

Question for written answer E-003374/2026
to the Commission
Rule 144
Biljana Borzan (S&D)

Subject: Disclosure of the species of origin for animal-derived excipients in human medicines

Article 59 of Directive 2001/83/EC¹ requires the package leaflet to list excipients, while Article 54 requires certain excipients to be listed on the outer packaging. However, neither provision requires disclosure of the species from which the product is derived. Excipients such as gelatine, stearates or lactose may be animal- or plant-derived, but this is not specified.

In correspondence with a citizen (Ares(2025)10521900; Ares(2026)1090942), the Commission confirmed that EU law does not require disclosure of species origin, while acknowledging the importance of informed patient choice based on ethical, cultural or religious considerations.

This lack of transparency affects citizens who follow dietary restrictions related to animal products (e.g., halal, kosher, Hindu, vegetarian or vegan diets). Unlike food labelling rules, EU pharmaceutical legislation provides no mechanism to identify the origin of excipients, despite manufacturers already holding this information for quality and supply-chain purposes.

Other jurisdictions have taken steps in this direction: Switzerland requires disclosure for certain excipients, and the American Medical Association supports such transparency.

1. Does the Commission plan to amend Directive 2001/83/EC or introduce other measures to require disclosure of the species from which excipients originate?
2. Has it assessed integrating this information into digital product information or e-leaflets?
3. What costs does it foresee, given that this information is already available to manufacturers?

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¹ Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use (ELI: <http://data.europa.eu/eli/dir/2001/83/oj>).