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Answer given by Ms Kyriakides
on behalf of the European Commission
(12.5.2022)

The applicable rules on pharmacovigilance for veterinary medicinal products are set out in Articles 73 to 81 of Regulation (EU) 2019/6[1].

On 4 May 2020, the Commission, the European Medicines Agency and the Heads of Medicines Agencies published a joint "Notice to Stakeholders" entitled "Questions and answers on regulatory expectations for veterinary medicinal products during the Covid-19 pandemic". An updated version of this Notice to reflect the changes in the relevant provisions of Regulation (EU) 2019/6 compared to those in the former legislation can be found on the Commission's website[2]. Section 2 deals with pharmacovigilance issues and question 2.1 specifically addresses adverse event reporting. Marketing authorisation holders may prioritise their reporting obligations if they are unable to continue standard reporting obligations for justified reasons relating to the pandemic. It is important that marketing authorisation holders contact the competent authorities in these instances.

The Honourable Member expresses concern that decreased marketing authorisation holders' capacities to follow the timelines for adverse events reporting might influence the timely performance of pharmacovigilance activities ensuring the safe use of authorised products. The Commission, however, sees no need for additional activities to monitor possible delays in adverse events reporting to Union pharmacovigilance database, as the control mechanisms defined by Regulation (EU) 2019/6 and Commission Implementing Regulation (EU) 2021/1281[3] are considered sufficient.

[1] OJ L 4, 7.1.2019, p. 43.
[2] https://ec.europa.eu/food/document/download/95061c8d-dac4-4baf-a3f6-8b8d9afff465_en
[3] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32021R1281