EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Union Pharmacovigilance Database - webinar on signal detection and analysis

Introduction

Presented by Jos Olaerts 23 November 2021
Head of Veterinary Risk and Surveillance Service

Regulation (EU) 2019/6

Commission Implementing Regulation EU 2021/1281

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

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
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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
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EMA/328998/2021

Guideline on veterinary good pharmacovigilance practices (VGVP) - Module: Glossary (PDF/135.23 KB) (new)

Adopted

First published: 18/11/2021
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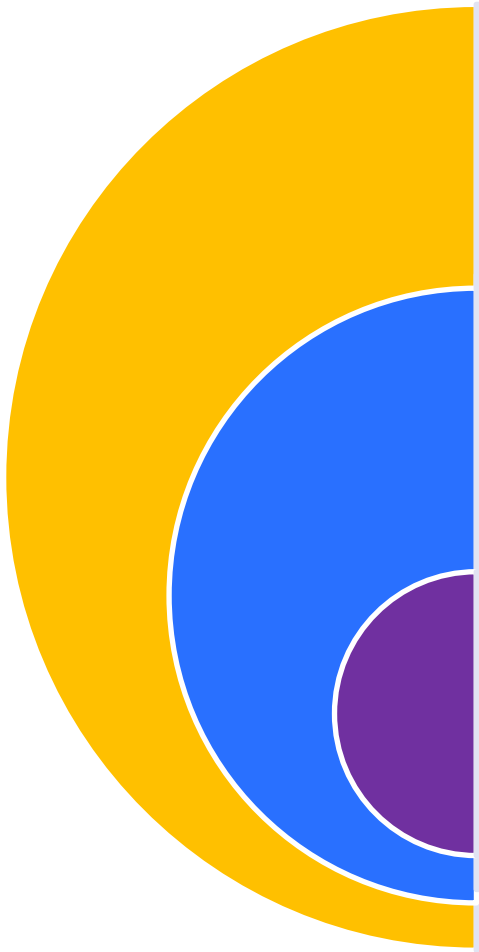
EMA/118227/2021

Trainings

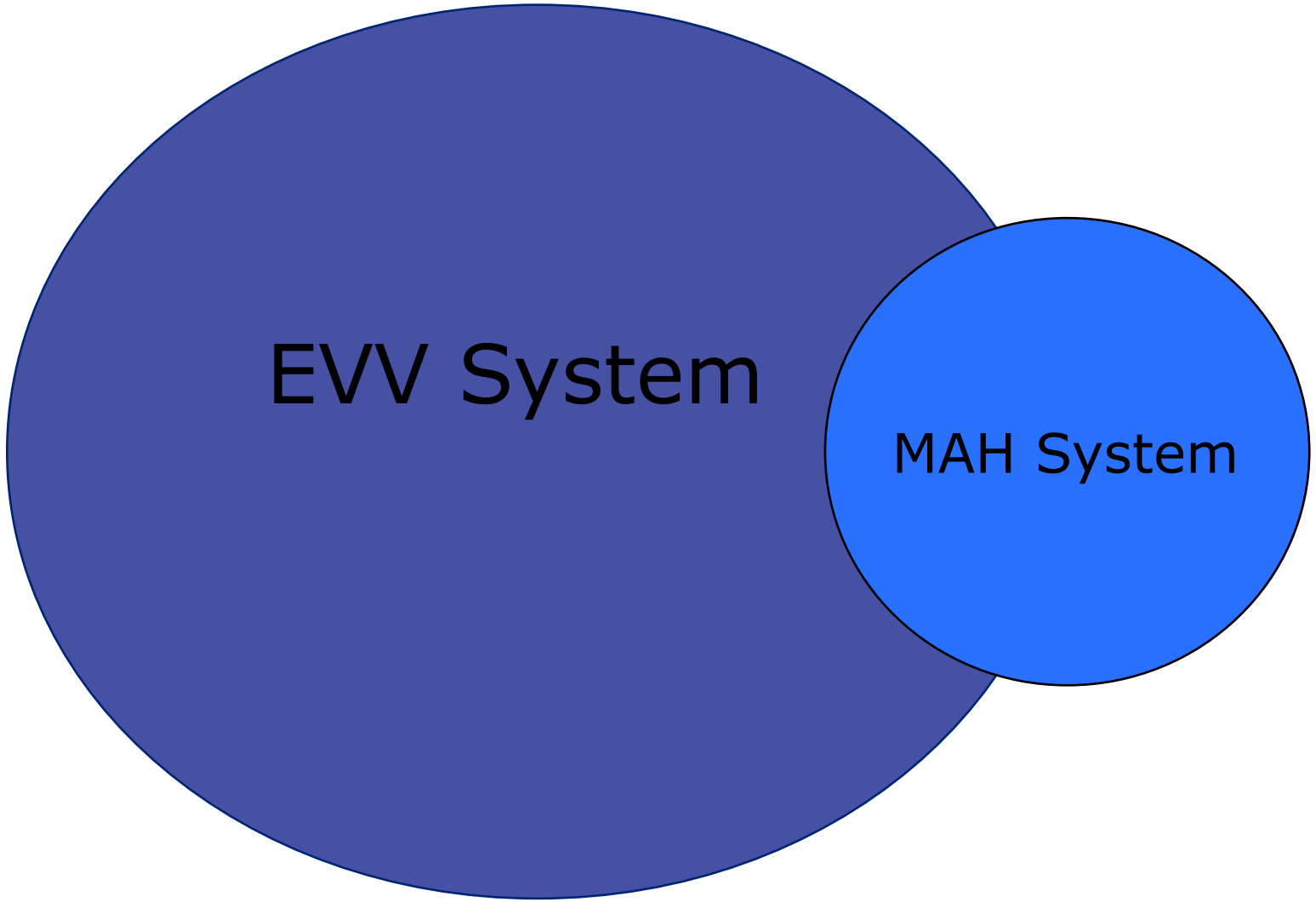
- **Adverse Event collection and recording**
  - 10 November 2021
  - 13 January 2022
- **Continuous Adverse Event analysis by MAH (signal management)**
  - 23 and 24 November 2021 (signal analysis)
  - 18 and 19 January 2022 (yearly statements and signal submission)
- **Pharmacovigilance Inspections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

Essential DATA systems



Union Product database	• QPPV • PSMF reference
Union Pharmacovigilance database	• AE reports • Data Warehouse
Signal Management reporting module	• Signals • Annual statements • Alerts

Signal Management – Signal analysis



Picture by Randy Fath on Unsplash

Key messages

- 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)

Picture by Matt Seymour on Unsplash