EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Veterinary Medicines Division

Procedural note for interim measures regarding notification of pharmacovigilance alerts by marketing authorisation holders under Regulation (EU) 2019/6

One of the functions of the Union pharmacovigilance database is to establish a data-processing network for data transmission between Member States, the Commission, the Agency and the marketing authorisation holders (MAHs) to ensure that in the event of an alert related to pharmacovigilance data[1], options for risk management and any appropriate measures[2] can be considered[3]. In relation to this, a new requirement has been established[4] for MAHs to use the data-processing network of the Union pharmacovigilance database for communication of alerts related to pharmacovigilance data.

The Union pharmacovigilance database module for communication of pharmacovigilance alerts will not however be fully functional when Regulation (EU) 2019/6 comes into force on 28 January 2022. Until this module is available, a list of contact points (see Annex to this document: EMA/586463/2021) has been established for use by MAHs for communication of pharmacovigilance alerts to competent authorities responsible for authorising the veterinary medicinal product (VMP) and the Agency, in the case of centrally authorised products (CAPs). This list will be maintained by the Agency and updated as necessary until the Union pharmacovigilance database is fully functional in this respect. This list of contact points may also be used by MAHs to notify competent authorities or the Agency and Commission of other important pharmacovigilance-related issues to enable streamlined and efficient communication and surveillance e.g. the intention to make public announcement on pharmacovigilance[5]; communication of regulatory measure taken in a third country related to pharmacovigilance data[6].

To facilitate consideration of the pharmacovigilance alert or other issue communicated to the competent authorities or the Agency, it is recommended that the following information is provided, as applicable:

1) reason for the communication/notification of issue, including the legal or procedural basis;

2) VMP(s) concerned, including the active substance:

[1] Pharmacovigilance alerts: potential concerns, including emerging safety issues arising from pharmacovigilance data or other information impacting animal or public health or the environment that may require urgent consideration by the competent authority responsible for the veterinary medicinal product(s).
[2] As referred to in Articles 129, 130 and 134 of Regulation (EU) 2019/6
[3] Regulation (EU) 2019/6, Article 74(5)
[4] Commission Implementing Regulation (EU) 2021/1281 Article 20(3)
[5] Regulation (EU) 2091/6, Article 77(11)
[6] Regulation (EU) 2019/6, Article 78(1)(k)

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a) authorisation route e.g. CAP; mutual recognition procedure (MRP); decentralised procedure (DCP); purely nationally authorised procedure (NAP)

b) authorisation number or procedural number for MRP/DCP products; and

c) for biological medicinal products, product batch details;

d) whether regulatory or other action has been taken, specifying the type of action, and the location concerned e.g. the names of the Member State(s) or third countries;

3) whether the issue is considered to impact on animal or public health or the environment;

4) any other relevant information, including background documents, relevant publications etc.

For any further information or queries concerning this matter, please contact: VetPhV@ema.europa.eu.