

## **ANONYMOUS v STRIDES**

### **Promotion of Strivit**

**An anonymous, contactable complainant who described him/herself as a pharmacist complained about the promotion of Strivit (colecalfiferol, vitamin D3) by Strides Pharma UK Ltd. The complaint was forwarded to the PMCPA by The Medicines and Healthcare products Regulatory Agency (MHRA).**

**The complainant included a poster with the claim 'suitable for vegetarians' and stated that he/she had found that the product contained gelatin derived from beef bones. The complainant referred to an email from Strides which stated that, as per European law, the gelatin in Strides capsules was suitable for vegetarians as it used lime bone gelatin and not meat-sourced gelatin. However, the product was not suitable for vegans. The email further explained that the limed bone gelatin was from beef bones and cartilages and not meat which was why the company had the halal and kosher status. This was said to be the same as a vegetarian diet including dairy and eggs (from animals but not meat).**

**The complainant stated that Strides was claiming that as the gelatin was not from meat, it could be classed as vegetarian. However, the Vegetarian Society UK, advised that vegetarians did not eat products or by-products of slaughter.**

**The complainant alleged that patients and health professionals might be misled by Strides' claim that the product was vegetarian when it was not.**

**The detailed response from Strides is given below.**

**The Panel noted that the advertisement at issue was headed 'Switch & save 30% with ... StritvVit D3' and listed bullet points, including that StritVit was 'Nut and soya free, suitable for vegetarians' and 'Kosher and Halal certified'.**

**The Panel noted the certificate of suitability, which appeared to have been provided to the complainant by Strides, stated that the gelatin was limed bone gelatin and the nature of animal tissues used in manufacture was bovine bones free from skulls, spinal cord and vertebrae.**

**The Panel noted that an email to the complainant, in response to a request, stated that StritVit was not suitable for vegans but was suitable for vegetarians: 'Ours is limed bone gelatine from beef bones and cartilages (not meat) hence why we also have the halal and kosher status. This is the same as vegetarian diet including dairy and eggs (from animals but not meat)'.**

**The Panel noted Strides' submission which included that defining a vegetarian was a difficult issue, with special reference to variation among different religious beliefs**

present, there were several types of vegetarians. Some ate dairy foods, others might choose to include eggs, while others abstained entirely from any food product that came from an animal. Further, that such questions had not been the focus of systematic empirical research and, in the company's view, could not be answered conclusively.

The Panel considered that given the sensitivity of claims regarding the vegetarian status of medicines and their importance to particular health professionals and patients, such statements needed to be clear and accurate so there was no potential to mislead. It noted that Strides withdrew the claim in April 2022.

In the Panel's view, whilst it acknowledged that there were various definitions for a vegetarian, the claim that StritVit was vegetarian would likely be interpreted by health professionals, and the wider public in the UK, as being free from gelatin from animals. It considered that, in general, vegetarians would view products from animals such as milk and eggs differently to products from animal bones, etc. The Panel considered that, in the circumstances, the claim that StritVit was vegetarian was misleading. A breach of the Code was ruled. The Panel, noting the sensitivities associated, considered that high standards were not maintained by Strides in that regard and ruled a breach of the Code accordingly.

An anonymous, contactable complainant who described him/herself as a pharmacist complained about the promotion of Strivit (colecalciferol, vitamin D3) by Strides Pharma UK Ltd. The complaint was forwarded to the PMCPA by The Medicines and Healthcare products Regulatory Agency (MHRA).

Strivit was available in various presentations and the indications included for prevention and treatment of vitamin D deficiency in adults and adolescents with an identified risk. As an adjunct to specific therapy for osteoporosis in patients with vitamin D deficiency or at risk of vitamin D insufficiency.

The complainant included a poster with the claim 'Nut and soya free, suitable for vegetarians'.

## **COMPLAINT**

The complainant stated that Strides claimed that Strivit was suitable for vegetarians. Upon further investigation, the complainant stated that he/she had found that the product contained gelatin. This had been derived from beef bones. The complainant referred to an email from Strides.

This email stated that, as per European law, the gelatin in Strides capsules was suitable for vegetarians as it used lime bone gelatin and not meat-sourced gelatin. However, the product was not suitable for vegans. The email further explained that the limed bone gelatin was from beef bones and cartilages and not meat which was why the company had the halal and kosher status. This was said to be the same as a vegetarian diet including dairy and eggs (from animals but not meat).

The complainant stated that Strides was claiming that as the gelatin was not from meat, then it could be classed as vegetarian. However, the definition from the Vegetarian Society UK, advised vegetarians did not eat products or by-products of slaughter.

The complainant was concerned that patients and health professionals might be misled by Strides' alleged claim that the product was vegetarian when actually, in the complainant's view, it was not.

When writing to Strides, the Authority asked it to consider the requirements of Clauses 5.1 and 6.1 of the Code.

## RESPONSE

Strides stated that the sales poster (A1 006) was used by representatives to send to mainly medicine manager customers and health professionals, to make them aware of the potential savings on offer by implementing Strivit-D3 by brand. Regarding the claim of being suitable for vegetarians, Strides referred to 4 points as to why the claim was made:

- 1 A vegetarian was generally thought of as a person who did not eat meat. Although such a straightforward criterion might seem sensible, the underlying social reality was much more complex. In terms of understanding vegetarianism as a social identity, Strides proposed that vegetarianism was best thought of as those who did not eat meat, whereas vegans avoided consuming all animal-based products (eg no meat, dairy, eggs, honey) and avoided using products derived from animals (eg no leather), lacto-vegetarians (vegetarians who ate dairy products), ovo-vegetarians (vegetarians who ate eggs), and pescatarians (vegetarians who ate fish) were less restrictive. Strivit-D3 could be consumed by vegetarians but not vegans.
- 2 The source of gelatin was bovine and a highly purified pharmaceutical grade meeting international pharmacopeia standard like USP/Ph.Eur.
- 3 Food habits varied from person to person and place to place. Religion was the vital source of such variation. Jainism people were vegetarian, but they did not take some vegetarian foods such as potato, carrot, onion, and garlic which were grown below earth. All the different cultures had their own beliefs and habits. Therefore, Strides must remember that medicine should not be treated as food articles and was independent of these thoughts or boundaries to save life of patients. Strides could see that both gelatin and non-gelatin capsules were comparable in toxicity.
- 4 Regarding the vegetarian versus non-vegetarian issue, defining vegetarian was a difficult issue, with special reference to variation among different religious beliefs present. Many a times, manufacturing of medicines required different reagents of animal origin. Again, different medicines were also of nonvegetarian origin, for example, hormonal products, heparin, insulin, antiserum, and human cell line-derived products. Involvement of all these complicated issues made determination of vegetarian and nonvegetarian capsules complicated. On the ethical basis, representation states that gelatin-based capsules should be allowed to be marketed without any additional labeling. Strides referred to the following minutes which noted:

‘Some members also pointed out that HPMC – a type of cellulose capsules – is basically of synthetic origin and as such cannot be considered as purely of vegetarian origin as in the case of food preparations,’

The company submitted that the DTAB's [Drugs Technical Advisory Board] decision was in line with the 2013 Supreme Court decision which stated that cosmetics and drugs could not be treated at par with food articles, when it came to labeling them with the vegetarian and nonvegetarian ingredients and hence, the DTAB was with the decision of the Supreme Court. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5830853/>.

Strides stated that defining vegetarian was a difficult issue, with special reference to variation among different religious beliefs present, there were several types of vegetarians. Some ate dairy foods, others might choose to include eggs, while others abstained entirely from any food product that came from an animal. Based on the altering views and not one defined definition, the company referred to an email dated 15 March 2022 to Strides' external marketing agent to alter the wording of the Strivit-D3 poster to show:

'Page 3: Strivit - Suitable for vegetarians – please can we change to: suitable for some  
 1Vegetarians  
 1Source of gelatine in capsules is bovine therefore this may not be suitable for all vegetarians.'

Strides stated that understanding the beliefs and attitudes associated with a vegetarian identity required understanding the reasons why people became vegetarians. As noted by Rosenfeld who suggested that the three most common motivations among vegetarians in developed Western nations were concerns about animals, health, and the environment. For this reason, the wording was changed to give health professionals full visibility of the source of gelatin and to advise patients accordingly in the decision-making process.

Strides submitted that, nevertheless, the existing research suffered from important limitations in that not enough attention had been paid to possible differences amongst types of vegetarians, such questions had not been the focus of systematic empirical research and could not be answered conclusively. Having done further research, it was never Strides' intention to misrepresent on this grey area, and as such, Strides had made a conscious decision to remove the wording completely from April 2022 onwards to ensure no further misunderstanding or misinterpretations could happen, until such time there was better clarity on vegetarian guidelines and status in human medicines.

## **PANEL RULING**

The Panel noted that the advertisement at issue was headed 'Switch & save 30% with ... StritvVit D3' and listed bullet points, including that StritVit was 'Nut and soya free, suitable for vegetarians' and 'Kosher and Halal certified'.

The Panel noted the complainant's concern that Strides Pharma claimed that StritVit was suitable for vegetarians despite containing gelatin. The certificate of suitability, which appeared to have been provided to the complainant by Strides Pharma in response to a request, stated that the gelatin was limed bone gelatin and the nature of animal tissues used in manufacture was bovine bones free from skulls, spinal cord and vertebrae.

The Panel noted that an email to the complainant, in response to a request, stated that StritVit was not suitable for vegans but was suitable for vegetarians: 'Ours is limed bone gelatine from beef bones and cartilages (not meat) hence why we also have the halal and kosher status. This is the same as vegetarian diet including dairy and eggs (from animals but not meat)'.

The Panel noted Strides' submission that defining a vegetarian was a difficult issue, with special reference to variation among different religious beliefs present, there were several types of vegetarians. Some ate dairy foods, others might choose to include eggs, while others abstained entirely from any food product that came from an animal. Further, that such questions had not been the focus of systematic empirical research and, in the company's view, could not be answered conclusively.

The Panel noted Strides' submission which appeared to be from an article in the Indian Journal of Pharmacology which referred to a meeting of the Indian Drugs Technical Advisory Board held in New Delhi in 2017 and the Indian Supreme Court. The article stated that:

'On the ethical basis, representation says that gelatin-based capsules should be allowed to be marketed without any additional labeling. 'Some members also pointed out that HPMC – a type of cellulose capsules – is basically of synthetic origin and as such cannot be considered as purely of vegetarian origin as in the case of food preparations,' the minutes noted. The DTAB's decision is in line with the 2013 Supreme Court decision which stated that cosmetics and drugs cannot be treated at par with food articles, when it comes to labeling them with a brown or green mark to distinguish the vegetarian and nonvegetarian ingredients and hence, we are with the decision of the Supreme Court.'

The Panel considered that given the sensitivity of claims regarding the vegetarian status of medicines and their importance to particular health professionals and patients, such statements needed to be clear and accurate so there was no potential to mislead. It noted that Strides withdrew the claim in April 2022.

In the Panel's view, whilst it acknowledged that there were various definitions for a vegetarian, the claim that StritVit was vegetarian would likely be interpreted by health professionals, and the wider public in the UK, as being free from gelatin from animals. It considered that, in general, vegetarians would view products from animals such as milk and eggs differently to products from animal bones, etc. The Panel considered that, in the circumstances, the claim that StritVit was vegetarian was misleading. A breach of Clause 6.1 was ruled. The Panel, noting the sensitivities associated, considered that high standards were not maintained by Strides in that regard and ruled a breach of Clause 5.1 accordingly.

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During the consideration of this case, the Panel noted that Strides had changed the claim to refer to 'some vegetarians' and to provide what appeared to be a footnote. The Panel was concerned whether the use of animal-derived gelatin would be suitable for 'some vegetarians' and requested that Strides be made aware of its concerns.

**Complaint received      15 March 2022**

**Case completed          9 November 2022**