



Brussels
SANTE.D.1/KS/pl(2026)652214

By email only



Subject: RE: Ethical Transparency and Labelling of Animal-Derived Ingredients in Medicines



Thank you for your thoughtful and detailed explanations and for raising the issue of transparency regarding the species origin of excipients in medicinal products. We appreciate your advocacy for clearer labelling to support patients in making informed decisions based on their ethical, cultural, or religious beliefs.

We acknowledge that Articles 54 and 59 of Directive 2001/83/EC do not necessitate the disclosure of the species origin of excipients, as the legislation is more focused on ensuring the safety, efficacy, and quality of medicinal products.

We recognise the importance of enabling patients to make informed choices in line with their ethical, cultural, or religious beliefs. We value your suggestions for regulatory improvements, including potential amendments to Directive 2001/83/EC, or the introduction of measures such as a centralised database or standardised symbols. In this context it is also essential to consider the possible resource implications on healthcare budgets and pharmaceutical companies, which might affect medicines and healthcare costs.

We will consider your points in discussions and studies related to improving transparency in medicinal labelling.

Thank you again for your engagement and for helping us identify ways to improve EU regulations to better serve citizens' needs.

Yours sincerely,

Electronically signed

Olga SOLOMON
Head of Unit