

Medicine Transparency



Know What's in Your Medicine.

**EU Law Amendment Proposal
to Mandate **Species-Origin** Disclosure
for Animal-Derived Excipients**

Dublin, Ireland
2026

What is the problem?

Tens of millions of EU citizens cannot verify whether their prescribed medicines align with their ethical, religious, or personal values.

Not only patients — even medical professionals are unable to confirm species origin.

Since manufacturers are not required to provide origin information even in professional product documentation (e.g. SmPCs), pharmacists and clinicians cannot reliably advise patients or identify suitable alternatives.



Unlike food or cosmetics, medicines are frequently non-substitutable, leaving these patients with no reliable means of making an informed choice at the point of prescription or dispensing.

Who is affected?

Every person who does not feel comfortable consuming animal-derived ingredients:

- **Vegans** and **vegetarians** object to **all animal**-derived substances on ethical grounds.
- Observant **Muslims** and **Jews** avoid **porcine**-derived ingredients.
- **Hindus** avoid **bovine**-derived ingredients.
- **Patients with lactose intolerance or sensitivities** to specific **animal proteins** face distinct medical constraints.

EU studies are lacking, but a 2022 study found that 74% of commonly prescribed medicines in the UK contained animal-derived components. Given shared pharmaceutical supply chains across the EU, a comparable pattern is likely reflected in every EU Member State.

What does the European Commission say?

The European Commission confirms that a **legislative gap exists** and acknowledges that the **issue affects millions of EU citizens**. In a formal response dated 29 January 2026, signed by Olga Solomon, Head of Unit, Directorate-General for Health and Food Safety, the Commission stated:

The Commission's own words confirm that current law does not mandate origin disclosure, that the ethical case is recognised, and that the proposed reforms are under active consideration.

“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.”



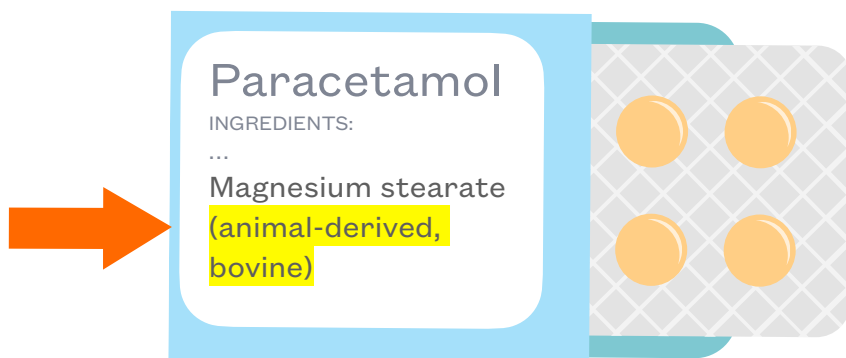
“We recognise the importance of enabling patients to make informed choices in line with their ethical, cultural, or religious beliefs.”

“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.”

Potential Solutions

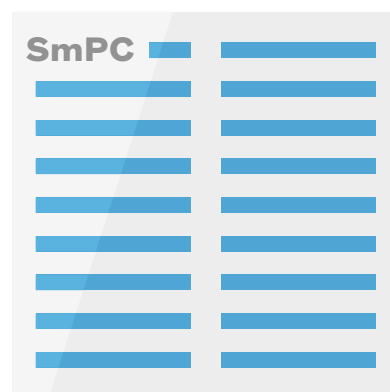
1. Simple labelling

Add species origin to already existing list of ingredients.
Little to no investment.



2. Extend description in SmPC

Add species origin to already existing list of ingredients.
Little to no investment.



3. Centralised EU Database

Adding species origin to already existing list of ingredients. Requires very little to no investment.



Evidence on Animal-Derived Excipients in Medicines

1. Widespread use of potentially animal-derived excipients

A UK clinical audit of the 100 most commonly prescribed medicines found that 74% contained at least one potentially animal-derived excipient such as lactose, gelatine, or magnesium stearate, and 20% contained gelatine. Prevalence can vary across jurisdictions, and no comparable EU-wide audit has been identified in the cited literature.

Tatham KC, Patel KP. Why can't all drugs be vegetarian? *BMJ*. 2014;348:g401

Lababidi H, Bobier C, Rodger D. Animal-derived ingredients in medicines a framework for ethical prescribing practices. *Front Pharmacol*. 2025;16:1693059

2. Species origin is not disclosed in EU-mandated information

The same audit reported that the presence or absence of animal-derived products was never disclosed, and that SmPCs, packaging and manufacturer information were inconsistent, incomplete or incorrect. Directive 2001/83/EC requires excipient information to be provided in the package leaflet and product information, but it does not require species origin, leaving patients and clinicians unable to determine whether gelatine or other excipients are bovine, porcine, fish-derived or plant-based.

Tatham KC, Patel KP. Why can't all drugs be vegetarian? *BMJ*. 2014;348:g401

Directive 2001/83/EC, Articles 54 and 59

3. Healthcare professionals cannot reliably identify origin in practice

Studies document major knowledge gaps consistent with the absence of routine, accessible excipient origin disclosure, including findings that about 70% of physicians were unaware that some medicines include ingredients derived from pork or beef, and that nearly 75% of urologists were not sure whether urological medicines contain gelatine. Related literature links these gaps to limited training and poor availability of ingredient-origin information in routine references. A recent study on lactose as an excipient shows the same pattern for clinically relevant excipient transparency, with 58% of surveyed healthcare professionals knowing lactose is present as an excipient in most drugs, and a review of 635 medicine leaflets finding that 50% contained lactose while only 25.35% of those specified the exact amount.

Sattar SP et al. Patient and physician attitudes to using medications with religiously forbidden ingredients. *Ann Pharmacother*. 2004;38(11):1830-1835

Warburton HE, Payne MS, Payne SR. The problems of gelatine and prescribing urologically specific medication to a diverse population in the UK an initial study. *Br J Med Surg Urol*. 2010;3(2):52-58

Hanna LA et al. Veganism are future pharmacists ready to provide advice? *Curr Pharm Teach Learn*. 2021;13(5):512-519

Lababidi H, Bobier C, Rodger D. Animal-derived ingredients in medicines a framework for ethical prescribing practices. *Front Pharmacol*. 2025;16:1693059

Almukainzi M et al. Using medications containing lactose as an excipient for lactose intolerance patients insights of clinical practices and regulators roles. *J Am Pharm Assoc*. 2025;65(6):102476

4. Ethical and informed-consent implications

Ethics literature argues that non-disclosure of animal-derived constituents can undermine patient autonomy and informed consent. It can also cause distress for patients with ethical or religious objections, especially where an objection is foreseeable and relevant to the patient's decision. Authors argue that disclosure should be treated as material information in relevant contexts. Professional pharmacy commentary also argues that SmPCs and package leaflets should state sources of origin and suitability for specialised populations, including faith and ethical objections.

Rodger D, Blackshaw BP. Using animal-derived constituents in anaesthesia and surgery the case for disclosing to patients. BMC Med Ethics. 2019;20:14

Rodger D. Why we should stop using animal-derived products on patients without their consent. J Med Ethics. 2022;48(10):702-706

Eriksson A et al. Animal derived products may conflict with religious patients' beliefs. BMC Med Ethics. 2013;14:48

Lababidi H, Bobier C, Rodger D. Animal-derived ingredients in medicines a framework for ethical prescribing practices. Front Pharmacol. 2025;16:1693059

Mansoor R. Disclosing ingredients of medicines to patients. The Pharmaceutical Journal. 16 March 2016. DOI 10.1211/PJ.2016.20200494

5. Patients ingest animal-derived ingredients unknowingly, with downstream trust and adherence impacts

The BMJ audit describes patients unwittingly ingesting animal-derived products while prescribers and dispensers may be unaware. Later discovery can cause distress and damage trust, and may affect adherence. Qualitative work with community representatives reports similar concerns about acceptability and disclosure.

Tatham KC, Patel KP. Why can't all drugs be vegetarian? BMJ. 2014;348:g401

Strickland S. Dietary restrictions implications on medication choice. Br J Gen Pract. 2014;64(627):e670-e671

Harding S et al. Animal-derived medicinal products community representatives' views of their use. Future Healthcare Journal. 2023;10(3):291-295

Lababidi H, Bobier C, Rodger D. Animal-derived ingredients in medicines a framework for ethical prescribing practices. Front Pharmacol. 2025;16:1693059

6. Alternatives exist in some therapeutic areas, but are hard to operationalise without disclosure

Clinical discussions identify non-animal alternatives in some cases, but systematic choice is difficult where excipient origin is opaque or variable.

Silk G et al. Are vegans being overlooked in our prescribing practices an orthopaedic perspective from Bristol, United Kingdom. J Clin Orthop Trauma. 2023;44:102250

Strickland S. Dietary restrictions implications on medication choice. Br J Gen Pract. 2014;64(627):e670-e671

Lababidi H, Bobier C, Rodger D. Animal-derived ingredients in medicines a framework for ethical prescribing practices. Front Pharmacol. 2025;16:1693059

7. Disclosure is feasible, but supply-chain certainty can be variable without standardisation

The BMJ audit states that a simple statement about animal content would be easy to implement. Other clinical literature notes that manufacturers may not always guarantee or differentiate specific sources consistently due to changing suppliers and processes, which strengthens the case for a structured, standardised disclosure method rather than ad hoc enquiries.

Tatham KC, Patel KP. Why can't all drugs be vegetarian? BMJ. 2014;348:g401

Silk G et al. Are vegans being overlooked in our prescribing practices an orthopaedic perspective from Bristol, United Kingdom. J Clin Orthop Trauma. 2023;44:102250

8. Medicines disclosure is weaker than established EU ingredient-disclosure regimes

In EU food and cosmetics law, consumers generally receive a standardised ingredient list with defined naming conventions, whereas medicines generally disclose excipient names but not the species origin of excipients that can be animal- or non-animal-derived.

Regulation (EU) No 1169/2011

Regulation (EC) No 1223/2009

Rodger D. Why we should stop using animal-derived products on patients without their consent. J Med Ethics. 2022;48(10):702-706