

(English version)

**Question for written answer E-003898/25
to the Commission**

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(3 October 2025)

Subject: Approval of effective vaccines against lumpy skin disease without undermining agricultural exports

Lumpy skin disease (LSD) is a major health threat to French and European cattle herds, and vaccination is the main tool for prevention.

A number of farmers and professional organisations have highlighted the existence of vaccines developed outside the EU, such as India, which are considered more effective than those currently available in the EU. Unlike the vaccines used to date, they make it possible to distinguish vaccinated animals from infected animals and thus put paid to any risk of exports being blocked.

However, owing to approval and mutual recognition procedures, they are not available on the European market. As a result, French farmers are being deprived of a solution that is potentially more protective and better suited to maintaining their international competitiveness.

1. With a view to their swift approval in the EU, does the Commission intend to assess the safety and effectiveness of those vaccines?

2. What guarantees can it provide French farmers that the LSD vaccination strategy will not undermine their exports?

Supporters ⁽¹⁾

Submitted: 3.10.2025

Answer given by Mr Várhelyi on behalf of the European Commission
(8 December 2025)

The EU vaccination plan against Lumpy Skin Disease (LSD) is regulated, in alignment with the World Organisation for Animal Health (WOAH) standards, by Regulation (EU) 2016/429 ⁽¹⁾ ('Animal Health Law') and Delegated Regulation (EU) 2023/361 ⁽²⁾.

A vaccination plan deemed compliant with these rules does not lead to undermining the trade in live animals or their products between the Member States, although there are some specific conditions for movements and derogations provided for in the above referred EU legislation which must be respected.

Under EU legislation, veterinary medicinal products including vaccines receive marketing authorisations further to applications submitted by pharmaceutical companies.

If a company submits an application for a marketing authorisation for a differentiating infected from vaccinated animals (DIVA) vaccine, the relevant Competent Authority will assess the vaccine's safety, efficacy, and quality.

The EU legal framework on Veterinary Medicinal Products — Regulation (EU) 2019/6 ⁽³⁾ — allows for accelerated assessments and marketing authorisations in exceptional circumstances related to animal or public health.

¹ This question is supported by Members other than the authors: Jean-Paul Garraud (PfE), Julien Leonardelli (PfE)

¹ OJ L 84, 31.3.2016, p. 1, ELI: <http://data.europa.eu/eli/reg/2016/429/oj>.

² Commission Delegated Regulation (EU) 2023/361 of 28 November 2022 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council as regards rules for the use of certain veterinary medicinal products for the purpose of prevention and control of certain listed diseases (OJ L 52, 20.2.2023, p. 1, ELI: http://data.europa.eu/eli/reg_del/2023/361/oj).

³ Regulation (EU) 2019/6 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>).