Medicine Transparency

Know What's in Your Medicine.

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

Dublin, Ireland
2026

How is this an issue?

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?

Anyone with a principled or medical objection to 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."

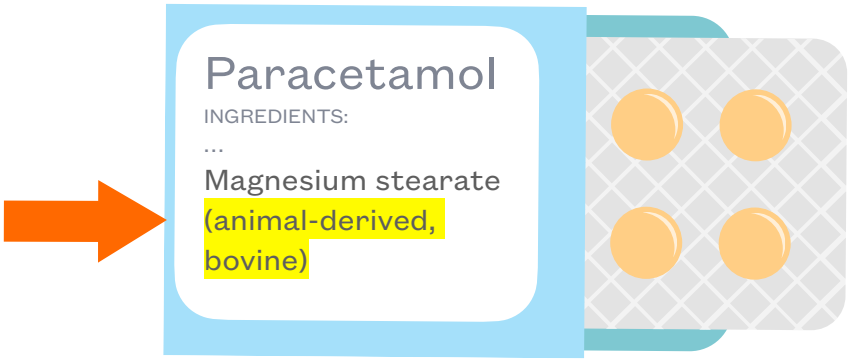
"**We recognise the importance of enabling patients to make informed choices** in line with their ethical, cultural, or religious beliefs."

"**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

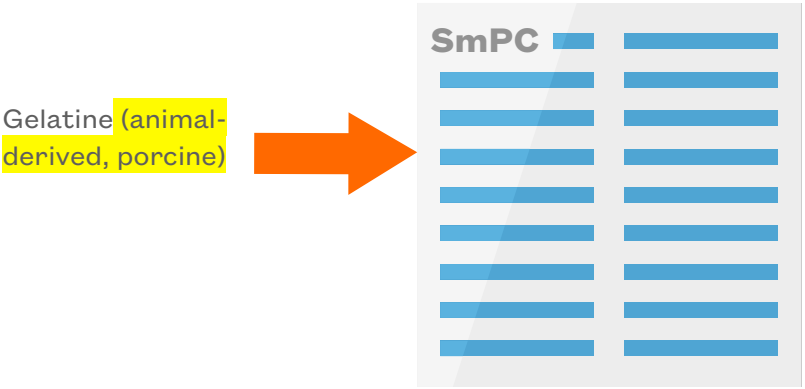
1. Simple labelling

Add species origin to already existing list of ingredients.



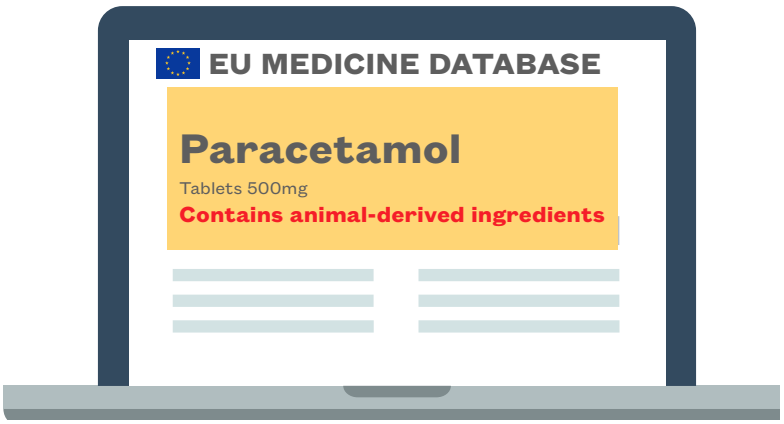
2. Extend description in SmPC

Require manufacturers to update SmPC and/or Patient Leaflet change information.



3. Centralised EU Database

Develop an easily accessible webpage, where EU citizens can look up medicines and their ingredients/excipients.



Evidence

1. Ethical and informed-consent implications

Non-disclosure of animal-derived constituents undermines patient autonomy and informed consent. Where a patient's ethical or religious objection is foreseeable, withholding origin information is withholding material information. SmPCs and package leaflets should state species origin and suitability for specialised populations, including those with faith-based or ethical dietary constraints.

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

2. Widespread use of potentially animal-derived excipients

74% of the 100 most commonly prescribed medicines in a UK clinical audit contained at least one potentially animal-derived excipient — lactose, gelatine, or magnesium stearate among them — and 20% contained gelatine. No comparable EU-wide audit exists.

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

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

Directive 2001/83/EC requires excipient names but not species origin. The same audit found that disclosure of animal-derived content was absent across SmPCs, packaging, and manufacturer information — with what little existed inconsistent, incomplete, or incorrect — 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

4. Healthcare professionals cannot reliably identify origin in practice

70% of physicians were unaware that some medicines contain pork- or beef-derived ingredients. Nearly 75% of urologists did not know whether urological medicines contain gelatine. 58% of healthcare professionals knew lactose is commonly used as an excipient, yet a review of 635 medicine leaflets found that while 50% contained lactose, only 25% specified the amount. These are not training failures — they reflect the absence of accessible, standardised origin information in routine clinical references.

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

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

Patients routinely ingest animal-derived ingredients without knowledge — and often so do their prescribers and dispensers. When patients discover this later, it causes distress, erodes trust, and can lead to non-adherence. Community representatives report the same concerns independently.

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

Non-animal alternatives exist in some therapeutic areas, but cannot be systematically chosen where origin is undisclosed.

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

Disclosure is straightforward to implement. Where supply chains involve changing suppliers or processes, manufacturers may not always guarantee a consistent source — which is precisely why structured, standardised disclosure is preferable to 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

EU food and cosmetics law requires standardised ingredient lists with defined naming conventions. Medicines require excipient names — but not species origin. The gap is anomalous and has no principled justification.

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

This is an independent citizen-led initiative. We are not affiliated with any EU institution. We do not encourage patients to avoid their prescribed medications. This brief advocates for transparency and respect for human dignity.

Gelatin, derived from bovine or porcine connective tissue, is among the most widely used excipients, appearing in capsule shells across thousands of product lines.

Lactose, magnesium stearate, and stearic acid are similarly prevalent, yet their species origin remains undisclosed on packaging and patient information leaflets.

Evidence

The European Commission

Every person who does not feel comfortable. Every person who does not feel comfortable. Every person who does not feel comfortable. Every person who does not feel comfortable. Every person who does not feel comfortable. Every person who does not feel comfortable. Every person who does not feel comfortable. Every person who does not feel comfortable. Every person who does not feel comfortable. Every person who does not feel comfortable. Every person who does not feel comfortable. Every person who does not feel comfortable. Every person who does not feel comfortable. Every person who does not feel comfortable. Every person who does not feel comfortable. Every person who does not feel comfortable. Every person who does not feel comfortable. Every person who does not feel comfortable.