GENERAL PRACTITIONER v PROSTRAKAN

Provision of a service

A senior partner in a two-handed GP practice complained that his partner and a receptionist had authorised ProStrakan to carry out a survey and that that company was given a list of the patients for it to write to direct and whoever did the survey also wrote [Adcal-D_3] which was promoted and made by ProStrakan.

The detailed response from ProStrakan is given below.

The Panel noted that the complainant firstly queried whether appropriate signatories had been obtained for the Practice Authorisation Form. That dated 6 May 2008 jointly listed the complainant and his partner as the lead GP and the second signatory as the practice manager. The declaration on the form read 'We hereby authorise [the agency] to undertake the Calcium and Vitamin D supplementation project and will inform all partners of this agreement. We are duly authorised to sign this form on behalf of the practice', beneath which the complainant's partner alone signed as the lead GP and the second signatory was the practice manager. The form subsequently signed on 21 July did not mention the complainant; his partner alone was listed as lead GP and signed as such alongside the practice manager.

The Panel noted that the Calcium and Vitamin D Supplementation Clinical Review Protocol required the practice authorisation form to be completed and signed by an authorised independent prescriber and the practice manager prior to any work being undertaken. ProStrakan explained that representatives were instructed to discuss the protocol in detail during a non-promotional call and ensure that any objections had been dealt with. Identification of lead GPs and their approval was dealt with during the detailed discussion of the protocol. In addition ProStrakan explained that the pharmacist from the agency was instructed to check the authorisation form to ensure that all relevant sections were complete and signed by a lead GP and to ensure practice understanding of the service. According to ProStrakan on neither 6 May nor 21 July did practice staff raise issues or concerns regarding either the signatories' authority or the awareness of other partners and the practice of the service.

The Panel noted that the complainant, the senior GP partner, was concerned that the service had been completed without his authorisation. The Panel noted ProStrakan's submission that neither the company nor its agents were responsible for determining whether a medical professional who signed as a lead GP was indeed the lead GP or verifying that signatories had abided by their commitment to inform all partners of the agreement to implement a therapy review. The Panel considered, however, that there might be circumstances where further enquiries about such matters ought to be made. The Panel queried whether the representative and pharmacist should have sought the complainant's view given the reference to him on the first form. The Panel noted however that he had not signed the declaration on the first form. The declaration placed the responsibility on the signatories to inform '… all partners of this agreement'.

ProStrakan had submitted that on 21 July the practice staff raised no concerns or issues regarding the authorisation of the therapy review. The Panel considered that whilst it was impossible to determine exactly what had transpired at the practice it had insufficient evidence to indicate that the service had not been authorised as required by the protocol. The Panel considered that although it might have been prudent to obtain the complainant's signature, failure to do so, given the declaration signed by his partner, did not mean that high standards had not been maintained. No breach of the Code was ruled.

The Panel noted that the service was run by an agency on behalf of ProStrakan. The protocol provided that ProStrakan played no role in the service provision other than reimbursement of the service provider. ProStrakan did not receive a list of practices or any patient details or have any patient contact. The pharmacist wrote to patients in accordance with the agreed protocol. There was no evidence before the Panel that ProStrakan had received patient data and/or written to patients as alleged. No breach of the Code was ruled.

The Panel noted the complainant's allegation that whoever did the survey also wrote ProStrakan's medicine. The Panel noted that any change in medicine as a result of the service had to be agreed by the lead doctor. The Panel considered that it did not have an allegation about whether the service was acceptable, as the complainant had made no specific comment in this regard. The Panel noted that pharmaceutical companies could provide medical and educational goods and services, including therapy review programmes, but these needed to comply with the Code. It was not necessarily a breach of the Code for products from the company providing the service to be prescribed. Taking all the circumstances into account the Panel decided in relation to the complainant's allegation that there was no breach of the Code.

A general practitioner complained about a calcium

and vitamin D_3 service run by ProStrakan Group plc. ProStrakan provided Adcal-D_3, a calcium and vitamin D_3 supplement.

COMPLAINT

A senior partner in a two-handed GP practice, complained that his partner and a receptionist had signed papers authorising ProStrakan to carry out a survey and that that company was given a list of the patients for it to write to direct and whoever did the survey also wrote [Adcal-D_3] which was promoted and made by ProStrakan.

When writing to ProStrakan the Authority asked it to respond in relation to Clauses 2, 9.1 and 18.1 of the Code.

RESPONSE

ProStrakan explained that on 6 May the practice was visited by two therapy review pharmacists from its agent. There appeared to have been a mix-up however, since the practice staff were unaware that the visit was to occur. The complainant's partner and the practice manager signed the protocol agreement. However, the therapy review did not occur on that occasion as the practice was not prepared and requested that the review be performed at a later date. An appointment was made for 21 July. Once again, the protocol was signed by the complainant's partner and the practice manager and the therapy review was implemented on that date.

ProStrakan noted the original protocol dated 6 May listed two GPs as 'lead'. The second protocol listed the complainant's partner as lead GP. He signed as lead GP on both occasions. Section 1 of the protocol signed 21 July stated 'We hereby authorise [the agency] to undertake the calcium and vitamin D_3 Deficiency Clinical Review and will inform all partners of this agreement. We are duly authorised to sign this form on behalf of the practice'. [the authorisation form dated 6 may described the service as 'The Calcium and Vitamin D Supplementation Project']. The complainant's partner signed this section of the protocol agreement. ProStrakan and its agents were not responsible for determining whether a medical professional who signed as a lead GP was indeed the lead GP for that practice, particularly when the form indicated that that individual was a lead GP. By the same token, ProStrakan and its agents were not responsible for verifying that signatories had abided by their commitment to inform all partners of the agreement to implement a therapy review.

Both signed protocols also indicated that one signatory was the practice manager, and she had signed as such. She signed the same section of the protocol as the complainant's partner, confirming her authority to approve the therapy review protocol. Again, it was not for ProStrakan or its agents to determine whether a signatory was or was not the practice manager.

ProStrakan took no part in the implementation of the therapy review service. Section 1 of the protocol clearly indicated that a named agency would undertake the therapy review. Section 4.2 of the protocol specified that 'ProStrakan will have no role in the service provision beyond reimbursement of [the agency]'.

ProStrakan was not given a list of patients by the practice. Rather, this was given to the agency pharmacist who conducted the agreed therapy review. ProStrakan did not see, nor did it wish to see, any patient details pertaining to the therapy review service. Nor did ProStrakan have any direct contact with any patient involved in the therapy review. According to Section 4.10 of the signed protocol agreement, 'Each patient will be informed of any change to their medication and any additional instructions necessary to ensure appropriate use, in accordance with the wishes of the individual practice'.

The complainant had indicated that the practice had provided a list of patients so that they could be written to. In writing to these patients, the pharmacist had therefore complied with the wishes of the practice as per the agreed protocol.

The preference for Adcal-D_3 on page 3 of the protocol was completed by the complainant's partner. He had also signed Section 5 of the protocol, to confirm that he had seen and reviewed the patient lists generated as a result of the therapy review and authorised the therapy review pharmacist to implement the agreed changes. In writing to the specified patients with letters indicating Adcal-D_3, ProStrakan's agent had again complied with the documented wishes of the practice and in accordance with the protocol agreement. These letters were discussed with, and approved by, the complainant's partner prior to being sent to patients.

A table listed the requested documentation and detailed the ProStrakan response in each case. ProStrakan provided copies of signed protocols dated 6 May 2008 and 21 July 2008. The company explained that no additional training materials were provided to the site. Full details of the service were contained in the protocol document and discussed with the site prior to implementation. Letters to patients contained patient identifiers and were therefore not seen or kept by ProStrakan.

ProStrakan regretted that the implementation of the therapy review service had led to a complaint at this site. Nevertheless, ProStrakan and its agents had acted at all times in agreement with the protocol which was signed by persons at the site who identified themselves as individuals with the authority to sign such a document. ProStrakan noted that there appeared to be a degree of misunderstanding on the part of the complainant as to the roles of ProStrakan and the agency pharmacist. It also appeared that the protocol

signatories did not abide by their commitment to inform all partners of the agreement, despite there being ample opportunity between the first and second visits of the therapy review staff for this to occur. ProStrakan trusted that its response clarified the situation and allayed the complainant's concerns.

In response to a request for further information ProStrakan explained that the first practice authorisation form was still valid for a visit on 21 July. However, due to the delay between the first and second visits, as a matter of good working practice, a second form was used. This was to ensure that the information pertaining to the practice and its instructions for the pharmacist were accurate and up-to-date.

The complainant's signature was not sought on 21 July. The complainant's partner had identified himself as lead GP with authorisation to sign the practice authorisation form on behalf of the practice. Both 6 May and the 21 July forms identified him as a lead GP for the practice. On both occasions, he signed in the box marked 'Lead GP Signature'. The sentence immediately prior to his signature read 'We are duly authorised to sign this form on behalf of the practice'. Since he had identified himself twice as a lead GP with the authority to allow the therapy review on behalf of the practice, there was no indication to the pharmacist that further signatures were required prior to commencement of the review. Had the practice indicated that the complainant's signature was necessary prior to commencement of the review, it would have been sought and the review would not have proceeded until it had been obtained.

Instructions about the status of the authorising GP were given to the representatives and agency personnel in the respective briefing documents.

For representatives, the brief stated, 'The pharmacist will only carry out work on behalf of the GP as authorised by a signature on the authorisation form… Only if authorised by the signatory GP in section 5 of the authorisation form will the pharmacist conduct any medication changes on the practice computer system for each patient'. The brief contained instructions to discuss the protocol 'in detail' (but not during a sales call) and to seek the agreement of the individual and ensure that any objections had been dealt with. Section 1 of the protocol, the practice authorisation form, contained boxes for recording of lead GP details and also for the lead GP signature. Identification of lead GP(s) and their approval was therefore covered during the detailed discussion of the protocol. Once all discussions had taken place, the brief stated the authorisation form might be completed and 'must be signed by an authorised practice signatory'.

The agency brief stated 'The [agency] pharmacist will attend the practice to:

- Clarify aims and objectives of the service
- Ensure Practice understanding of the service'

Furthermore, on the day of the visit, 'The pharmacist will check the Authorisation Form to ensure that all relevant sections are completed and signed as appropriate'. The [agency] pharmacist would therefore check that the authorisation form had been signed by a lead GP or would obtain their signature if it was not already on the form.

The agency pharmacists were instructed to check the authorisation form on the day of their visit and to clarify the aims and objectives of the service and ensure practice understanding of the service. These discussions allowed the practice staff to highlight any issues that might impact upon the implementation of the service.

ProStrakan understood that a full discussion between the pharmacist and practice staff occurred on 21 July, as evidenced by the completion and signature of a new protocol on that date. This was in accordance with the brief given to the agency pharmacists.

On 21 July the practice staff raised no concerns or issues regarding the authorisation of the therapy review, or any others that might have impacted on the implementation of the review.

The steps taken to ensure the lead GP had agreement from all other partners in the practice were as follows: the representative was briefed to discuss the protocol, including the practice authorisation form, in detail; the representative was briefed to 'Ask the GP to seek agreement from all the partners in the practice. An agreed time period for this is crucial and will also test the individual's commitment to the offer. If necessary re-book another appointment, to gain confirmation from other partners that they are happy with the service'. It should be noted that the practice did not request an additional appointment for other partners, during either the visit on 6 May or 21 July; the pharmacist was briefed to check the authorisation form and ensure practice understanding of the service; in discussing and checking the authorisation form, the representative and pharmacist highlighted to practice staff the requirement for signature by individuals authorised to do so on behalf of the practice and the individual who identified himself as lead GP was required to sign the practice authorisation form which [on the form dated 6 May] stated 'We hereby authorise [the agency] to undertake the Calcium and Vitamin D Supplementation Project and will inform all partners of this agreement' [the authorisation form dated 21 July described the service as 'the calcium and vitamin D_3 Deficiency Clinical Review']. The complainant's partner duly signed this section on both 6 May and 21 July and therefore gave this undertaking twice.

In summary, both the representative and pharmacist were briefed to ensure that practice staff fully understood the protocol and its requirements. Such an understanding was based on a comprehensive discussion of each of the individual parts of the protocol, including the practice authorisation form. This form allowed the practice to identify staff with

the requisite authority to approve the therapy review. The form also required that the signatories commit to informing all partners of the agreement.

In this case, discussions with the practice staff occurred twice and on neither occasion did practice staff raise issues or concerns regarding either the signatories' authority or the awareness of other partners at the practice of the therapy review. Had any concerns been raised regarding these issues, the therapy review would not have occurred unless and until the issues had been resolved.

PANEL RULING

The Panel noted that the complainant firstly queried whether appropriate signatories had been obtained for the practice authorisation form. That dated 6 May 2008 jointly listed the complainant and his partner as the lead GP and the second signatory as the practice manager. The declaration on the practice authorisation form read 'We hereby authorise [the agency] to undertake the Calcium and Vitamin D supplementation project and will inform all partners of this agreement. We are duly authorised to sign on behalf of the practice', beneath which the complainant's partner alone signed as the lead GP and the second signatory was the practice manager. The form subsequently signed on 21 July did not mention the complainant; his partner alone was listed as lead GP and signed as such alongside the practice manager.

The Panel noted that the Calcium and Vitamin D Supplementation Clinical Review Protocol required the practice authorisation form to be completed and signed by an authorised independent prescriber and the practice manager prior to any work being undertaken. The Panel noted ProStrakan's explanation that representatives were instructed to discuss the protocol in detail during a non-promotional call and ensure that any objections had been dealt with. Identification of lead GPs and their approval was dealt with during the detailed discussion of the protocol. In addition ProStrakan explained that the pharmacist was instructed to check the authorisation form to ensure that all relevant sections were complete and signed by a lead GP and to ensure practice understanding of the service. According to ProStrakan on neither 6 May or 21 July did practice staff raise issues or concerns regarding either the signatories' authority or the awareness of other partners and the practice of the service.

The Panel noted that the complainant, the senior GP partner, was concerned that the service had been completed without his authorisation. The Panel noted ProStrakan's submission that neither the company nor its agents were responsible for determining whether a medical professional who signed as a lead GP was indeed the lead GP or verifying that signatories had abided by their commitment to inform all partners of the agreement to implement a therapy review. The Panel considered, however, that there might be circumstances where further enquiries about such matters ought to be made. The Panel queried whether the representative and pharmacist should have sought the complainant's view given the reference to him on the first form. The Panel noted however that he had not signed the declaration on the first form. The declaration placed the responsibility on the signatories to inform '... all partners of this agreement'.

ProStrakan had submitted that on 21 July the practice staff raised no concerns or issues regarding the authorisation of the therapy review. The Panel considered that whilst it was impossible to determine exactly what had transpired at the practice there was insufficient evidence before it to indicate that the service had not been authorised as required by the protocol. The Panel considered that although it might have been prudent to obtain the complainant's signature the failure to do so, given the declaration signed by his partner, did not mean that high standards had not been maintained. Thus the Panel ruled no breach of Clause 9.1.

The Panel noted that the service was run by an agency on behalf of ProStrakan. A pharmacist ran the service at the practice in consultation with the lead GP. Section 4.2 of the protocol provided that ProStrakan played no role in the service provision other than reimbursement of the service provider. ProStrakan did not receive a list of practices or any patient details or have any patient contact. The pharmacist wrote to patients in accordance with the agreed protocol. There was no evidence before the Panel that ProStrakan had received patient data and/or written to patients as alleged. No breach of Clause 9.1 was ruled in this regard.

The Panel noted the complainant's allegation that whoever did the survey also wrote [Adcal-D_3] which was promoted and made by ProStrakan. The Panel noted that any change in medicine as a result of the service had to be agreed by the lead doctor. The Panel considered that it did not have an allegation about whether the service was acceptable, as the complainant had made no specific comment in this regard. The Panel noted that pharmaceutical companies could provide medical and educational goods and services, including therapy review programmes. Such services needed to comply with the Code, particularly Clause 18.4. It was not necessarily a breach of the Code for products from the company providing the service to be prescribed. Taking all the circumstances into account the Panel decided in relation to the complainant's allegation that there was no breach of Clause 18.1 and ruled accordingly.

Given its rulings above the Panel also ruled no breach of Clause 2.

Complaint received	**4 December 2008**
Case completed	**12 February 2009**