EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

High level overview of pharmacovigilance in the EU for veterinary medicinal products

Focus group on promotion of pharmacovigilance for food producing animals

Presented by Jos Olaerts on 23 November 2016

An agency of the European Union

Pharmacovigilance

Adverse reactions (including off label adverse events)

Lack of efficacy

Human reactions

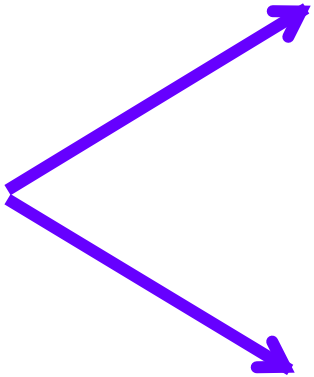
Residue violations

Environmental issues

Unintended transmission of infectious agent

Expedited reporting

AER (suspected adverse event report)



Periodic reporting

PSUR (periodic safety update report)

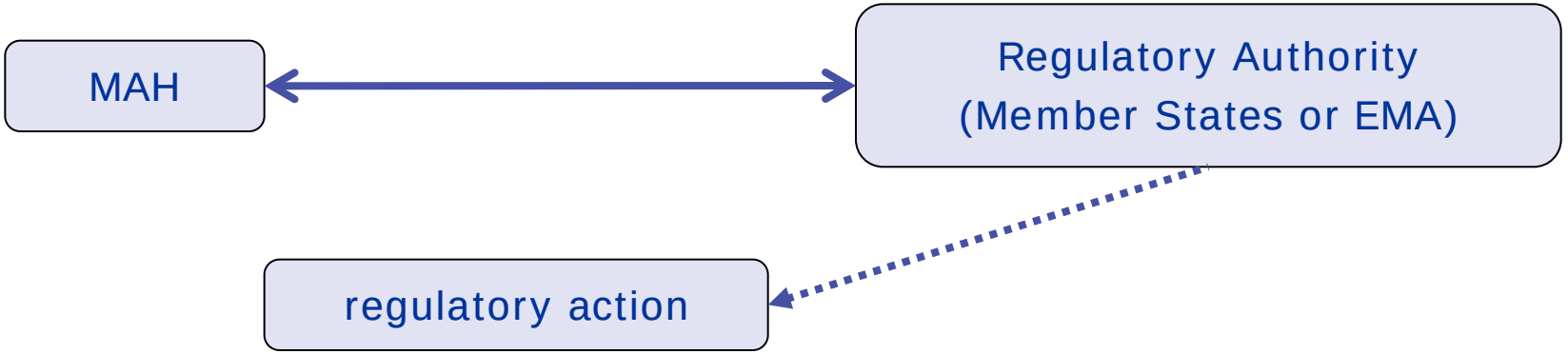
Periodic Safety Update Reports by MAHs

REPORT

covering a specific period

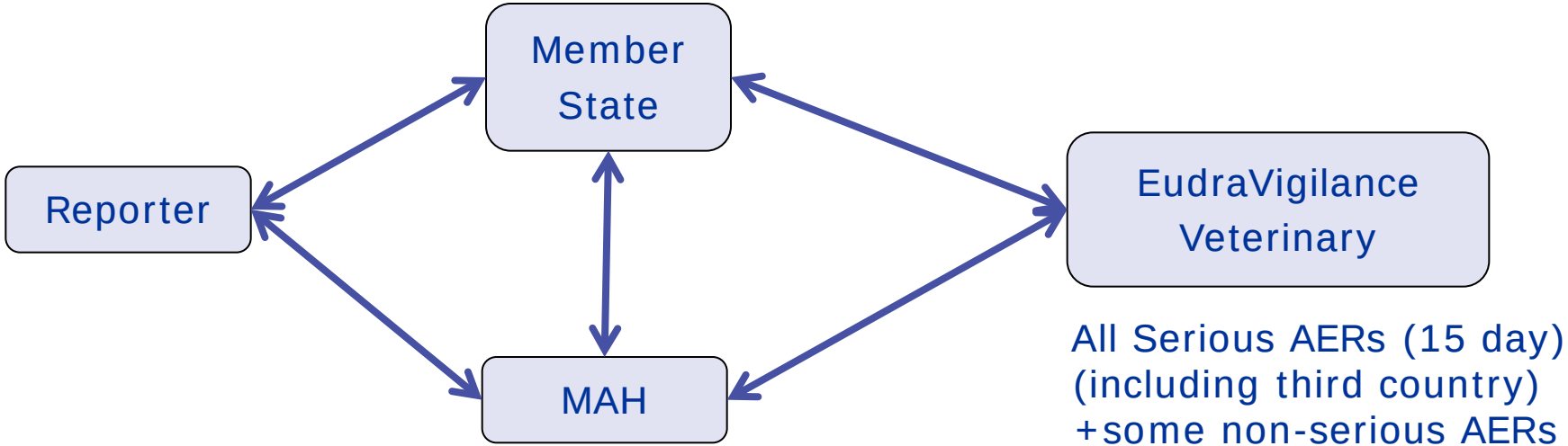
- 6-6-6-6 months following launch then yearly for 2 years then every 3 years
- Contains all AERs during that period (serious and non-serious)
- Sales and incidence estimation
- Overall safety information (including literature)
- Benefit – Risk conclusion

Assessing PSURs



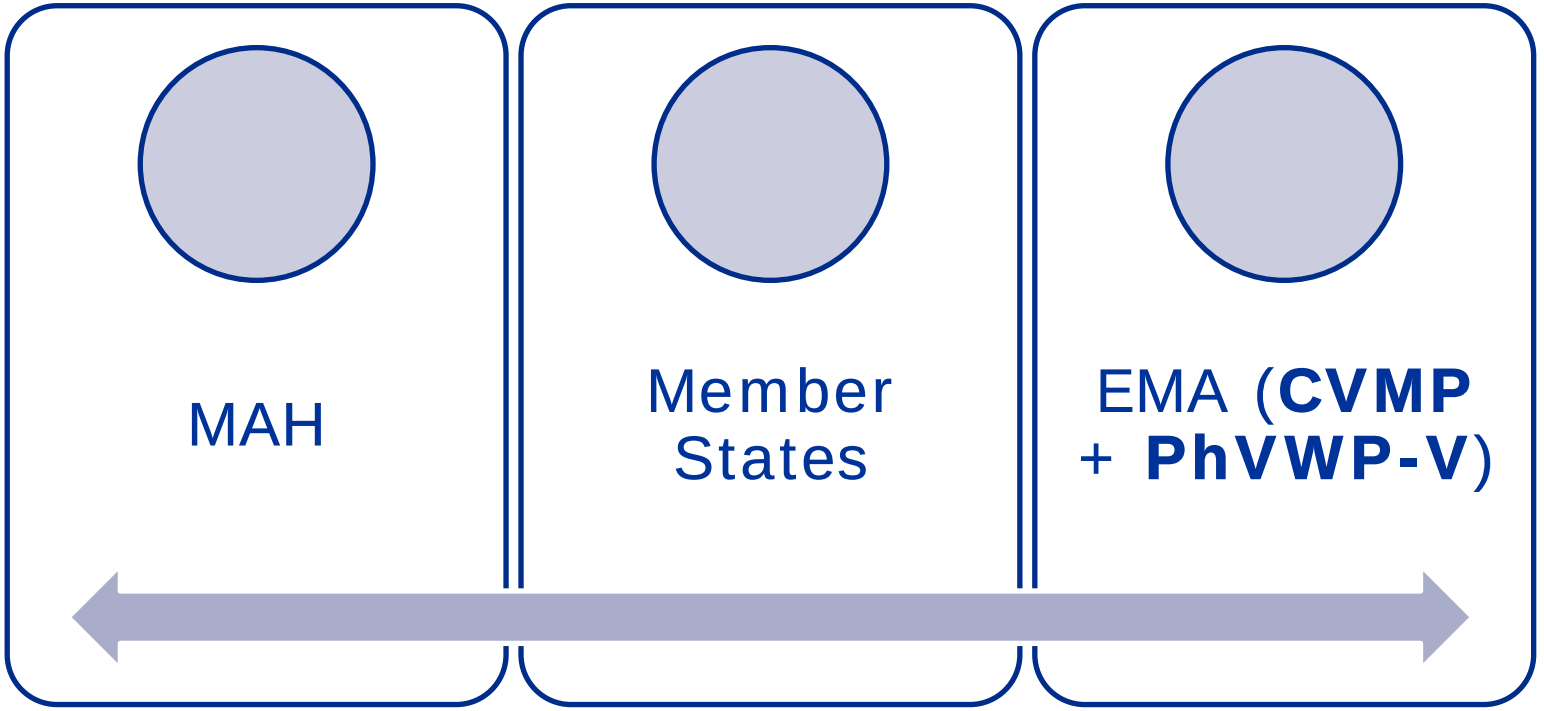
- Product literature changes (variation)
- PASS study
- Suspension

Reporting (day to day)



All Serious AERs (15 day)
(including third country)
+some non-serious AERs

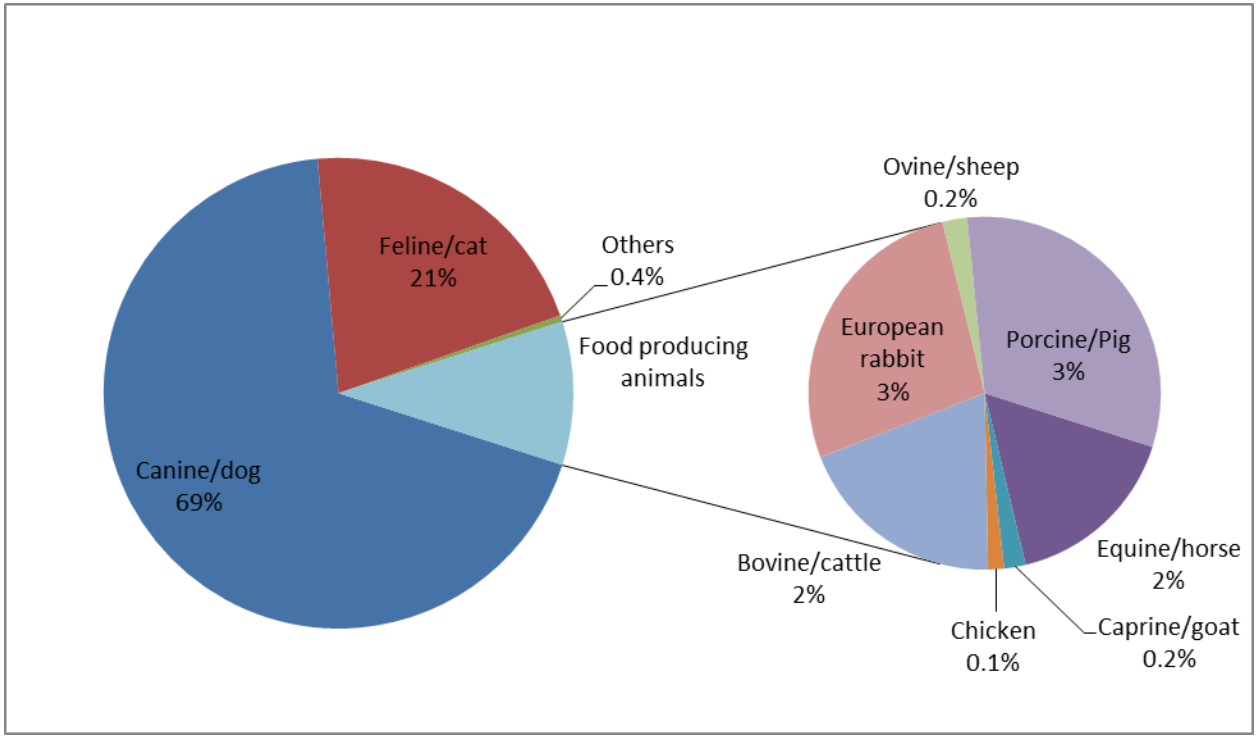
Responsibilities of monitoring.



Signal Management - how to get added value from EVVET?

- Allows analysis of data across the EU
- Allows analysis of all lifecycle data
- Allows relative product/substance comparison
- Only available for centrally authorised products

% of adverse event reports by species for reports received during 2015 related to the use of centrally authorised products



Thank you for your attention

Further information

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