CASE AUTH/2517/6/12

ANONYMOUS v PROSTRAKAN

Promotion of Adcal D_3 Caplet

An anonymous, non-contactable complainant who signed his/her complaint 'An aggrieved Surgery' complained about certain practices by ProStrakan and its representatives in relation to Adcal-D_3 Caplet (calcium carbonate and colecalciferol).

The complainant recently saw a sales representative and manager who had promoted the latest addition to the Adcal range, Adcal-D_3 Caplet.

The complainant noted that the same information was used to promote other products in the range. The representative and manager assured the complainant that the data in the detail aid and leavepieces were relevant to Adcal-D_3 Caplet and the product was included in the clinical trials cited. This was alleged to be misleading as the studies were almost a decade old and Adcal-D_3 Caplet could not be included as it was not a year old.

The complainant stated that his/her surgery had used ProStrakan's switch programme to swap patients from other calcium supplements to Adcal-D_3 Caplet based on misleading data in the material. However the complainant and his/her colleagues considered that they had compromised their patients by unwittingly believing the data and the 'carrot' that was dangled in the form of a switch programme. The surgery would review those patients that had been inconvenienced by the switching of medication.

The detailed response from ProStrakan is given below.

The Panel noted ProStrakan's submission that the claims made for Adcal-D_3 Caplet were based on Chapuy *et al* and Tang *et al*. Neither included any of the Adcal range of products. However, the results of Chapuy *et al* were detailed in Section 5.1, Pharmacodynamic properties, of the Adcal-D_3 Caplet summary of product characteristics (SPC). The 18 month efficacy data to support the UK marketing authorization application for Adcal-D_3 Caplet were derived from Chapuy *et al*.

The Panel noted that page 3 of the detail aid was entitled 'The NEW Adcal-D_3 Caplet – offering your patients an effective dose of calcium and vitamin D_3'. The page gave the results of Chapuy *et al* in relation to the use of 1200mg elemental calcium and 800IU vitamin D_3 daily in significantly reducing hip fractures and non-vertebral fractures vs placebo over 18 months. Page 4 of the detail aid had the same title and noted that a meta-analysis (Tang *et al*) concluded that daily doses of at least 1200mg calcium and 800IU vitamin D_3 had been shown to achieve a better therapeutic effect than lower doses. Similar information appeared in the leavepiece. The Panel noted that the adult and elderly daily dose of Adcal-D_3 Caplet (two tablets twice a day) delivered a total daily dose of 3000mg of calcium carbonate (equivalent to 1200mg of calcium) and 800IU of colecalciferol (equivalent to 20mcg vitamin D_3).

The Panel considered that the detail aid and leavepiece were clear that the efficacy data included was for 1200mg calcium and 800IU vitamin D_3 daily rather than specifically for Adcal-D_3 Caplet. They were not misleading in that regard. The Panel noted that the marketing authorization for Adcal-D_3 Caplet was granted on the basis of established use including Chapuy *et al* data. The Panel considered that in principle Chapuy *et al* and Tang *et al* could substantiate claims for Adcal-D_3 Caplet and, on this narrow ground, such claims were not misleading. No breaches of the Code were ruled.

The Panel noted that the complainant bore the burden of establishing his/her case on the balance of probabilities. The Panel noted that ProStrakan had denied the allegations but it was unable to identify those concerned and respond in detail to the allegations. The Panel noted that it was difficult in cases involving discussions between representatives and a health professional to know exactly what had transpired. A judgement had to be made on the available evidence. The Panel did not consider that the complainant had shown that, on the balance of probabilities, the representative and his/her manager had failed to maintain a high standard of ethical conduct in relation to claims about the product. No breaches of the Code were ruled.

The Panel noted its rulings above about the representatives but nonetheless was concerned about the briefing material. Whilst it was made clear in the detail aid briefing document that Adcal-D_3 was not included in Tang *et al* no such caveat was applied to Chapuy *et al*. The Panel considered that it was particularly important to give clear instructions to representatives about this matter. The failure to make any relevant comment in relation to Chapuy *et al* followed by unequivocal statements that Adcal-D_3 was not used in Tang *et al* was misleading by omission. The specific briefings on the two studies had not provided the representatives with a clear message in this regard. Consequently the briefing material was likely to lead to a breach of the Code and a breach was ruled. This did not amount to a failure to maintain high standards and no breach, including Clause 2, was ruled.

The Panel noted ProStrakan's submission that it did not offer a switch service but that it did support a therapy review service for patients who might be at risk of osteoporosis. The Panel noted that the Code permitted therapy reviews, providing they enhanced

patient care, or benefited the NHS whilst maintaining patient care.

The Panel noted that the sales force briefing for the review service stated that the service was offered as an aid to improve patient care with respect to the provision of appropriate calcium and vitamin D supplementation. The service comprised of a review conducted within GP practices, which aimed to identify patients who might have calcium and/or vitamin D deficiency and therefore might be at risk of developing osteoporosis.

The briefing stated that the review would focus on patients: receiving bisphosphonates to assess the need for adjunctive calcium/vitamin D therapy; with a Read code of osteoporosis who were not receiving necessary treatment; with a prior fragility fracture and those who were elderly, housebound or institutionalised. The service might also include, if requested, a review of patients in line with an enhanced service for osteoporosis.

The service was open to any GP practice which was computerised and was not to be linked in any way to promotional activity or be carried out in such a way as to be an inducement to prescribe, supply, administer, recommend or buy any medicine. Representatives were instructed that if they had included a product detail in a call then the service should only be discussed in brief and another call arranged to discuss it in detail. If a doctor had volunteered that he wished to switch any patients to a ProStrakan product then the service could not be offered as this would be seen as facilitating a switch programme. The briefing provided detailed steps for the representative to undertake once a practice had agreed to the service and the protocol was signed. The representative introduced the pharmacist carrying out the review to the practice but then the representative was to leave and have no further interaction with the pharmacist. There could be no promotional activity in the location on the day of the therapy review or for three days before or after.

The Panel noted that, without details of the surgery, ProStrakan was unable to respond in detail to allegations about the offer and implementation of the service at the surgery in question. The Panel further noted that the complainant had produced no evidence in relation to the allegation that the service provided by ProStrakan was a switch service and/or that it was offered as such. The Panel did not consider that the calcium and vitamin D therapy review service was a switch service as alleged nor was it offered as such. The service was not an inducement to prescribe, supply, administer, recommend, buy or sell a medicine and no breach was ruled including Clause 2.

An anonymous, non-contactable complainant who signed off his/her complaint 'An aggrieved Surgery' complained about certain practices by ProStrakan Limited and its representatives which the complainant considered unethical. The complaint was in relation to Adcal-D_3 Caplet (calcium carbonate and colecalciferol) which was indicated as an adjunct to specific therapy for osteoporosis and in situations requiring therapeutic supplementation of malnutrition.

COMPLAINT

The complainant stated that he/she recently saw a sales representative and his/her manager who had promoted the latest addition to the Adcal range (Adcal-D_3 Caplet).

However, on closer inspection of the promotional material the complainant noted that it seemed to be the same information used to promote other products from the range. When the complainant questioned the representative and manager he/she was assured that the data in the detail aid and leavepieces were relevant to Adcal-D_3 Caplet and the product was included in the respective clinical trials cited in those materials.

Upon further investigation the complainant considered that the information in ProStrakan's promotional material and the conduct of its representatives was misleading. The studies cited in the promotional material were almost a decade old; so how could Adcal-D_3 Caplet be included in the data when it was not a year old?

The complainant stated that his/her surgery had used ProStrakan's switch programme to swap patients from other calcium supplements to Adcal-D_3 Caplet based on misleading data in the promotional material. However the complainant and his/her colleagues considered that they had compromised their patients by unwittingly believing the data that was put before them and the 'carrot' that was dangled in the form of a switch programme. The surgery had spoken to the local prescribing advisor and would review those patients that had been inconvenienced by the switching of medication. When writing to ProStrakan, the Authority asked it to respond in relation to the requirements of Clauses 7.2, 7.4, 15.2, 15.9, 18.1, 18.4, 9.1 and 2.

RESPONSE

ProStrakan submitted that the complaint concerned data to support promotional claims for Adcal-D_3 Caplet. As the complainant did not stipulate which claims or clinical papers were at issue, ProStrakan assumed that the complaint related to the two key papers which supported the efficacy claims for the product. The other references used in the Adcal-D_3 Caplet materials related either to competitor products or to the therapy area more broadly.

ProStrakan stated that the promotional claims for Adcal-D_3 Caplet were supported by Chapuy *et al* (1992) and Tang *et al* (2007). No data from the use of any of the products in the Adcal range, including Adcal-D_3 Caplet, was included in Chapuy *et al*. However, the results of this study featured prominently in Section 5.1, Pharmacodynamic properties, of the Adcal-D_3 Caplet summary of product characteristics (SPC), which stated:

> 'Strong evidence that supplemental calcium and vitamin D_3 can reduce the incidence of hip and other non-vertebral fractures derives from an 18 month randomised placebo controlled study in 3270 healthy elderly women living in nursing homes or apartments for elderly people. A

positive effect on bone mineral density was also observed.'

The section then discussed the results of Chapuy *et al* in more detail. Indeed, all of the 18 month efficacy data to support the successful marketing authorization application in the UK for Adcal-D_3 Caplet (a bibliographic filing based on established use) were derived from Chapuy *et al*.

ProStrakan submitted that as the regulatory authorities clearly accepted the approach that strong evidence of efficacy could be based on established use and an assumption of a class effect, the Tang *et al* meta-analysis was also relevant to the promotion of Adcal-D_3 Caplet as it included calcium/vitamin D doses equivalent to that of the recommended dose of Adcal-D_3 Caplet, ie 1200mg of elemental calcium and 800IU of colecalciferol daily.

ProStrakan stated that it had not claimed that Adcal-D_3 Caplet or the Adcal product ranges were included in the studies discussed above. Indeed, the Adcal product range was developed at the single commercialised dosage strength because of the work completed by Chapuy *et al* to meet the therapeutic needs identified by this research. As such this study provided the pivotal efficacy data for the UK marketing authorization approval for Adcal-D_3 Caplet and the Adcal product range.

ProStrakan also disputed the complainant's claim that the data was 'old'. Whether data was 'old' was a relative assessment, and one that must be made with consideration to the other information available. ProStrakan's products, and the claims for its products, were supported by the best clinical evidence. Indeed, the efficacy data referred to in the current SPC was approved by the regulatory authorities as recently as last year. The data from Chapuy *et al* had proven satisfactory for licensing purposes for Adcal-D_3 Caplet and the rest of the Adcal range. Given the therapy area, new trials arose infrequently and given the available evidence base, further placebo controlled trials would not receive ethics committee approval given the known benefits of therapy vs the morbidity and mortality risk associated with hip fracture. Tang *et al* provided a more recent and valuable meta-analysis that added significant statistical value to the claims.

ProStrakan submitted that the complainant was correct in that the clinical data used to support Adcal-D_3 Caplet was the same as that included in the materials for the rest of the Adcal range. This was because all these marketing authorization applications took the form of a bibliographic filing based on established use including the Chapuy *et al* efficacy data.

A copy of the sales force briefing document (Key Account Team Brief – Adcal-D_3 Caplet Campaign (ref M004/0018)) was provided which ProStrakan submitted was the brief most likely to be in use when the alleged complaint occurred. This document had been withdrawn from use in line with the undertaking submitted in relation to Case AUTH/2481/2/12. The current briefing differed only in relation to the line concerning the Halal status of the product that was at issue in that case.

ProStrakan stated that this briefing document covered the key materials used to promote Adcal-D_3 Caplet (the detail aid (ref M004/0001), doctor leavepiece (ref M004/0002) and pharmacy leavepiece/sales aid (ref M004/0003)) and gave general information regarding the campaign. While this document covered the key papers cited above, the sales team was not instructed to claim that Adcal-D_3 Caplet (or the Adcal range in general) was included in any of the relevant studies. Indeed, on two occasions the brief explicitly stated that representatives should be clear that the Adcal range was not part of these trials. On page 6 of the document the briefing covered the sales aid to be used in calls. It stated:

'The RCTs [Randomised Controlled Trials] included in the study included varying doses of calcium and/or vitamin D_3 products, and Adcal-D_3 was not used in the trials. It is important that you do not insinuate that Adcal-D_3 was used in any of the trials involved in this meta-analysis.'

This point was later reiterated on page 10 in relation to the pharmacy leavepiece.

A copy of the detail aid and the doctor leavepiece were provided. ProStrakan noted that whilst the clinical trials mentioned above were referenced in both items neither made claims that any member of the Adcal range was included in the studies.

With respects to the complainant's reference to a 'switch programme', ProStrakan clarified that it did not offer a switch service. It did support a therapy review service to facilitate the review of patients who might be at risk of osteoporosis using a practice-agreed protocol specifically designed in conjunction with each participating practice. This service had been reviewed and certified in line with the Code, and was supplied in compliance with it.

A copy of the briefing document used to train representatives on the provision of the therapy review service (ProStrakan Sales Force Briefing: Calcium and Vitamin D Therapy Review Service (ref NPR/0153)) was provided. ProStrakan stated that this document was clear about the strict conditions which governed the provision of the service. ProStrakan's therapy review service was offered to any computerised practice that requested it.

ProStrakan submitted that considerable effort had been made to ensure that the conditions under which the service was offered were in line with the Code. This brief explicitly mentioned the way in which this service was differentiated from switch programmes:

'If the doctor has volunteered that he wishes to switch any patients onto a ProStrakan product, the service cannot be offered, as this would be seen as facilitating a switch programme, which would constitute a breach of the Code.'

ProStrakan stated that the brief also detailed the other regulations it had instituted to ensure that the service was offered in a compliant manner. The service must only be discussed in detail by the sales team in a separate, non-promotional, call.

Representatives were not permitted to be in the practice when the review took place (with the exception of introducing the pharmacist on day one) and no promotional activity could take place three days before or after the review.

In order to further investigate the claims made by the complainant ProStrakan had interviewed key members of staff responsible for the promotion and commercialisation of Adcal-D_3 Caplet. As the complainant was associated with a GP surgery the interviews focused on the key account team (KAT) which worked in primary care. All of the KAT regional managers were interviewed, as were randomly selected representatives from each region. The sales director responsible for the promotion of all ProStrakan products in the UK, was also interviewed. The marketing manager for the Adcal range and the manager responsible for commercial operations in the UK (senior vice president commercial Northern Europe) were also involved.

ProStrakan noted that although the complainant had referred to the national sales manager, no-one in the company had that job title. The equivalent position (ie the individual responsible for sales teams nationally) was the sales director who had not been out on a field visit with a KAT representative in the last six months.

ProStrakan submitted that a number of the interviewees (both management and representatives) commented on how rare it was for a customer to ask questions about the clinical studies which supported Adcal-D_3 Caplet. Most had found that health practitioners were more than happy with the clinical data supporting calcium/vitamin D supplementation. As the Adcal range was well established, and the clinical data consistent throughout the range, most customers met by ProStrakan's teams were already clear on this data.

ProStrakan stated that in advance of specific questions regarding the complaint each interviewee was questioned on the clinical data underpinning the Adcal-D_3 Caplet campaign and the regulations regarding therapy review. Each could reference the key studies and a number spontaneously mentioned that the Adcal range was not included as part of the studies. All were clear on the procedure for offering a therapy review. Considerable surprise was expressed that a customer would still refer to a switch programme. This term was not used by ProStrakan employees.

ProStrakan submitted that the interviews did not identify the individuals referred to by the complainant. The complainant had offered no clues as to his/her identity or location and his/her anonymity meant that no further detail could be sought. ProStrakan had found no evidence that its representatives had acted in contravention to the Code and so the company denied a breach of Clause 15.2.

Further, ProStrakan considered that the briefing documents which instructed its teams on how they should conduct themselves were sufficiently clear and did not advocate a course of action that was likely to lead to a breach of the Code. ProStrakan thus denied a breach of Clause 15.9.

ProStrakan stated that neither the interviews nor the material review identified claims that were not capable of substantiation. The clinical data which underpinned the Adcal-D_3 Caplet campaign clearly corroborated the claims made in it, and was of sufficient quality to support the campaign. ProStrakan argued that neither Clauses 7.2 nor 7.4 had been breached.

ProStrakan noted that its therapy review service offered the practices which requested it the chance to have an independent, third party company review the treatments provided to key patient groups in order to raise the standards of care in relation to osteoporosis. This therapy review service was reviewed and provided under the provision for medical and educational goods and services in the Code. Indeed, ProStrakan had developed appropriate supporting materials to ensure that the integrity of this service to medicine was maintained and that it was provided in a manner that complied with the Code. The brief that accompanied the service clearly stated that it must not be offered to those who had decided to use ProStrakan's products so as to ensure that no confusion could occur on this score. ProStrakan therefore denied a breach of either Clause 18.1 and 18.4.

ProStrakan submitted that high standards had been upheld, and no breach of Clause 9.1 had occurred. As a consequence it also considered that a ruling of a breach of Clause 2 was not justified.

ProStrakan stated that it would value the opportunity to investigate the matter more fully, but without any further detail on the complainant or the employees involved, this was not possible. Whilst it respected the complainant's anonymity, ProStrakan noted that an anonymous complaint limited its ability to investigate allegations in detail and deprived the company of the standard reassurances provided by the PMCPA that the complainant had been asked to declare any conflict of interest.

ProStrakan provided copies of the protocol for the calcium and vitamin D therapy review service (ref NPR/0178) and the specific briefings on Chapuy *et al* (ref M001/1417) and Tang *et al* (ref M001/1422).

PANEL RULING

The Panel noted ProStrakan's submission that the promotional claims made for Adcal-D_3 Caplet were based on Chapuy *et al* and Tang *et al*. The Tang *et al* meta-analysis had included Chapuy *et al*. Neither Tang *et al* nor Chapuy *et al* included any of the Adcal range of products. However, the results of Chapuy *et al* were detailed in Section 5.1, Pharmacodynamic properties, of the Adcal-D_3 Caplet SPC. All of the 18 month efficacy data to support the marketing authorization application in the UK for Adcal-D_3 Caplet were derived from Chapuy *et al*.

The Panel noted ProStrakan's submission that the clinical data used to support claims for Adcal-D_3 was identical to that used for the rest of the Adcal range

because the marketing authorization applications were each a bibliographic filing based on established use, including the Chapuy *et al* data.

The Panel noted that page 3 of the Adcal-D_3 Caplet detail aid (ref M004/0001) was entitled 'The NEW Adcal-D_3 Caplet – offering your patients an effective dose of calcium and vitamin D_3'. The page then went on to detail the results of Chapuy *et al* which confirmed the use of 1200mg elemental calcium and 800IU vitamin D_3 daily in significantly reducing hip fractures and non-vertebral fractures vs placebo over 18 months. Page 4 of the detail aid had the same title and noted that a meta-analysis (Tang *et al*) concluded that daily doses of at least 1200mg calcium and 800IU vitamin D_3 had been shown to achieve a better therapeutic effect than lower doses. Similar information appeared on page 2 of the doctor leavepiece (ref M004/0002). The Panel noted that the adult and elderly daily dose of Adcal-D_3 Caplet (two tablets twice a day), as stated in the SPC, delivered a total daily dose of 3000mg of calcium carbonate (equivalent to 1200mg of calcium) and 800IU of colecalciferol (equivalent to 20mcg vitamin D_3).

Given the above, the Panel considered that the detail aid and doctor leavepiece were clear that the efficacy data included was for 1200mg calcium and 800IU vitamin D_3 daily rather than specifically for Adcal-D_3 Caplet. The Panel did not consider that either the detail aid or the doctor leavepiece were misleading in that regard and no breach of Clause 7.2 was ruled. The Panel noted that the marketing authorization for Adcal-D_3 Caplet was granted on the basis of established use including Chapuy *et al* data. The Panel considered that in principle Chapuy *et al* and Tang *et al* could substantiate claims for Adcal-D_3 Caplet and, on this narrow ground, such claims were not misleading. No breach of Clauses 7.2 and 7.4 were ruled.

The Panel noted that the complainant was anonymous and non-contactable thus further queries could not be raised with him/her. The complainant bore the burden of establishing his/her case on the balance of probabilities. The Panel noted that ProStrakan had denied the allegations but without details of the individuals concerned and/or the surgery it was unable to identify those concerned and respond in detail to the allegations. The complainant alleged that when questioned about the data used in promotional material the representative and national sales manager assured him/her that the data was relevant to Adcal-D_3 Caplet and the medicine was included in the studies cited. The Panel noted that it was difficult in cases involving discussions between representatives and a health professional to know exactly what had transpired. A judgement had to be made on the available evidence. The Panel did not consider that the complainant had shown that, on the balance of probabilities, the representative and his/her manager had failed to maintain a high standard of ethical conduct in relation to claims about the product. No breach of Clause 15.2 was ruled.

The Panel noted that the briefing document 'Key Account Team Brief – Adcal-D_3 Caplet Campaign' (ref M004/0018) stated that pages 3 and 4 of the detail aid focused on the results of two studies in which 1200mg calcium and 800IU vitamin D_3 produced statistically significant results on fragility fractures; page 3 summarised Chapuy *et al* and page 4 featured the key outcomes of the Tang *et al* meta-analysis. The briefing document noted that the randomized controlled trials included in Tang *et al* used varying doses of calcium and/or vitamin D_3 products and Adcal-D_3 was not used in the trials and stated 'It is important that you do not insinuate that Adcal-D_3 was used in any of the trials involved in this meta-analysis'. It was not, however, made clear that Chapuy *et al* was included in this meta-analysis nor did a separate, similar statement appear in relation to page 3 and Chapuy *et al*. The same instruction appeared later in the briefing document in relation to the two leavepieces and was similarly limited to Tang *et al*. Neither of the specific briefings on the two studies clearly and unambiguously stated that Adcal-D_3 was not used in the relevant study. The Panel noted its rulings above about the representatives but nonetheless was concerned about the briefing material. Whilst it was made clear in the detail aid briefing document that Adcal-D_3 was not included in Tang *et al* no such caveat was applied to Chapuy *et al*. The Panel considered that it was particularly important to give clear instructions to representatives about this matter given that the marketing authorization was granted on the basis of existing use. The Panel considered that the failure to make any relevant comment in relation to Chapuy *et al* followed by unequivocal statements that Adcal-D_3 was not used in Tang *et al* was misleading by omission. The specific briefings on the two studies had not provided the representatives with a clear message in this regard. The Panel considered that consequently the briefing material was such that it was likely to lead to a breach of the Code; a breach of Clause 15.9 was ruled.

The Panel did not consider that the briefing document amounted to a failure to maintain high standards and ruled no breach of Clauses 9.1. No breach of Clause 2 was consequently ruled.

Turning to the alleged switch programme, the Panel noted ProStrakan's submission that it did not offer a switch service but that it did support a therapy review service to facilitate the review of patients who might be at risk of osteoporosis. The Panel noted that Clause 18.4 permitted the provision of medical and educational goods and services, including, *inter alia*, therapy reviews, providing they enhanced patient care, or benefited the NHS whilst maintaining patient care, subject to the provisions of Clause 18.1.

The Panel noted that the sales force briefing for the review service (ref NPR/0153) stated that the service was offered as an aid to improve patient care with respect to the provision of appropriate calcium and vitamin D supplementation. The service comprised of a review conducted within GP practices, the aim of which was to identify patients who might have calcium and/or vitamin D deficiency and therefore might be at risk of developing osteoporosis. The review aimed to improve patient care and to benefit the practice and the NHS.

The briefing noted that the review would focus on patients: receiving bisphosphonates to assess the need for adjunctive calcium/vitamin D therapy; with a Read code of osteoporosis who were not receiving necessary treatment; with a prior fragility fracture and those who were elderly, housebound or institutionalised. The service might also include, if requested, a review of patients in line with either the directed enhanced service for osteoporosis (England) or with a local enhanced service or similar.

The Panel noted from the sales force briefing that the service was open to any GP practice which was computerised. It stated that the service must not be linked in any way to promotional activity or be carried out in such a way as to be an inducement to prescribe, supply, administer, recommend or buy any medicine now or in the future. Representatives were instructed that if they had included a product detail in a call then the service should only be discussed in brief and another call arranged to discuss it in more detail. If a doctor had volunteered that he wished to switch any patients to a ProStrakan product then the service could not be offered as this would be seen as facilitating a switch programme. The briefing provided detailed steps for the representative to undertake once a practice had agreed to the service and the protocol was signed. The representative introduced the pharmacist carrying out the review to the practice but then the representative was to leave the practice and have no further interaction with the pharmacist. There could be no promotional activity in the location on the day of the therapy review or for three days before or after.

The service protocol (ref NPR/0178), which was provided to each participating practice prior to the service commencing, stated that it was not linked to the use of any particular product and that the independent prescriber retained full control over the entire process and could amend, remove or add any aspect. Section 2 of the protocol detailed the patient selection criteria as noted in the briefing above and section 3 provided an alphabetical list of 14 calcium and vitamin D formulations. A box at the bottom of the list stated 'Other – please specify'. The review pharmacist would, *inter alia*, search the GP clinical system to identify patients as determined and authorized in the protocol then review each patient file. Summary sheets were prepared by the pharmacist for review, amendment and where necessary authorization by the GP before any changes were made to the patient's electronic records. The summary sheets were left with the practice.

The Panel noted that, without details of the surgery, ProStrakan was unable to respond in detail to allegations about the offer and implementation of the service at the surgery in question. The Panel further noted that the complainant had produced no evidence in relation to the allegation that the service provided by ProStrakan was a switch service and/or that it was offered as such. The Panel did not consider that the calcium and vitamin D therapy review service was a switch service as alleged nor was it offered as such and in that regard it ruled no breach of Clause 18.4. The service was not an inducement to prescribe, supply, administer, recommend, buy or sell a medicine and no breach of Clause 18.1 was ruled.

The Panel noted its rulings above and consequently ruled no breach of Clauses 9.1 and 2.

Complaint received **18 June 2012**

Case completed **5 September 2012**