EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Pharmacovigilance

- Latest development

2013 European Medicines Agency/IFAH-Europe Info Day

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Prerequisite, *essential, precondition*

- Adverse Event Reporting
- VeDDRA list
- Causality Assessment
- EVVet
- Signal Detection
- PSUR
- Communication

Prerequisite, *essential, precondition*

- VeDDRA list

  Annual review

  Potential training this year, focus grp

- Recommendation on harmonising the approach to causality assessment for adverse reactions to veterinary medicinal products (EMEA/CVMP/552/2003-Rev.1)

  Volume 9B consistency, Annex with OLU, LEE

  3 month public consultation

Prerequisite

- EudraVigilance Veterinary

EVVEt 2 running,

EVVet 3 project put on hold (6 out of 13(+2 contingency) construction iterations finished) for reasons of budget reallocation and overall Agency review of all projects,

Emphasis and priority to development of EU veterinary product database development on which EVVET3 is depending for automisation, access and overall surveillance capabilities.

Prerequisite

- Recommendation for the basic surveillance of Eudravigilance Veterinary data

  Since 2011

- Recommendation on pharmacovigilance surveillance and signal detection of veterinary medicinal products

  in progress, surveillance interval algorithm under evaluation

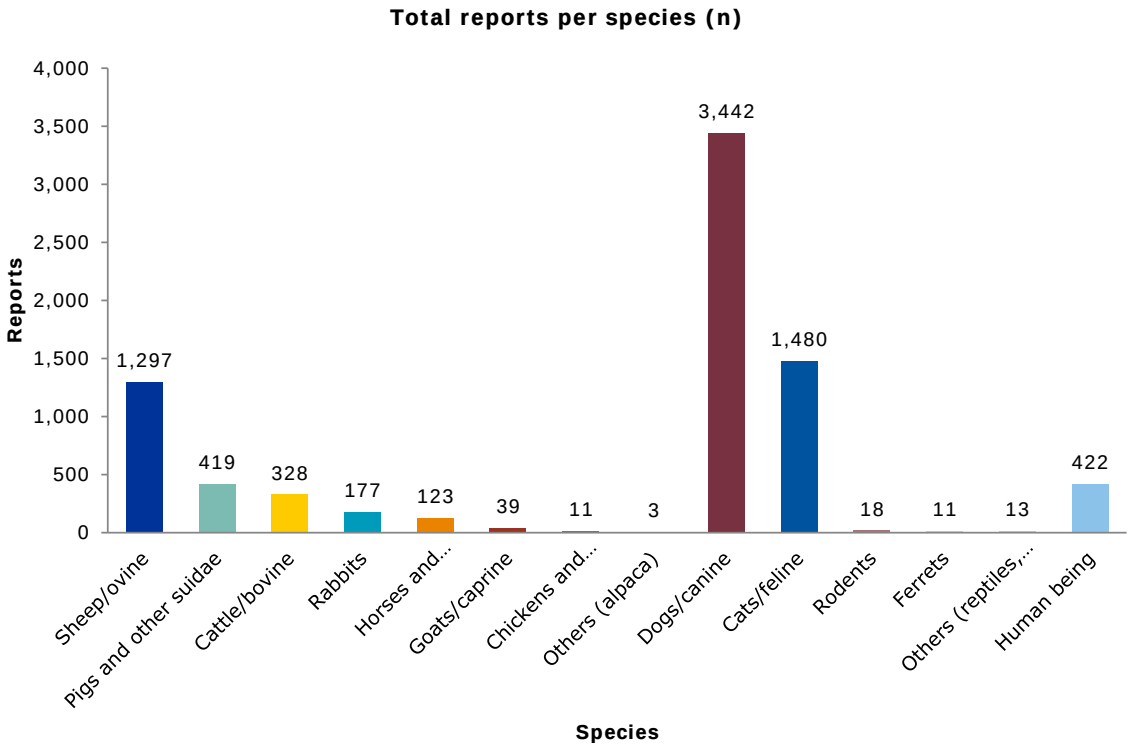
  Potential training this year, focus grp

Veterinary pharmacovigilance 2012 Public Bulletin

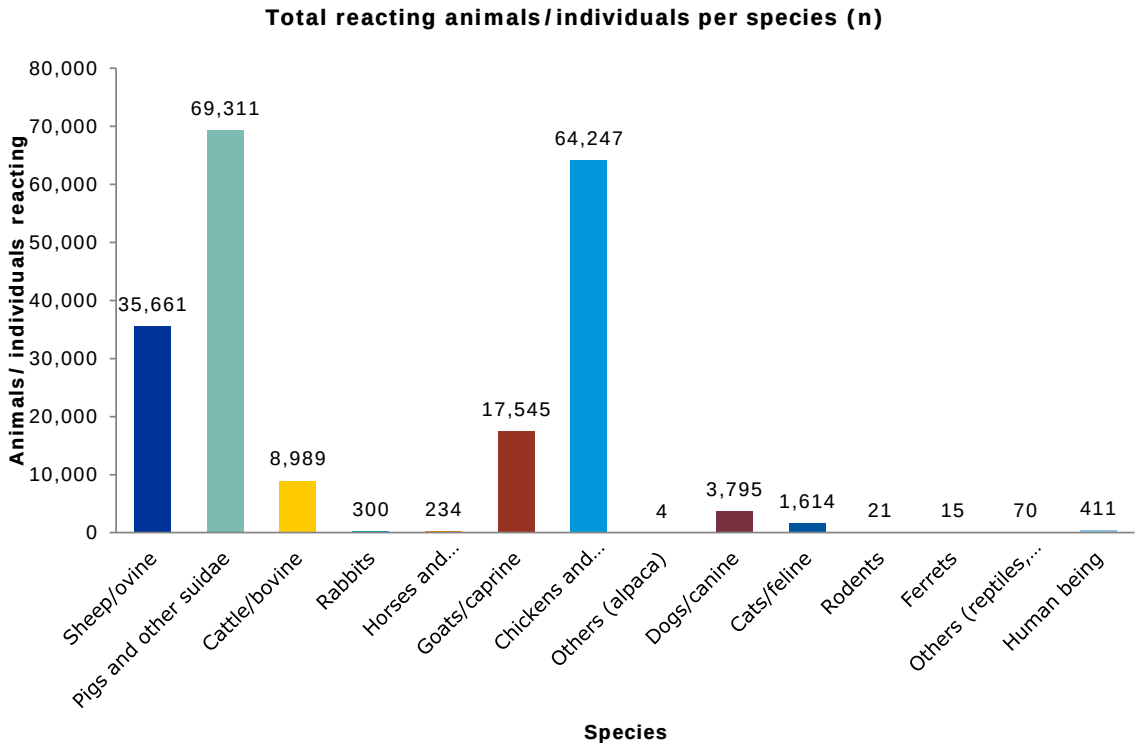
A total of 7,783 reports relating to exposure to centrally authorised veterinary medicinal products were received in 2012, concerning 7,361 adverse events in animals and 422 adverse events in humans.

Electronic reporting became mandatory in November 2005, and EVVet now contains more than 90,000 reports of adverse events, approximately 59,000 of which occurred within the EU and 31,000 outside the EU.

Public Bulletin 2012



Public Bulletin 2012



EVVet

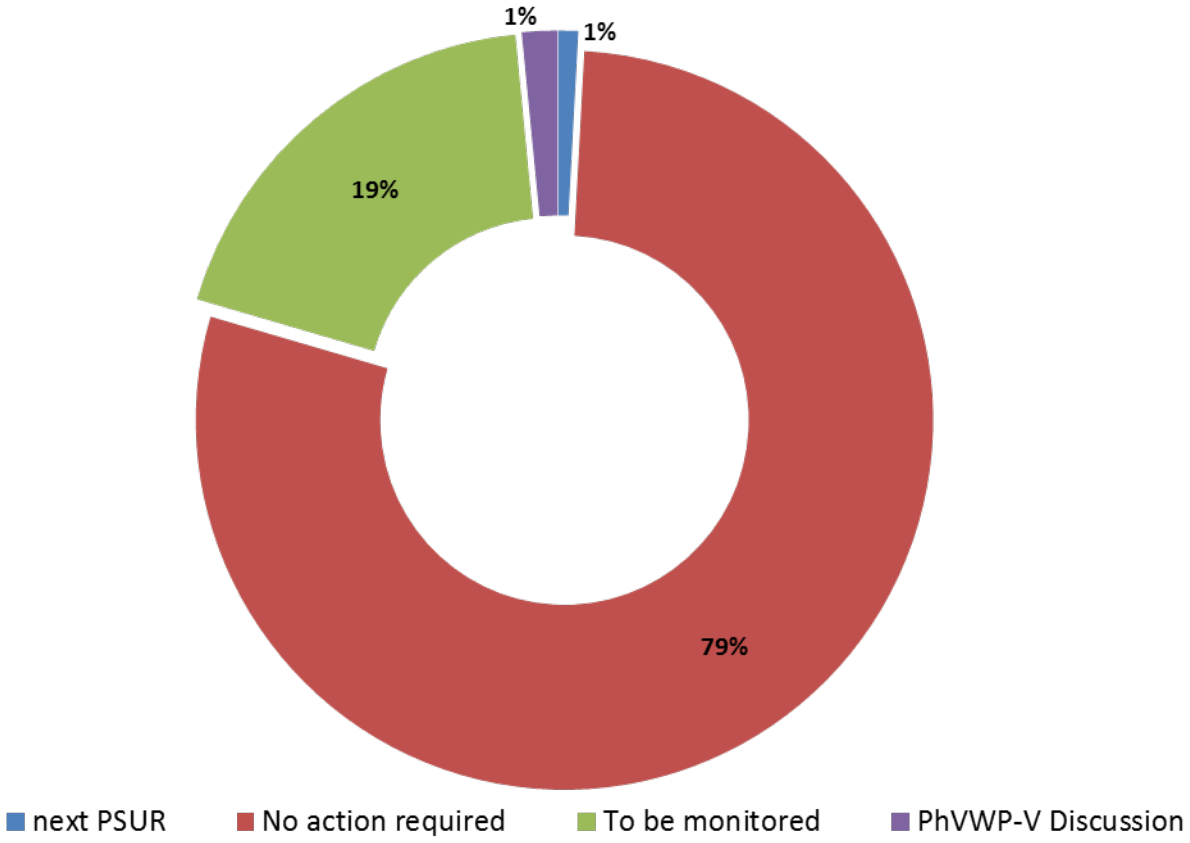
- Surveillance of CAPs

  System/structure for analysis and documentation

  Discussion of findings each WP meeting

  To CVMP for endorsement

Surveillance of CAPs - 580 analysis for 132 products



EVVet

- Potential surveillance of NAPs

  Serious and Non-serious event

- Support for PSUR assessment

  Pilot using EVVet to analysis all event for CAPs

Added Value

- Reflection paper on pharmacovigilance communication concerning veterinary medicinal products

  3 month public consultation

Question and answer document on serious non-fatal adverse events and reporting rules

In progress

Development of question and answer document(s) based on PhVWP-V interested parties meeting on implementation of Volume 9B

In progress

It is all about benefit/risk, precautionary measures and user safety.