combinations of pyrethrines | pyrethrins/pyrethroids | n/a | n/a |
| 13 | QP53AC51 pyrethrum, combinations | pyrethrins/pyrethroids | n/a | n/a |
| 14 | QD DERMATOLOGICALS | organ class | Apoquel | IE |
| 15 | QD DERMATOLOGICALS | organ class | Cytopoint | IE |
| 16 | QD DERMATOLOGICALS | organ class | Cortavance | DK |
| 17 | QD DERMATOLOGICALS | organ class | Hydrocortisone aceponate Ecuphar | FR |
| 18 | | | | |
| 19 | | | | |
| 20 | | | | |



Regulatory overview

- **Establishing a Pilot EU expert group is ongoing;**
 - **To ensure a consistent EU approach to PhV signal management**
 - **To ensure a risk-based approach**
 - **Measuring resource effectiveness**





Signal management

- **The analysis part**
- **To procedural part**
- **The publication part – focus on veterinarians in practice**

A blue directional sign with a white arrow-shaped background pointing to the left. The sign is mounted on a blue metal post. The text on the sign is in a bold, black, sans-serif font. The background of the image is a blurred natural setting with green and brown foliage.

**Veterinary
surgery**



Any questions?

Further information

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