Pharmacovigilance 2021- input from the veterinary profession

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EMA/FVE Webinar on Pharmacovigilance

FVE | Federation of Veterinarians of Europe

EU Regulation 2019/6 – pharmacovigilance

7.1.2019 EN Official Journal of the European Union L 4/43

REGULATION (EU) 2019/6 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 11 December 2018

on veterinary medicinal products and repealing Directive 2001/82/EC

(Text with EEA relevance)

EU Regulation 2019/6 – pharmacovigilance

Recitals:

„No. 55: Pharmacovigilance rules are necessary for the protection of public and animal health and of the environment. Collection of information on **suspected adverse events** should contribute to the good usage of veterinary medicinal products.“

“No. 58: In the light of experience, it has become clear that it is necessary **to take measures to improve** the operation of the pharmacovigilance system […]”

Chapter 4 Section 5 Pharmacovigilance

Article 73 - Union pharmacovigilance system

…

Article 81 - Signal management process

Stakeholders adressed in the articles:

- Marketing authorisation holder
- Agency
- Member states
- Commission
- Competent authorities
- General public

- And yes – vets!

Article 79 (2)

"Competent authorities may impose specific requirements on veterinarians and other healthcare professionals in respect of the reporting of suspected adverse events. The Agency may **organise meetings or a network for groups of veterinarians** or other healthcare professionals, where there is a **specific need for collecting**, collating or analysing **specific pharmacovigilance data**."

Signal detection, the cornerstone of the future pharmacovigilance system, can only work properly if the sensors (= **the veterinarians**) are well integrated into the system

Adverse event reporting – the current situation

- 98 % of all reports on adverse events are reported by vets either directly to the competent authority or via the marketing authorisation holder

- Other stakeholders like animal owners or pharmacists report < 2 % of all cases

Any effort to improve the quality of the data available for the pharmacovigilance system needs to **focus** on the **veterinarian**

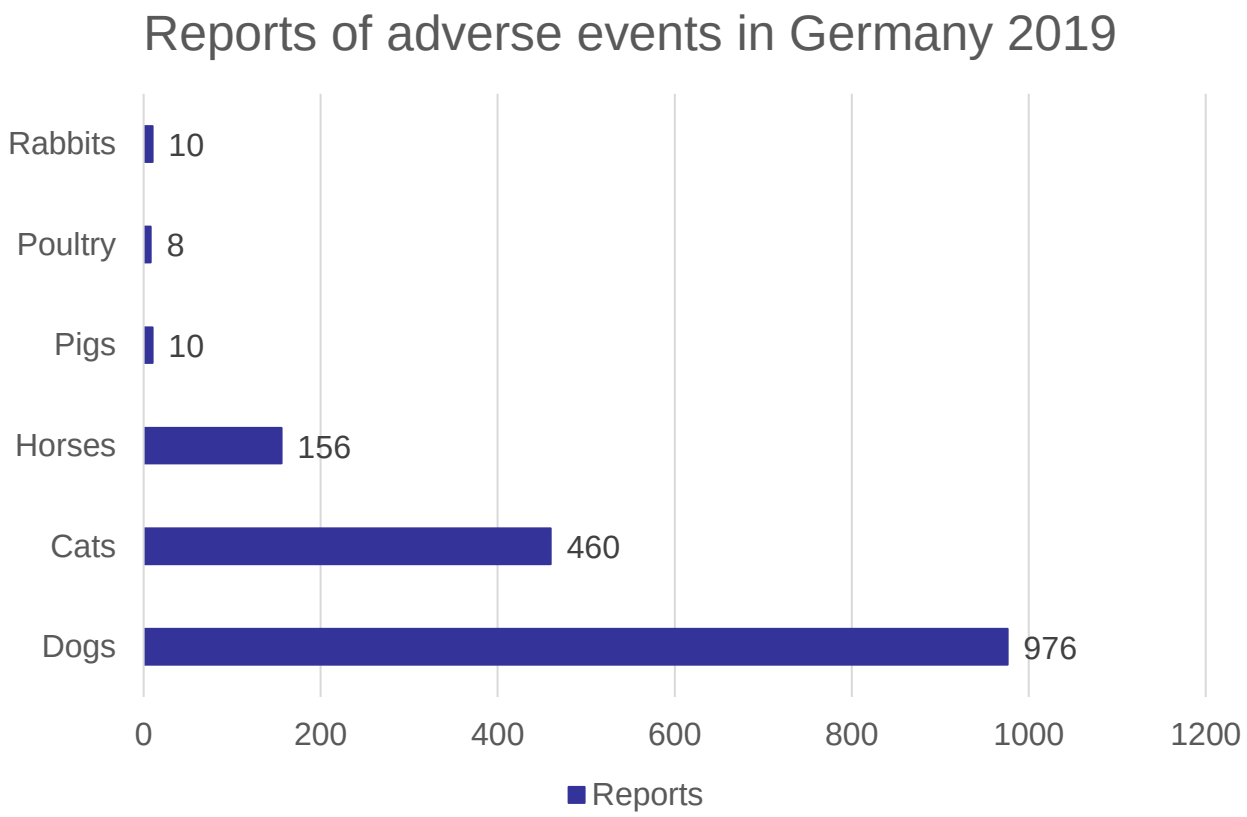
Adverse event reporting – the current situation

- Underreporting of adverse events:
  - Almost all practitioners (95 %) have experienced side effects of drugs in their own practice
    - Only ≈ 40 % of vets have made a report in the past year / ever
    - 1 in 2 vets have not reported adverse events in the past year /ever
  - Large differences in reporting behaviour between different member states
    - Between 10 % - 60 % of vets reported adverse event in the past year in the different member states

De Briyne N, Gopal R, Diesel G, et al. Veterinary pharmacovigilance in Europe: a survey of veterinary practitioners. Veterinary Record Open 2017;4:e000224. doi:10.1136/vetreco-2017-000224
Sander S, Böhme B, McDaniel C. Wie können wir das Mleden von UAWs erleichter – BVL Umfrage auf dem Leipziger Tierärztekongress. Dtsch Tierärztebl. 2020 (12) 1113

Adverse event reporting – the current situation

- Large differences in reporting in different species



Adverse event reporting – the current situation

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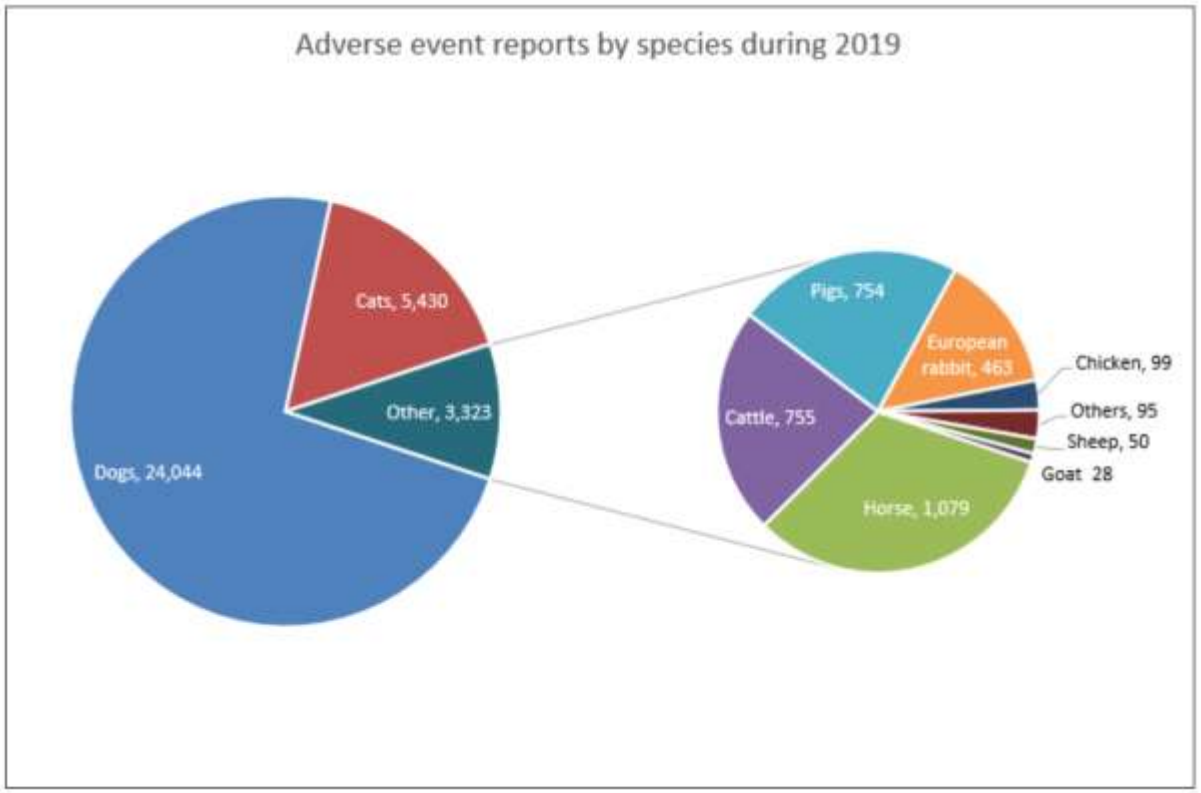


From: EMA Veterinary pharmacovigilance 2019 annual bulletin

Adverse event reporting – the current situation

- Large differences in reporting in different species:
  - Reporting in small animal medicine relatively better
  - Reporting in farm animals almost non existent
- Differences in reporting by type of adverse event
  - Lack of efficacy often not regarded as adverse event
  - Adverse events occurring during off label use often not reported
  - Suspected adverse events where causality is not obvious are often underreported

Adverse event reporting – how to improve the situation ?

- First - **ask the vets**:
  - What stops you from reporting adverse events ?
  - What would increase your willingness to report adverse events ?

<u>A good place to start:</u>

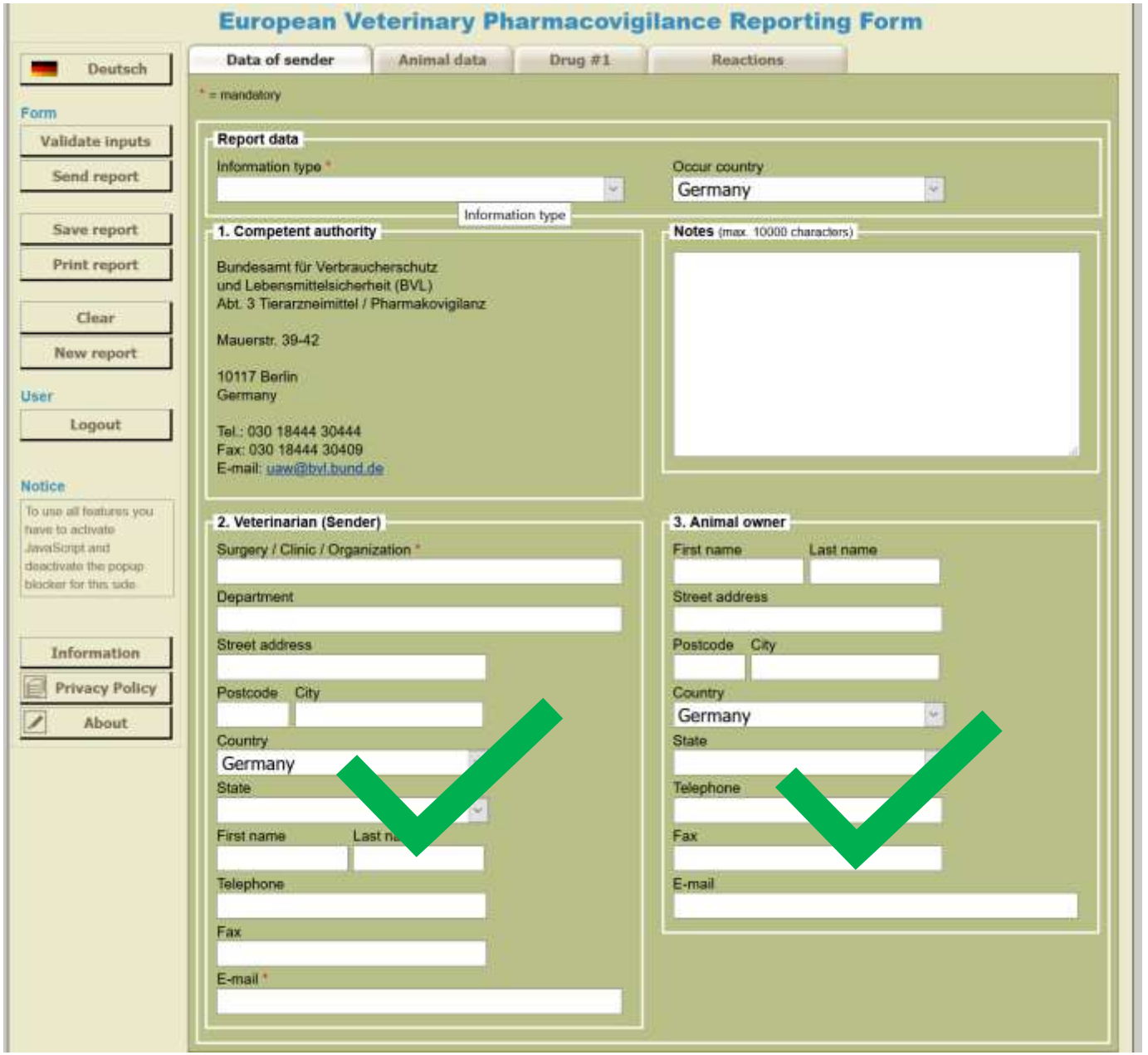
De Briyne N, Gopal R, Diesel G, et al.
Veterinary pharmacovigilance in Europe: a survey of veterinary practitioners. Veterinary Record Open 2017;4:e000224. doi:10.1136/vetreco-2017-000224

What stops you from reporting adverse events?

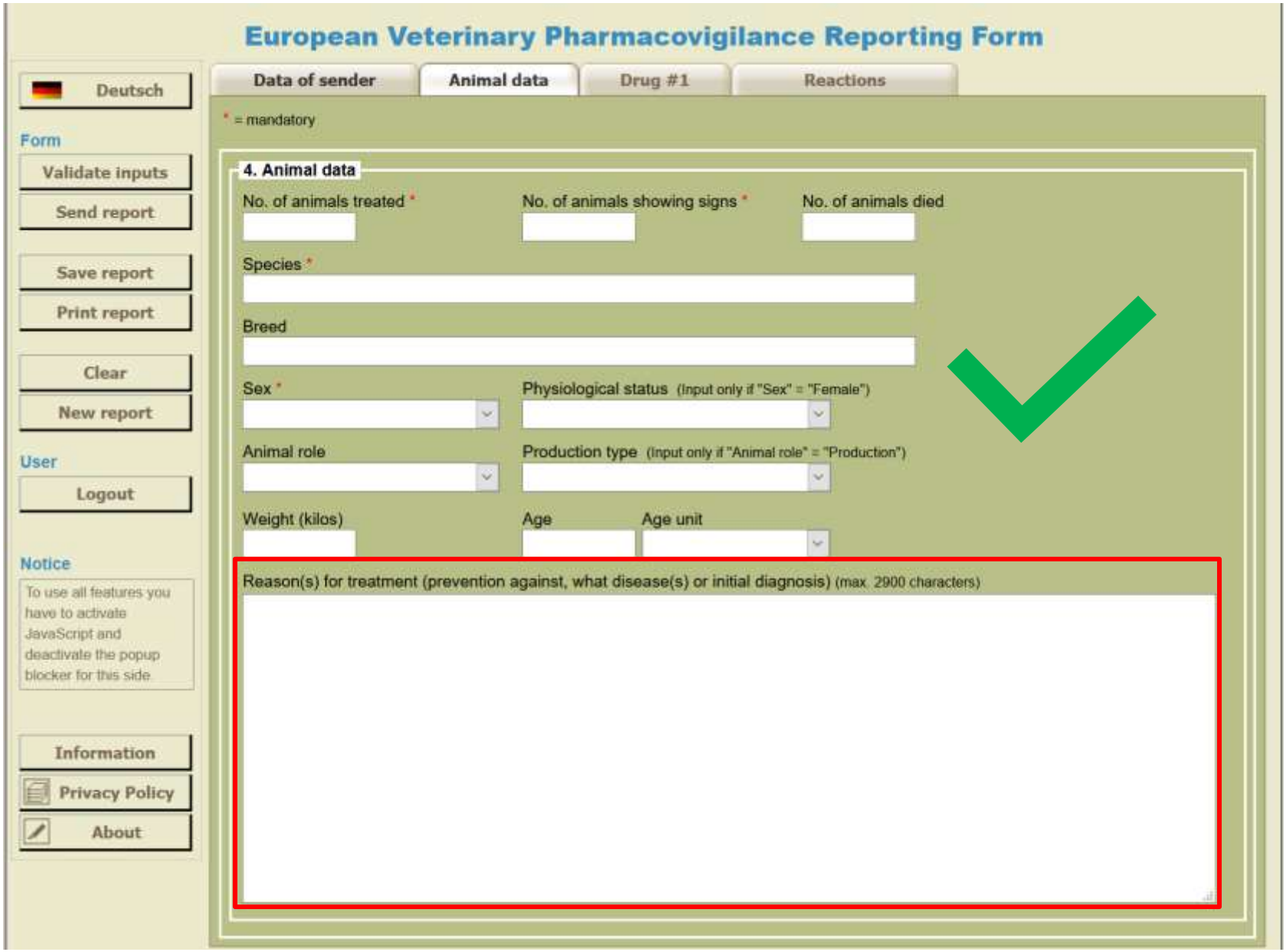
- Reporting is time consuming
  - 50 % of the reports take > 30 minutes
  - 24 % of the reports take > 1 h
  - Vets do not receive remuneration for this effort
- How to reduce the time needed for reporting – Ideas:
  - Make reporting as easy as possible
    - Allow user accounts on the website of CAs → No need to re-enter data about the reporting vet
  - Make websites nice, intuitive and quick
    - Example: Opening the German CA website for reporting takes about 25 sec before one can enter the first letter
  - Offer a working mobile version / App esp. for more reporting in farm animals
  - Offer support on the website (phone and/or chat) if users run into problems

What stops you from reporting adverse events?

- How to reduce the time needed for reporting – Ideas:
  - Make APIs (application programming interface) available for the software manufacturers of practice management software
  - Integration of adverse event reporting in this software would allow:
    - Automatic completion of
      - data about the reporter
      - data about the animal (species, age etc.)
      - data about the drugs used
      - data about pre-existing conditions etc.
    - Documentation of adverse events / notices about safety issues could prompt a “do you want to report an adverse event” notification
  - Result would be easier, faster and more accurate way to report
  - Public funding of a pilot project could be beneficial



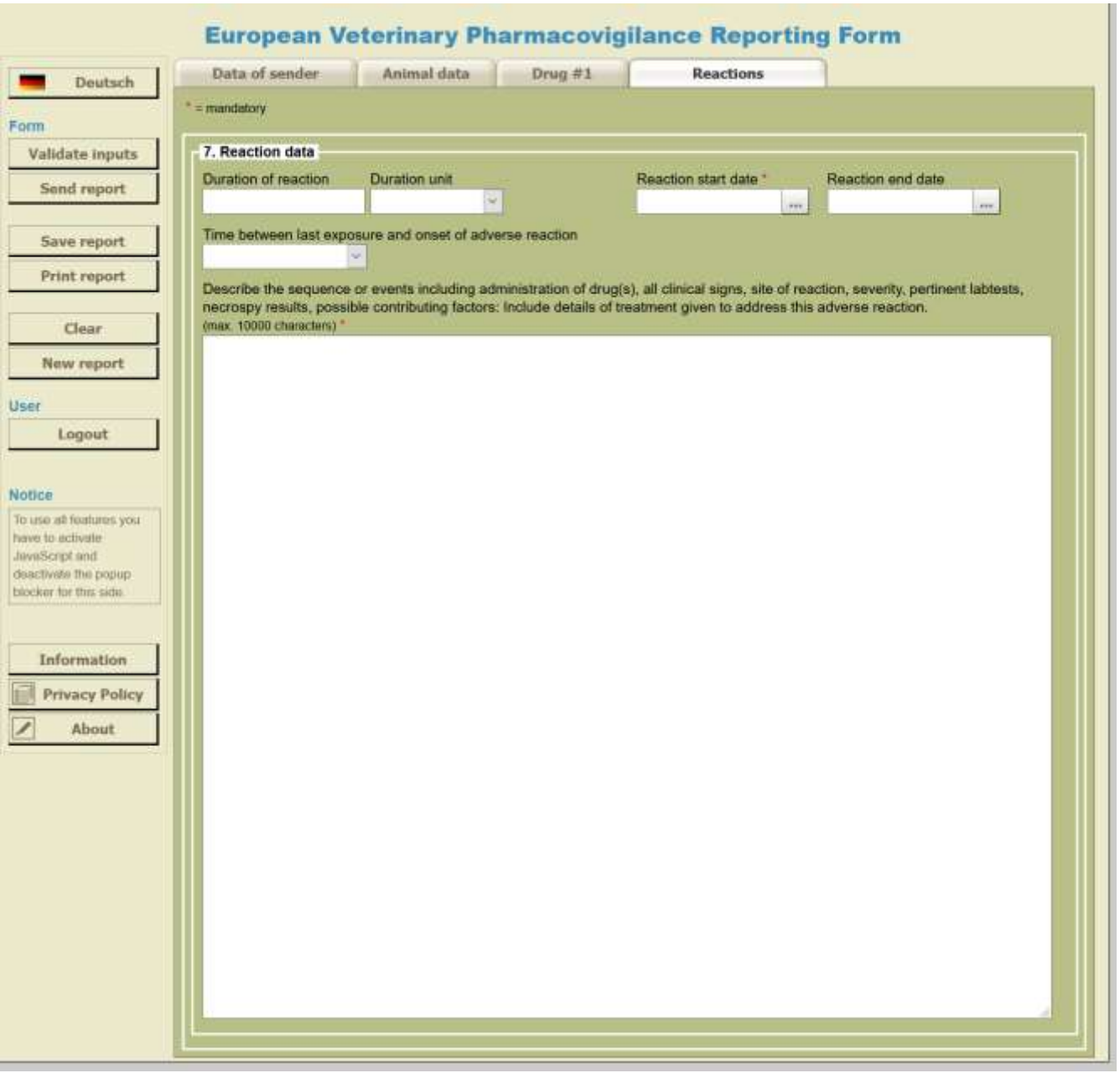
vet-uaw.de – Official german adverse event reporting website



vet-uaw.de – Official German adverse event reporting website

Data about the drugs could come from practice management software and/or from the future Union product database (UPD)

vet-uaw.de – Official German adverse event reporting website



- 2/3 of data field could be autocompleted from the practice management software
- Vet could focus on the description of the actual event
- Time needed for the report would be reduced significantly

vet-uaw.de – Official German adverse event reporting website

What stops you from reporting adverse events?

- Lack of feedback:
  - 75 % of vets are unhappy about the feedback
  - 50 % of vets never received any feedback after making a report

- How to improve the feedback – Ideas:
  - Give immediate feedback that the report was received and will be reviewed
  - Thank the vets for their effort in the feedback
  - Inform vets about the outcome of the assessment of the report
  - Inform vets about the impact their report made on the SPC or other issues if vets opt in to receive this information
    - Knowing the reporting leads to real actions e.g. changes to the SPC will be motivating
  - Summary publications like the annual pharmacovigilance bulletin can only be an add-on for individual feedback

http://www.adrreports.eu/vet

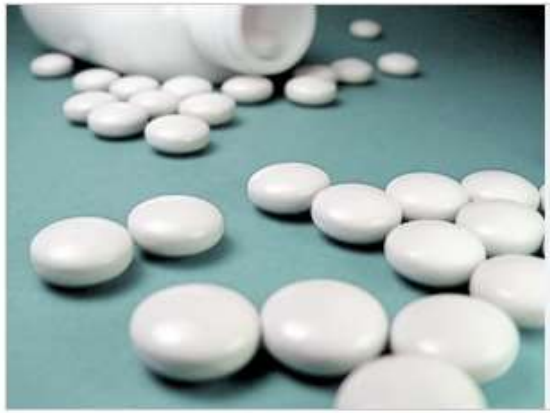
EudraVigilance - European database of suspected adverse drug reaction reports

Contacts | Glossary

English (en)

Home | Understanding reports | Search | Switch to Human

Online access to suspected side-effect reports



This website was launched by the European Medicines Agency in 2012 to provide public access to reports of suspected side effects (also known as suspected adverse drug reactions) observed following administration of human medicines.

In 2019 the website was extended to provide corresponding information on suspected adverse events following administration of veterinary medicines as well.

Search for a report

Search here for suspected adverse drug reaction reports

- Good start, but should become more useful for the practitioner
- The question „What do vets expect from a database“ should be considered
- Hard to find starting at ema.europa.eu → Why not make a section for health care professionals (vets and human doctors alike ?)

What stops you from reporting adverse events?

- 60 % of vets do not report possible adverse events because they are unsure if an event was actually caused by a drug

- What to do about this – Ideas:

  - Improve post gradual education on adverse events
    - Why not make an adverse event report mandatory in Colleges or other types of post gradual education (Fachtierarzt etc.)

  - Topic could and should be included in the curriculum

  - Offer workshops and courses for continued education where vets can earn continued education points (CEP)

Thank you for your attention!