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E-002247/2025

Answer given by Mr Várhelyi
on behalf of the European Commission
(20.8.2025)

1. The Commission notes that enforcement of Regulation (EU) 2019/6 on veterinary medicinal products¹ falls under the responsibility of the Member States' competent authorities.

2. It would also like to recall that the granting of a marketing authorisation for a veterinary medicinal product is primarily subject to the submission of an application and a supporting scientific dossier by a pharmaceutical company, in accordance with the requirements of Regulation (EU) 2019/6. Since there is no remdesivir or GS-441524 based veterinary medicine authorised in the EU, the use of the centralised authorisation procedure² would be mandatory.

¹ 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 OJ L 4, 7.1.2019, p. 43–167 ELI:
<http://data.europa.eu/eli/reg/2019/6/oj>.

² In accordance with article 42(2)(c) of Regulation (EU) 2019/6 on veterinary medicinal products; the centralised marketing authorisation procedure is mandatory to veterinary medicinal products containing an active substance which has not been authorised as a veterinary medicinal product within the Union at the date of the submission of the application.