MUSLIM AFFAIRS SPECIALIST v PROSTRAKAN

Promotion of Adcal-D3 Caplets

An NHS and Muslim affairs advisor to a healthcare management company complained that ProStrakan representatives had described Adcal-D₃ Caplets (calcium carbonate and vitamin D3) as Halal without the necessary approval from a relevant Halal certifying body. The complainant noted the conduct of one local representative in that regard.

The detailed response from ProStrakan is given below.

The Panel noted ProStrakan's submission that the gelatin free status of the new caplets used in Adcal- D_3 together with the fact that the vitamin D in the medicine was derived from a Halal source might have led to the misconception that the caplets were Halal.

The Panel noted ProStrakan's submission that no promotional material for Adcal-D₃ Caplets contained a claim about the suitability of the medicine for Halal diets and that promotion of the medicine as a Halal option was never its aim or intention. Most of the promotional material provided referred to the fact that Adcal-D₃ Caplets were gelatin free; none of it referred to the medicine being suitable for those following a Halal diet. The Panel noted however that representatives' briefing material contained the statement that 'A key feature which will appeal to many patients is that Adcal-D₃ Caplets are gelatin free, and therefore suitable for vegetarians, and patients adhering to strict halal diets'.

In the Panel's view, although the caplets were gelatin free and the vitamin D was derived from a Halal source, Adcal-D₃ Caplets as a product were not Halal. The Panel considered that the claim in the briefing document that Adcal-D₃ Caplets were suitable for patients adhering to strict Halal diets was misleading and could not be substantiated. Breaches of the Code were ruled. The briefing material advocated a course of action that was likely to lead to a breach of the Code and in that regard the company had failed to maintain high standards. Further breaches of the Code were ruled. These rulings were upheld on appeal.

With regard the activity of the representative in question, the Panel noted that the parties' accounts differed. The complainant had referred to second and third hand reports that the representative had discussed the Halal status of Adcal-D₃ Caplets. No details of the discussions were provided. ProStrakan submitted that the representative had stated that he had never claimed that the caplet itself was Halal; the term Halal had been discussed but only in response to customer questions about the source of the vitamin D. However, the representatives' briefing material stated that Adcal-D₃ Caplets were

suitable for patients on a strict Halal diet and so in that regard the Panel considered that on the balance of probabilities the representative had implied that the medicine had been granted Halal status. Although the representative had used material provided by the company and followed company instructions all the relevant requirements of the Code had not been complied with. A breach of the Code was ruled.

Upon appeal, the Appeal Board noted the statement 'A key feature which will appeal to many patients is that Adcal-D₃ Caplets are gelatin free, and therefore suitable for vegetarians, and patients adhering to strict halal diets' in the representatives' briefing material dated August 2011. The Appeal Board noted from ProStrakan that this statement had been included to equip representatives with a means to respond to questions from health professionals; the company did not expect the representatives to use the claim promotionally. The Appeal Board considered, however, that briefing material was part of the promotional material for the product and describing something as a 'key feature' would have highlighted its importance as a point to note.

The Appeal Board considered that the representative who had used the briefing document to refer to the Halal status of Adcal-D₃ Caplets had only been doing as instructed by ProStrakan. The Appeal Board thus ruled no breach of the Code.

An NHS and Muslim affairs advisor to a healthcare management company, complained about the use of the term Halal to describe Adcal-D₃ Caplets (calcium carbonate and vitamin D3) by ProStrakan UK Limited.

COMPLAINT

The complainant stated that in his capacity as a Muslim affairs specialist and working with the community and voluntary sector he had received a number of enquiries from members of the community about the term Halal being loosely used for Adcal-D₃ Caplets.

Local Imams and various community activists in areas populated by Muslims had vehemently questioned this claim. Making such claims could lead to community tension, hence the need to contact the PMCPA to assist in averting any repercussions for the local health community.

The complainant understood that representatives from ProStrakan, not just locally, but regionally and nationally, had made the assertion without the necessary approval on the Halal status of Adcal-D₃ Caplets. Approvals of this nature were in most cases made by the relevant Halal certifying bodies, of which there were several in the UK, yet upon inquiry, it appeared that none had granted ProStrakan any kind of certification for Adcal-D₃ Caplets.

The complainant submitted that this clearly was a very worrying development and suggested that $Adcal-D_3$ Caplets had, during their manufacture, been deemed Halal; not only during preparation but that no animal trials were conducted in the manufacture of this medicine. Conducting animal trials on non-Halal animals and then including those very products in medicines and labelling them as Halal would be questioned by the most senior Muslim Jurists. Naturally if there was no alternative available to treat a person's condition it might be deemed appropriate to use, however that would be a decision for a Muslim with the relevant expertise on Halal/Haram matters.

The complainant raised a number of questions regarding the Halal status of Adcal-D₃ Caplets.

Following a request from the case preparation manager for additional information the complainant stated that he had been informed by a number of local GPs that the ProStrakan representative had informed GPs of Adcal-D₃ Caplets' Halal status. A deputy director of medicines management at a primary care trust had also heard from some GPs that they believed Adcal-D₃ Caplets were suitable for Muslims.

When writing to ProStrakan, the Authority asked it to respond in relation to Clauses 7.2, 7.4, 9.1, 15.2 and 15.9 of the Code.

RESPONSE

ProStrakan stated that it took its responsibilities under the Code very seriously, and appreciated the opportunity to address the concerns raised by the complainant.

As an organisation with the capacity to influence the health and wellbeing of patients, ProStrakan held the views of its customers, and the wider community, in very high regard. It submitted that it had always endeavoured to ensure that the information provided to these groups was clear, accurate and appropriate. However, it would appear that in this instance some confusion had arisen with respect to the use of the term Halal in connection to Adcal-D₃ Caplets.

ProStrakan had never sought to promote Adcal-D₃ Caplets as Halal. The term did not appear on any promotional materials. The promotional campaign that supported the launch was centred on the swallowability of the caplet itself, a claim that was intended to counter patient concerns about the unpalatable nature of certain calcium supplements.

However, the company believed that some confusion had arisen as a consequence of the gelatin free status of the new caplets. As the caplet itself was gelatin free, and the vitamin D in the product was derived from a Halal source, this might have led to the misconception that the caplet itself was Halal. As a consequence and to ensure that no further confusion arose, a telecon was held on the 28 February 2012 between the field based management team and the senior vice president, commercial operations, in order to clarify the conditions under which the term Halal might be used in relation to the caplets. This telecon was used to further reinforce the importance of accurately communicating the characteristics of the product.

ProStrakan submitted that the caplets and associated promotional materials were launched during the annual sales conference in September 2011. No promotional materials contained a claim that Adcal-D₃ Caplets were Halal. Copies of the current promotional materials and of representatives' briefing material were provided. ProStrakan submitted that the key selling messages for Adcal-D₃ Caplets were centred on ease of swallowing and clinical evidence, a fact reinforced by the documentation discussed above. Promoting the medicine as a Halal option was never an aim or intention. Only one section of the briefing document referred to the term Halal; the paragraph which discussed the sales aid stated:

'A key feature which will appeal to many patients is that Adcal-D₃ Caplets are gelatin free, and therefore suitable for vegetarians, and patients adhering to strict halal diets.'

This was included in the briefing document to equip representatives with the necessary information to respond to questions from health practitioners about patients with dietary restrictions. It was intended to allow representatives to explain that the medicine was gelatin free and so could be an alternative for patients with strict religious backgrounds given that the vitamin D component of Adcal-D₃ Caplets was certified as Halal. The oral brief accompanying this document made it clear that this was an issue that must be considered on a case-by-case basis between the doctor and their patient.

When taken in consideration with the rest of ProStrakan's materials, and the remainder of the briefing document, it was clear that the promotion of Adcal-D₃ Caplets as a Halal option was not advocated. ProStrakan therefore denied a breach of Clause 15.9.

The representative responsible for the area at issue was interviewed as were his manager and the partnership development executive (PDE) for the region.

The representative in question had considerable experience in the industry and treated the distinction between Halal and Haram substances with the utmost respect. When interviewed the representative stated that, while he had discussed Adcal-D₃ Caplets with customers, he had never claimed that the caplet itself was Halal; although the term Halal had been discussed this was in response to customer questions regarding the source of the vitamin D, which he understood had a Halal certificate.

The representative's account of events was confirmed by both his manager and the PDE responsible for his territory. Both had monitored the representative in a number of calls, but neither had observed him making inappropriate claims concerning the Halal status of the product. This view was backed up by his call records. No calls held with customers since the launch of Adcal-D₃ Caplet referred to the product as Halal, or indicated that it had been promoted to customers as such. Given this evidence ProStrakan denied a breach of Clause 15.2.

ProStrakan had not conducted any animal trials on the product.

ProStrakan stated that it was never its intention to promote Adcal-D₃ Caplet as a Halal product and therefore no approval was sought from Muslim scholars or other bodies which regulated the use of the term. Had it been the intention to promote the product in this fashion it would, as a matter of course, have engaged with the community to ensure that its required standards were met.

With regard to whether patients made aware of the Halal status, ProStrakan submitted that the patient education leaflet supporting the medicine did not use the term Halal. No direct to patient advertising for Adcal-D₃ Caplets was produced for patients as this was prohibited by the Code.

ProStrakan did not know how many patients had taken Adcal-D₃ Caplets on the assumption that it was Halal as the collection of information on patient prescriptions was prohibited by the Code.

ProStrakan submitted that documentation had been provided from a Halal certifying body certifying the vitamin D component of Adcal-D₃ Caplets. However, this certification was not actively sought by ProStrakan. The certificate was provided as standard by the organisation responsible for producing the product.

ProStrakan stated that as it had not promoted the product as Halal, no attempt had been made to contact the NHS regarding this matter.

ProStrakan submitted that as noted above, none of the promotional materials contained the claim that Adcal-D₃ Caplets were Halal. Nor had the company sought to verbally make claims regarding the product that it was unable to substantiate.

ProStrakan therefore denied breaches of Clauses 7.2 and 7.4.

ProStrakan stated that it endeavoured to follow both the spirit and the letter of the Code, and as such it had made every effort to address the complainant's concerns to the fullest degree possible. The company was concerned to hear that misunderstandings appeared to have occurred in relation to the Halal status of the caplets, and had already taken steps to address this. The company submitted that its inquiry had established that the promotion of the Adcal-D₃ Caplets complied with the Code. It had never promoted the medicine as a Halal option, as was evidenced by the materials supporting the medicine and the investigation detailed above. ProStrakan thus denied a breach of Clause 9.1.

PANEL RULING

The Panel noted ProStrakan's submission that some confusion had arisen as a consequence of the gelatin free status of the new caplets used in Adcal-D3. That, together with the fact that the vitamin D in the medicine was derived from a Halal source, might have led to the misconception that the caplets were Halal. ProStrakan provided a copy of a certificate from a certifying body with regard to the vitamin D component of the Adcal-D₃ Caplets.

The Panel noted ProStrakan's submission that no promotional material for Adcal-D₃ Caplets contained a claim about the suitability of the medicine for Halal diets and that promotion of the medicine as a Halal option was never its aim or intention. Most of the promotional material provided referred to the fact that Adcal-D3 Caplets were gelatin free; none of it referred to the medicine being suitable for those following a Halal diet. The Panel noted however that a briefing document for representatives entitled 'Key Account Team Brief - Adcal-D₃ Caplet Campaign' (ref M004/0018) contained the statement in relation to the first page of the sales aid that 'A key feature which will appeal to many patients is that Adcal-D₃ Caplets are gelatin free, and therefore suitable for vegetarians, and patients adhering to strict halal diets'.

The Panel noted ProStrakan's submission that this was included in the briefing document to help representatives respond to questions from health professionals about patients with dietary restrictions. It was intended to allow representatives to explain that the product was gelatin free and as such could provide an alternative for patients with strict religious backgrounds given that the vitamin D component of Adcal-D₃ Caplets was certified as Halal.

In the Panel's view, although the caplets were gelatin free and the vitamin D was derived from a Halal source, Adcal-D₃ Caplets as a product were not granted Halal status. The Panel considered that the claim in the briefing document that Adcal-D₃ Caplets were suitable for patients adhering to strict Halal diets was misleading. It was not made sufficiently clear that only the vitamin D component of the medicine was certified as Halal. A breach of Clause 7.2 was ruled. The Panel considered that the claim was not capable of substantiation and a breach of Clause 7.4 was ruled. The briefing material advocated a course of action that was likely to lead to a breach of the Code. A breach of Clause 15.9 was ruled. Further, the company had failed to maintain high standards in this regard and a breach of Clause 9.1 was ruled.

With regard to the activity of the representative in question, the Panel noted that the parties' accounts differed. The complainant had referred to second and third hand reports that the representative had discussed the Halal status of Adcal-D₃ Caplets. No details of the discussions were provided. ProStrakan submitted that the representative had stated that while he had discussed Adcal-D₃ Caplets with customers he had never claimed that the caplet itself was Halal; the term Halal had been discussed but only in response to customer questions about the source of the vitamin D, which he understood had a Halal certificate. As noted above, however, the representatives' briefing material stated that Adcal-D₃ Caplets were suitable for patients on a strict Halal diet and so in that regard the Panel considered that on the balance of probabilities the representative had implied that the medicine had been granted Halal status. Although the representative had used material provided by the company and followed company instructions all the relevant requirements of the Code had not been complied with. A breach of Clause 15.2 was ruled.

APPEAL BY PROSTRAKAN

ProStrakan submitted that it had never made any promotional claims regarding the Halal status of Adcal-D₃ Caplets as evidenced by its previous provision of, *et al*, a detail aid, two leavepieces and two advertisements none of which made such claims.

ProStrakan submitted that the briefing document entitled 'Key Account Team Brief - Adcal-D₃ Caplet Campaign', developed to help representatives respond to questions from health professionals, contained the statement 'A key feature which will appeal to many patients is that Adcal-D₃ Caplets are gelatin free, and therefore suitable for vegetarians, and patients adhering to strict halal diets'. Although ProStrakan's previous response indicated that Adcal-D₃ Caplets were gelatin free and the vitamin D component in the medicine was derived from a Halal source, the statement in the briefing document was nonetheless ruled to be in breach of Clauses 7.2, 7.4, 15.9 and 9.1. This ruling was made on the basis that Adcal-D₃ Caplet as a product had not been granted Halal status despite the fact that the caplets were gelatin free and the vitamin D component was derived from a Halal source.

ProStrakan took this matter very seriously. Out of respect for the concerns of the complainant in this case, the PMCPA, health professionals throughout the UK and not least to Muslim patients, it had tried to resolve this matter by providing definitive evidence regarding the Halal status of Adcal-D₃ Caplet. This matter was particularly important given the therapeutic needs of Muslim patients who, given Shariah dress requirements and Halal dietary restrictions, might be at particular risk of calcium and vitamin D deficiency and for whom there might be limited therapeutic options due to the same Halal restrictions. To this effect ProStrakan had worked closely with a body that sanctioned the Halal status of products.

ProStrakan submitted that this body thoroughly reviewed its procedures and facilities in line with the above criteria. Subsequent to that review the Adcal-D₃ Caplet (including all ingredients) as supplied to the UK from the manufacturing site in Germany, which had also been fully audited by the body, had been Halal certified as in accordance with Islamic Shariah Law and as suitable for use by Muslims. A copy of the Halal certificate of authentication and the Halal certification record for Adcal-D₃ Caplet was provided. As the manufacturing authorization and product specification of Adcal-D₃ Caplet was both tightly regulated by the appropriate competent authorities and unmodified since the UK launch in September 2011, ProStrakan therefore appealed the Panel's rulings with regards to Clauses 7.2, 7.4, 15.9 and 9.1 as Adcal-D₃ Caplets were indeed Halal and had been since their UK launch. The briefing document was thus not misleading, it could be substantiated and did not advocate a course of action likely to lead to a breach of the Code and consequently ProStrakan had maintained high standards.

ProStrakan submitted that with regard to the activity of its representative and the ruling of a breach of Clause 15.2, the representative in question had never claimed that Adcal-D₃ Caplets were themselves Halal. Indeed, no first hand evidence to the contrary had been provided to substantiate this complaint. However, given that Adcal-D₃ Caplets had been certified as Halal by a certifying body, the briefing document issued to the representative in question was neither misleading nor incapable of substantiation on this point, nor did it advocate a course of action that was likely to lead to a breach of the Code. ProStrakan consequently appealed the ruling of a breach of Clause 15.2 and submitted that the representative in question had at all times maintained a high standard of ethical conduct in the discharge of his duties and had complied with all relevant requirements of the Code.

In summary, ProStrakan submitted that Adcal-D₃ Caplets had been Halal certified in accordance with Islamic Shariah Law and had been deemed suitable for use by Muslims. ProStrakan therefore appealed all of the Panel's rulings.

ProStrakan submitted that it had both a clinical and ethical obligation to appeal as the Halal diet and Shariah dress requirements might put Muslim patients, especially women, at increased risk of osteoporosis, and increased the clinical need for therapeutic supplementation of malnutrition for example in pregnancy and in established vitamin D dependent osteomalacia. Since the requirements for Halal limited the treatment options for Muslim patients in this therapy area, hence the nature of this complaint, ProStrakan submitted it would be wrong for it to let the rulings in the case go unchallenged. Indeed, ProStrakan was concerned that the Panel's rulings might make health professionals think that Adcal-D₃ Caplets were not Halal, which was not the case, and that as an unintended consequence of these rulings, an important and high risk section of the community might be inappropriately deprived of a licensed medicine from which it might benefit.

RESPONSE FROM THE COMPLAINANT

The complainant provided witness statements, (one from a pre-registration pharmacist and a pharmacy manager, one from a deputy director, medicines management and one from a pharmacist) which referred to ProStrakan representatives discussing the Halal status of Adcal-D₃ Caplets with local health professionals. The complainant alleged that this had in some instances confused not only health professionals but also, more importantly, Muslim patients.

The complainant noted the claim in the ProStrakan briefing document 'A key feature which would appeal to many patients was that Adcal-D₃ Caplets were gelatin free, and therefore suitable for vegetarians, and patients adhering to strict halal diets'. The complainant alleged that gelatin free and Halal had completely different connotations, therefore, this again was very confusing. The complainant queried what ProStrakan understood by a 'strict Halal diet'.

ProStrakan, in its response to the complaint, acknowledged that this misconception had arisen from the fact that only the vitamin D in the Adcal-D₃ Caplet was Halal, consequently, between the response to the complaint and the appeal the product had been granted full Halal status. The complainant welcomed submission of evidence to the Appeal Board that supported this.

Further, the complainant noted ProStrakan's reference to confusion having occurred and as a result, and without the necessary jurisprudential guidance, clarified to the field based management team under what conditions the term Halal could be used, and, again, the complainant welcomed the necessary evidence, which allowed ProStrakan to use the term Halal.

The complainant noted that in its response ProStrakan had stated that it had never intended to promote Adcal-D₃ Caplet as a Halal product and therefore no approval was sought from Muslim Scholars or other bodies which regulated the use of the term. Additionally, ProStrakan had cited certification from one body but in its appeal had included certification from another. The complainant queried why the latter certification was omitted from ProStrakan's response to the complaint.

The complainant submitted that the community was now utterly perplexed because it had two different sanctioning bodies, with conflicting reports, one which claimed that the vitamin D component of Adcal-D₃ Caplets was Halal and the other which suggested the whole Adcal-D₃ Caplet was Halal. The complainant queried how this process was undertaken, particularly given that the first body would only certify the vitamin D component of the Adcal-D₃ Caplet as Halal.

The complainant stated that in his view ProStrakan representatives, in their contact with health professionals, had shown the highest degree of

unethical behaviour towards the health community and particularly Muslim patients. The Halal certificate provided by the first body clearly suggested the vitamin D was provided by a nutrition company. Was this company a part of ProStrakan? There was no basis from this certification for Adcal-D₃ Caplets to be considered Halal, when only the vitamin D component was Halal certified. There was no mention of Adcal-D₃ Caplets being Halal certified.

ProStrakan appeared to suggest that Muslims had wholly different therapeutic needs to the wider indigenous population. ProStrakan had also stated that Muslims, given Shariah dress requirements and Halal dietary restrictions, might be at particular risk of calcium and vitamin D deficiency. The complainant stated that he would welcome any evidence to corroborate this claim. ProStrakan suggested, for the same reason, that there might be limited therapeutic options due to Halal restrictions. Observing a Halal code did not restrict nor limit therapeutic options; on the contrary, it empowered patients to make informed decisions and provided guidance on a holistic approach to life. ProStrakan suggested it had a close working relationship with the second body which provided Halal certification for Adcal-D₃ Caplets. This organisation had no track record of providing Shariah compliant services, locally, regionally or nationally, and had only been registered for fourteen months, furthermore for only seven months when Adcal-D₃ Caplets were launched.

The complainant alleged that the most fundamental point and the crux of this matter was, what schools of Madhhab (law) were consulted prior to gaining Halal certification? The complainant listed eight and noted that the principles that should govern Halal certification of any medicine for Muslim patients might differ from school to school.

The complainant stated that in his view, prior to and including the September launch date of $Adcal-D_3$ Caplets, no real and meaningful attempts were made by ProStrakan to consult appropriately with the significant Halal bodies in the UK.

The complainant noted that it was further suggested by ProStrakan that the second body conducted a 'thorough' review of ProStrakan procedures and facilities. No evidence had been submitted to substantiate this claim.

The complainant alleged that evidently, from the witness statements provided, it should be considered whether the ProStrakan representative had made unsubstantiated claims of the Halal status of Adcal-D₃ Caplets, therefore confusing the health community and Muslim patients.

The complainant emphasised that there was no irrefutable evidence of the Halal status of Adcal- D_3 Caplets.

The complainant stated that he would welcome any evidence which supported ProStrakan's claim that by observing a Halal diet and Shariah dress requirements, Muslim women were especially at risk of osteoporosis. Indeed, there were several options available to patients who might be at risk of osteoporosis and if there was no Halal option available a non-Halal option, to preserve life and wellbeing, could be offered. Therefore to suggest, without the necessary clinical evidence, because a Muslim woman dressed in line with Shariah, she was at increased risk of osteoporosis was wholly unacceptable.

The complainant urged the Appeal Board to uphold the rulings of the breaches of the Code.

APPEAL BOARD RULING

The Appeal Board noted the statement 'A key feature which will appeal to many patients is that $Adcal-D_3$ Caplets are gelatin free, and therefore suitable for vegetarians, and patients adhering to strict halal diets' in the representatives' briefing document entitled 'Key Account Team Brief – Adcal-D₃ Caplet Campaign'. The briefing material was dated August 2011. The Appeal Board noted from ProStrakan that this statement had been included to equip representatives with a means to respond to questions from health professionals; the company did not expect the representatives to use the claim promotionally.

In the Appeal Board's view, ProStrakan's submission that none of its promotional material had ever included claims regarding the Halal status of Adcal- D_3 Caplets was inaccurate given the statement in the briefing document. The Appeal Board considered that briefing material was part of the promotional material for the product and was concerned that ProStrakan did not consider it to be so. The statement in the briefing material was clearly a promotional claim that Adcal- D_3 Caplets were Halal. Describing something as a 'key feature' would have highlighted its importance as a point for the representatives to note. The Appeal Board considered that given the sensitivity of claims regarding the Halal 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. The statement in the briefing document implied that Adcal-D₃ Caplets were Halal as a consequence of being gelatin free. The Appeal Board's understanding was that Halal status was more than the absence of gelatin.

The Appeal Board considered that although the caplets were gelatin free and the company had a certificate (dated 22 November 2011) that stated that the vitamin D component met the Halal requirements, it did not have a certificate when the briefing material was prepared in August 2011 to show that Adcal-D₃ Caplets were Halal. The certificate from the second body was dated 20 April 2012. The Appeal Board considered, therefore, that when the claim in the briefing document that Adcal-D₃ Caplets were suitable for patients adhering to strict Halal diets was approved it was misleading, not capable of substantiation and advocated a course of action that was likely to lead to a breach of the Code and it upheld the Panel's rulings of breaches of Clauses 7.2, 7.4 and 15.9. Further, the company had failed to maintain high standards in this regard and the Appeal Board upheld the Panel's ruling of a breach of Clause 9.1. The appeal on these points was unsuccessful.

The Appeal Board considered that the representative in question who had used the briefing document to refer to the Halal status of Adcal-D₃ Caplets had only been doing as instructed by ProStrakan. The Appeal Board thus ruled no breach of Clause 15.2. The appeal on this point was successful.

Complaint received	24 February 2012
Case completed	21 June 2012