bmj.com Personal view: End the silence on animal products in drugs (*BMJ* 2013;346:f722)

Why can't all drugs be vegetarian?

Many patients avoid eating animal products for various reasons, but how many doctors consider this when prescribing a drug? Even if they do, **Kate Tatham** and **Kinesh Patel** find it is hard to determine whether drugs meet the patient's dietary requirements

Specific dietary preferences regarding animal products in food are common in the general population.[1] Influences such as religion, culture, economic status, environmental concern, food intolerances, and personal preferences all play a part in the foods that people choose to consume. In the United Kingdom, Food Standards Agency data indicate that 5% of the population are vegan or vegetarian, increasing to 12% in non-white people.[2] Vegetarians are defined as individuals that do not consume foods either directly obtained or using products from the slaughter of an animal, whereas vegans do not consume any foods originating from animals.[3 4] Some religious groups also avoid certain animal products.

Many patients and doctors are unaware that commonly prescribed drugs contain animal products—for example, low molecular weight heparin (pigs), Gelofusine (cows), and conjugated oestrogen (Premarin, horses). Furthermore, with some commonly used ingredients, simply reading the list of ingredients will not make it clear whether the product meets the patient's dietary preferences.

Sources of information on content of drugs

British National Formulary (*BNF*)
UK Medicines and Health Products Regulatory Agency public assessment reports
Summary of product characteristics
European Medicines Agency public assessment reports
Patient information leaflets
Drug packaging

KEY MESSAGES

- Most medications prescribed in primary care contain animal derived products and it is unclear whether they are suitable for vegetarians
- Labelling of animal content in medication is poor and variably instituted
- Patients with specific dietary restrictions are likely to be consuming animal products unwittingly
- Disclosure of animal content and excipients would help patients make an informed personal choice

Problem ingredients

Lactose, which is derived from cows' milk, is traditionally extracted using bovine rennet. It is used as a filler and diluent powder and as an aid in the manufacturing of medications. Some manufacturers now use vegetarian processes to extract lactose from milk, leading to potential confusion about its suitability for vegetarians.

Similarly, gelatine is widely used to encapsulate medications and is sourced from bovine or porcine skin, hide, or bone and occasionally fish. If derived from pigs it can be a problem for some Muslims and Jews. The largest kosher certification body, the Orthodox Union's Kosher division, does not accept porcine gelatine as kosher[5] whereas other Jewish organisations are more permissive. In 1995, the World Health Organization held a seminar for religious scholars to discuss the consumption of porcine products in medications by Muslims. This concluded that the gelatine formed from the transformation of impure bones was itself pure and the ingestion of such products was permitted.[6] Despite these reassurances, last year a campaign to vaccinate children in Scotland against influenza was halted because of concern in the Muslim community about pork gelatine within the vaccine.[7] Other published data have shown similar levels of concern among certain ethnic groups regarding gelatine ingestion.[1] These concerns have even prompted Saudi Arabia and Malaysia to collaborate to produce camel gelatine in an effort to meet the rising demand for non-porcine products.

Another common ingredient is magnesium stearate, a lubricant used in tablet processing and one that improves the solubility of medications. Historically it was sourced from the rendered fat of cows, pigs, and sheep, but now it can also be produced from vegetable matter.

How common are animal derived products?

Even though the absolute levels of animal products in many medications are likely to be minimal, adherence to religious doctrine can be dogmatic, and doctors need to consider this when prescribing. To ascertain the scale of the problem, we investigated the frequency with which animal products are found in the commonly prescribed medications in primary care in the United Kingdom by searching various public sources (box).

We identified the 100 most commonly prescribed drugs in primary care in January 2013 from the NHS Business Services Authority. Of these, 74 contained one or more of lactose, gelatine, or magnesium stearate (table 1). Lactose was found in 59 medications, of which 48 had accompanying public assessment reports—the only information source referring to the origins of excipients. In 10 cases (21%), the report did not specifically declare that the medication contained material of animal origin. Of the 38 reports mentioning animal content, the method used for the production of lactose was stated only in a minority of cases, with eight (21%) declaring the use of calf rennet. When the use of animal rennet was not declared, we contacted the manufacturers of the 10 most commonly prescribed medications in this category. Of 10 manufacturers contacted, five responded. One manufacturer confirmed that the lactose was rennet-free with four confirming the use of calf rennet.

Magnesium stearate was found in 49 of the top 100 medications, with the animal form declared in four products and the vegetarian form confirmed in 31. Fourteen products had no information on provenance.

Gelatine was used in 20 drugs. However, two of the product assessment reports wrongly stated that there was no animal content and seven did not mention animal content. Of the 11 that stated the presence of ingredients of animal origin, eight

Table 1 | Identification of animal derived products in 100 most common drugs in primary care

	No of drugs	No not suitable for vegetarians	No suitable for vegetarians	Unknown
Lactose	59	12*	1	46
Gelatine	20	20†	0	0
Magnesium stearate	49	4	31	14

*Calf rennet used in production.
†Two stated that gelatine was porcine derived and one that it was bovine; the remainder gave no information on animal source.

Table 2 | Information available on animal content of 10 most commonly prescribed drugs from MHRA public assessment reports or summary of product characteristics

		Gelatine		Lactose		Magnesium stearate		
Drug/manufacturer	Suitable for vegetarians	Present	Which animal identified	Present	Calf rennet used?	Present	Animal derived	Information in MHRA report
Simvastatin								
Tillomed	No	No	—	Yes	Not stated	Yes	Not stated	None
M & A Pharmachem	No	No	—	Yes	Not stated	Yes	Yes	None of excipients excluding MS contain material of animal origin. "Milk used in the production of lactose…is sourced from healthy animals"
Kent Pharmaceuticals	Unknown	No	—	Yes	Not stated	Yes	Not stated	None
Aspirin								
Bristol Laboratories	Yes	No	—	Yes	Not stated	No	—	"No other materials [excluding lactose]…of animal origin are included in the product"
Intrapharm Laboratories	Yes	No	—	Yes		No	—	Not available
Actavis	Unknown	No	—	No	—	Yes	Not stated*	Not available
Paracetamol								
Rockspring Healthcare	Yes	No	—	No	—	Yes	No	"None of the excipients contain materials of animal…origin"
Medreich	Yes	No	—	No	—	Yes	No	"None of the products contain material of animal…origin"
Peter Black	Yes	Yes	No	No	—	Yes	No	"Magnesium stearate is not derived from animal origins"
Levothyroxine								
Amdipharm	Yes	No	—	Yes	Not stated*	Yes	Not stated*	Not available
Actavis	Unknown	No	—	Yes	Not stated*	Yes	Not stated*	Not available
Wockhardt	Unknown	No	—	Yes	Not stated*	Yes	Not stated*	Not available
Omeprazole								
Zanza	No	Yes	No (states no animal products)	No	—	No	—	"No material of…animal origin contained or used in the manufacturing process"
Winthrop	No	Yes	No	Yes	Yes	No	—	"Lactose and gelatin…are materials of animal origin…lactose is prepared without the use of ruminant material other than milk and calf rennet"
Teva	No	Yes	No	No	—	No	—	"With the exception of gelatin, none of the excipients contain materials of animal…origin"
Lansoprazole								
Jenson	No	Yes	No (states no animal products)	No	—	No	—	"There are no materials of…animal origin contained in or used in the manufacturing process for this product"
Teva	Unknown	No	—	Yes	Not stated	Yes	Not stated	None
Dexcel	No	Yes	No	No	—	No	—	"With the exception of gelatin, none of the excipients contain materials of animal…origin"
Salbutamol								
STD Pharmaceuticals	Yes	No	—	No	—	No	—	"None of the excipients contain materials of animal…origin"
Noeolab	Yes	No	—	No	—	No	—	None
Ramipril								
Pliva	No	Yes	Yes	No	—	No	—	"Gelatin of bovine and porcine origin may be used"
Aurobindo	No	Yes	—	No	—	No	—	"The only excipient that contains material of animal…origin is gelatine"
Teva	Yes	No	—	No	—	No	—	None
Amlodipine								
Arrow	Yes	No	—	No	—	Yes	Not stated	None
Ivowen	Yes	No	—	No	—	Yes	No	"None of the excipients are sourced from animal…origin"
Quality	Yes	No	—	No	—	Yes	No	"Magnesium stearate ... is of vegetable origin…no materials of animal origin are used in the manufacture of the tablets"
Atorvastatin								
Dexcel	No	No	—	Yes	Not stated	Yes	Not stated	None
Teva	Yes	No	—	No	—	Yes	No	"None of the excipients are of animal…origin"
Alkaloid	Unknown	No	—	Yes	Not stated	Yes	No	"With the exception of lactose…none of the excipients contain materials of animal…origin"

*No public assessment report available and information not included in summary product of characteristics.

did not identify the animal used, one listed porcine origin, one bovine origin, and one both porcine and bovine origin.

Accessing the information

We found that it was difficult to determine the suitability of common drugs for patients with specific dietary preferences. Furthermore, suitability varied between different formulations of the same product (table 2). Although the presence of lactose was declared on 90% of exterior packaging, this was the case for only 19% of medications containing gelatine, and the presence or absence of animal derived products was never disclosed. The *British National Formulary* provides only medication indications, contraindications, dosage, and cost. Patient information leaflets and summaries of product characteristics listed the excipients but did not specify the origins. Only the Medicines and Healthcare Products Regulatory Agency product assessment report provided statements regarding animal product contents, but even these were inconsistent, incomplete, and on two occasions wrong. In all the data sources analysed, there was no statement about the suitability of gelatine containing preparations for vegetarians.

Differentiation between vegetarian and non-vegetarian lactose was poor, with the manufacturing processes and materials involved not usually divulged. Contact with manufacturers of lactose containing products also revealed uncertainty about whether medications were suitable for vegetarians. One manufacturer stated: "though calf rennet is used to extract lactose from milk, however it does not appear on the tablet and hence tablets are suitable for vegetarians," although this definition of vegetarianism would not be consistent with that of either the Food Standards Agency or the Vegetarian Society.

It is likely that patients are unwittingly ingesting medications containing animal products with neither prescriber nor dispenser aware

Our data suggest that it is likely that patients are unwittingly ingesting medications containing animal products with neither prescriber nor dispenser aware. Previous studies assessing the acceptability of oral gelatine containing medication to patients found that 40% of patients in an inner city area would prefer to take medication without animal derived products.[1]

Though national, international, and religion specific recommendations may exist, individual patient choice should be paramount and it is difficult to predict preferences. It therefore seems prudent for prescribers to ask patients about their preferences to avoid non-adherence, which is a major healthcare concern. Up to half of prescribed medications are not taken as directed, and the National Institute for Health and Care Excellence has recommended that healthcare professionals ask about and address patients' specific concerns before prescribing.[8] For prescription medications in taxpayer funded healthcare systems, such as in the United Kingdom, patients have little choice about the exact pharmaceutical preparation dispensed by their pharmacist. There have been reports of medications being discontinued without medical consultation to avoid the ingestion of animal derived products with documented adverse effects on patients.[9] Poor labelling also hinders the ability of patients to find over the counter medicines that conform to their requirements.

Better labelling

Information about animal derived products in medicines is difficult to obtain, unclear, inconsistently reported, and sometimes incorrect. Improvement in drug labelling, mirroring those standards advised for food where manufacturers voluntarily use the Vegetarian Society's seedling symbol, would help inform prescribers, dispensers, and patients. However, manufacturers in the EU are currently prohibited from making statements in product information leaflets about suitability for vegetarians or vegans as these are deemed to be "lifestyle choices." A change to this rule to permit a simple statement about animal content in medications would be easy to implement and improve clarity and patient choice.

Current legislation in Europe mandates listing all the contents of medications in often lengthy patient information leaflets accompanying products. But the origin of the contents is not specified and the introduction of such a requirement would undoubtedly allay many concerns.

Labelling on exterior packaging would be an even more accessible way of communicating with patients and pharmacists. European guidelines on the listing of ingredients on exterior packaging do exist but include only those substances that may cause a medical adverse reaction, such as sucrose in patients with sucrase-isomaltase insufficiency. No standards have been proposed for those with dietary preferences.

It is unlikely that any labelling standard could address all dietary requirements, and the ultimate solution would be to eliminate animal derived products where possible from medications. The first vegetarian capsules, made from hypromellose, were produced in 1989 and production has expanded significantly since then as demand for gelatine-free medications has grown.[10] Other than the benefits to patients with dietary preferences, use of these capsules avoids the need for compliance with regulations regarding bovine spongiform encephalopathy.

Lactose is already produced by some manufacturers without using rennet; magnesium stearate can be made chemically without animal ingredients. Although vegetarian friendly ingredients may be more expensive than those produced by traditional processes, the costs would diminish as production expanded and they would limit the exposure of patients to products they find unacceptable.

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Contributors and sources: KT is a clinical research fellow in anaesthetics and intensive care with a long term interest in delivering effective patient care. KP is a research fellow in gastroenterology working in an area with a large ethnic minority population. The article arose from observations and discussions around the blanket administration of medications such as intravenous Gelofusine to various ethnic groups while simultaneously offering hospital food options to suit restricted dietary preferences. KT had the idea for the article and collected the data. KT and KP jointly interpreted the data, drafted the manuscript, and approved the final version. KT is guarantor.
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References are in the version on bmj.com.
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STATEMENT FROM MHRA

"This issue has been considered in previous reviews of labelling policy and has been discussed within a number of European forums. There is no opportunity for the UK to act unilaterally in the area of medicines labelling so we cannot take our own action. On the issue of 'suitable for vegetarians/vegans under the regulations although some ingredients are derived from animals many of these are now also derived from plant sources. There is no requirement for a company to declare how an inactive ingredient is sourced at the time of licensing. Only information which is supported by the licence documents can be referenced in the labelling of a medicine."