EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Collaborate with stakeholders to modernise veterinary pharmacoepidemiology and pharmacovigilance

Underlying actions

EMA's Regulatory Science Strategy to 2025 – Veterinary Stakeholder Workshop

Presented by Frank Verheijen, MEB / Gabriel Beechinor, CVMP on 6 December 2019
Supported by Barbara Freischem, EMA

Disclaimer

Comments to the underlying actions represent the views of stakeholders and not the European Medicines Agency.

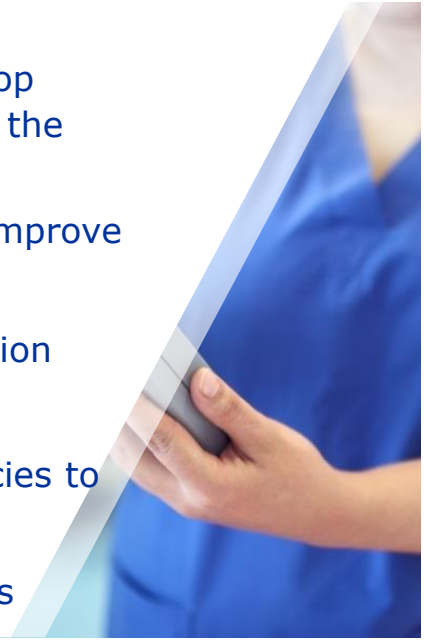
The fact that these comments from stakeholders are displayed in the presentation does not mean we endorse them or commit to fulfil them in any way.

Collaborate with stakeholders to modernise veterinary pharmacoepidemiology and pharmacovigilance

- High level concerns/recommendations from stakeholders
- Original underlying actions with comments received
- Actions identified by the EMA secretariat for further discussion

Collaborate with stakeholders to modernise veterinary pharmacoepidemiology and pharmacovigilance

- Motivate increased international and stakeholder involvement in pharmacovigilance
- Using data on the sales of veterinary products made available, develop methodology to collate, analyse and communicate information about the incidence of adverse reactions related to medicines' use
- Develop methodology to analyse the results of signal detection and improve communication of veterinary pharmacovigilance to the general public
- Develop new and improved continuous surveillance and signal detection methodology using the network's pharmacovigilance database
- Establish stakeholder expert groups for different food-producing species to access actual-use data of products in the field, both off and on label
- Facilitate development of methodology using new technology, such as mobile phone apps, to increase reporting rates of adverse events.



High level concerns/recommendations (1)

- Pharmacovigilance is over-regulated and should return to simple in-house evaluations by industry and legal obligation to inform the regulatory authorities, as in the 90s.
- We need systems and operations in place to minimise the administrative burden.
- Better systems to assure the public about the safety of veterinary medicines.
- The establishment of expert groups to access actual-use data is welcomed and is a good recommendation.

High level concerns/recommendations (2)

- Priority on simplified reporting tools into the PhV Dbase and then as second step focus on new technologies for reporting , e.g. mobile phone
- What is pharmacoepidemiology in veterinary medicine?
- The institution of a pharmacovigilance network and robust system will provide better tools to constantly monitor the benefits and risks of veterinary medicines, a clear allocation of roles and responsibilities and transparency. This will strengthen the benefit risk management of medicines on the European market.

Key high level concerns/recommendations - discussion

- Pharmacovigilance is over-regulated and should return to simple in-house evaluations by industry and legal obligation to inform the regulatory authorities, as in the 90s.
- What is pharmacoepidemiology in veterinary medicine?

Develop new and improved continuous surveillance and signal detection methodology using the network's pharmacovigilance database

- We need systems and operations in place to minimise the administrative burden.
- Better systems to assure the public about the safety of veterinary medicines.
- The institution of a pharmacovigilance network and robust system will provide better tools to constantly monitor the benefits and risks of veterinary medicines, a clear allocation of roles and responsibilities and transparency. This will strengthen the benefit risk management of medicines on the European market.
- Priority on simplified reporting tools into the pharmacovigilance database and then as second step focus on new technologies for reporting , e.g. mobile phone.

Establish stakeholder expert groups for different food-producing species to access actual-use data of products in the field, both off and on label

- The establishment of expert groups to access actual-use data is welcomed and is a good recommendation.

Develop methodology to analyse the results of signal detection and improve communication of veterinary pharmacovigilance to the general public

- Better systems to assure the public about the safety of veterinary medicines.

Motivate increased international and stakeholder involvement in pharmacovigilance

Using data on the sales of veterinary products made available, develop methodology to collate, analyse and communicate information about the incidence of adverse reactions related to medicines' use

No comment received

Facilitate development of methodology using new technology, such as mobile phone apps, to increase reporting rates of adverse events

No comment received

Any questions?

Further information

RegulatoryScience2025@ema.europa.eu

Temporary visiting address Spark building • Orlyplein 24 • 1043 DP Amsterdam • The Netherlands
For deliveries refer to www.ema.europa.eu/how-to-find-us
Send us a question via www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

Follow us on **@EMA_News**

#RegScience2025