Transparency on Animal-Derived Excipients in Human Medicines

Purpose

To outline the absence of species-origin information for excipients of animal origin in human medicines authorised in the EU, explain why this creates an ethical and information-rights gap for many citizens, and summarise practical policy options to improve transparency within the existing EU medicines framework.

Background

A substantial proportion of medicines marketed in the EU contain excipients that can be animal-derived, but EU-required product information does not disclose species origin. Patients and clinicians therefore cannot determine whether ingredients such as gelatine are bovine, porcine or fish-derived, or whether stearates and glycerol are of animal or plant origin. Manufacturers typically document origin for supply-chain and quality-control purposes.

Under the current legal framework (Directive 2001/83/EC, including Articles 54 and 59), excipients must be listed qualitatively in the package leaflet and, in specified cases, on the outer packaging. However, EU law does not require disclosure of species origin. As a result, origin remains unclear even when an excipient name is listed.

A UK audit and related European literature indicate that a substantial proportion of commonly prescribed medicines contain at least one potentially animal-derived excipient, suggesting the issue is structural rather than isolated (see Evidence on Animal-Derived Excipients in Medicines).

Who is affected

This information gap affects a wide range of EU citizens who avoid certain animal products for ethical, cultural or religious reasons, including vegans, vegetarians, people observing halal or kosher requirements, and individuals with personal ethical objections to specific forms of animal use. For these groups, species origin is a material characteristic that determines whether a medicine is acceptable for use.

Healthcare professionals are similarly limited. Because 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.

Policy gap

EU medicines legislation focuses on safety and efficacy, and the current framework requires qualitative listing of excipients. However, there is no requirement to state whether an excipient is of animal origin, and there is no mechanism for recording or communicating this information to patients or professionals.

In contrast, food and cosmetic sectors have clearer frameworks for origin and composition labelling when ethically or religiously relevant, creating an asymmetry in transparency standards. Medicines, which are often unavoidable, provide less origin information than consumer goods for which substitutes commonly exist.

This issue concerns transparency, informed choice and respect for ethical and religious convictions. It does not question the safety or quality of authorised medicines.

Possible policy approaches

Origin qualifiers in product information. Requiring that excipients that may be animal- or plant-derived carry a simple origin designation in the SmPC and package leaflet, and where feasible on packaging, e.g. “gelatine (porcine)”, “gelatine (bovine)”, “glycerol (plant origin)”.

Standardised symbol or notation. Introducing a clear visual indicator for the presence of animal-derived excipients, with an explanation provided in the leaflet and digital materials.

Centralised origin-transparency database. Developing an EU-level database, coordinated with EMA and national authorities, where manufacturers disclose species origin for excipients in authorised products. This could be linked via QR codes or digital labelling tools to avoid packaging constraints.

These measures would support informed decision-making, ethical and religious accommodation, and encourage manufacturers to adopt non-animal excipients where alternatives exist. Manufacturers already possess the origin information, so the primary change would be disclosure rather than new data collection.

Purpose of sharing this briefing

The aim is to clarify why the absence of species-origin information in medicines affects many EU citizens and to show how it fits within ongoing work on transparency, digital labelling and patient information. These issues are already prominent in EU policy discussions, and questions around excipient origin fall naturally within that wider context. Because Parliament plays a role in scrutinising medicines information and protecting patient rights, the matter may also warrant attention at parliamentary level.

info@medicinetransparency.eu

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