

HOSPITAL CHIEF PHARMACIST v SERVIER

Conduct of representative

A hospital chief pharmacist complained on behalf of an NHS trust about the activities of a Servier representative promoting Protelos (strontium ranelate).

The complainant made a number of allegations concerning: repeated and frequent requests for time with a consultant; provision of biscuits and other snacks for secretarial staff in order to gain access to the consultant; interrupting the consultant during an outpatient clinic; promotion of Protelos to junior medical and ward staff; obtaining clinical details of an inpatient; repeated requests to seek an appointment with the complainant, when the representative was told that the complainant did not see company representatives; entering clinical areas of the hospital uninvited to obtain names of pharmacists to contact later and on refusal of an appointment with the medicines management pharmacist, going to the ward on which this pharmacist routinely worked to find her to promote Protelos.

The Panel noted that the number of contacts with the consultant in the twelve months prior to the representative being asked not to visit the trust (6 proactive calls, 3 at the consultant's request and 2 chance encounters) exceeded that permitted by the supplementary information to the Code. A breach of the Code was ruled as acknowledged by Servier.

The provision of biscuits and snacks for secretarial staff in order to gain access to health professionals was contrary to the Code which prohibited the use of inducements to gain an interview. A breach of the Code was ruled as acknowledged by Servier.

The Panel noted that the representative had visited an outpatient clinic to see the consultant at the end of July 2006. The Panel noted that the parties' accounts of this visit differed. The complainant stated that the visit was in the middle of an outpatient clinic whilst the company stated that the representative arrived after the last patient had left. The complainant understood that the representative had asked to discuss clinical details of a hospital inpatient. Servier denied this stating that the request was to discuss the management of geriatric inpatients. Given these differing accounts the Panel considered that it was not possible to determine whether on the balance of probabilities the representative's conduct amounted to breaches of the Code and thus no breach was ruled.

With regard to the allegation that the representative had promoted Protelos to junior medical and ward staff who had subsequently pressurised the ward consultant, the Panel noted that the complainant did not identify those grades of ward staff that had been promoted to. The Panel was concerned that the representatives' training material referred to student nurses, auxiliary nurses and medical students and did not differentiate between contact with these and more senior staff such as consultants. Despite its concerns about the briefing material and in the absence of further information from the complainant, the Panel did not know to whom the product had been promoted or the hospital policy in this regard. No breach of the Code was ruled.

With respect to the allegation that the representative had obtained details of a hospital inpatient, the Panel noted that

the parties' accounts differed. Servier denied the allegation. The complainant had not responded to the Panel's request for further information. It was impossible to determine where the truth lay. No breach of the Code was ruled.

Similarly, in relation to the allegation that the representative had sought appointments with the complainant despite knowing that she did not see representatives, the parties' accounts differed. The Panel did not know where the truth lay and thus ruled no breach of the Code.

In relation to the allegation that the representative had entered clinical areas of the hospital uninvited and obtained names of pharmacists, the Panel considered that whether such conduct was ever acceptable in the absence of a clear invitation to do so would depend, *inter alia*, on the hospital policy. The Panel was concerned that the representatives' briefing document whilst instructing representatives to enter ward areas and such like did not provide any advice on the relevant requirements of the Code. The Panel noted that the acceptability of the representatives' briefing material was the subject of a separate complaint, Case AUTH/1906/10/06. Without further information from the complainant the Panel considered that there was insufficient evidence to establish whether, on the balance of probabilities, such conduct was contrary to either hospital policy, or any direction from those health professionals concerned, to establish breaches of the Code. No breach was ruled.

In relation to the attempts to see the medicines management pharmacist, the Panel noted that the parties' accounts differed. The Panel also noted its comments above about the existence of a hospital policy and activity in clinical areas. It was impossible to determine where the truth lay. The Panel ruled no breach of the Code.

The Panel noted its rulings of breaches of the Code above in relation to call rates and the provision of biscuits and snacks for secretarial staff. The Panel was concerned about the activities of the representative. High standards had not been maintained. A breach of the Code was ruled. Nonetheless the Panel considered that overall, the circumstances did not warrant a ruling of a breach of Clause 2 which was reserved for particular censure.

A district general hospital chief pharmacist complained on behalf of an NHS trust about the way in which a representative of Servier Laboratories Limited promoted Protelos (strontium ranelate).

COMPLAINT

The complainant alleged the following against the representative:

- Repeated and frequent requests for time with a consultant rheumatologist. These requests and just bumping into the consultant outside her office appeared to be more frequent than just by chance.
- Provision of gifts of biscuits and other snacks for secretarial staff in order to gain access to the consultant.
- Requests for the consultant to give the representative two minutes of her time whilst she was in the middle of an outpatient clinic. This request was to discuss clinical details of an inpatient from ward 10 of the hospital which was highly inappropriate.
- Direct promotion of Protelos to junior medical and ward staff. The consultant of this ward was subsequently pressurised to prescribe this medicine. Promotion of a medicine in this way was unacceptable to the organisation.
- Obtaining clinical details of a hospital inpatient.
- Repeated requests for an appointment with the complainant, the chief pharmacist, even though the representative was told that she did not see company representatives.
- Entering the clinical areas of the hospital uninvited and obtaining names of pharmacists whom he later tried to contact.
- On refusal of an appointment with the medicines management pharmacist, going to the ward on which this pharmacist routinely worked to find her and to discuss and promote Protelos.

The trust alleged that the representative was in breach of the Code, particularly with regard to the handling of appointments with health professionals within the trust. The representative had used inducements to try to gain appointments and the frequency and duration of his calls had caused a great deal of inconvenience. He had inappropriately promoted Protelos to junior medical and nursing staff and had used specific patient details in his conversations with consultants.

The complainant had met the representative in July and informed him that he was no longer permitted to visit the trust.

When writing to Servier, the Authority asked it to respond in relation to Clauses 2, 9.1, 15.2, 15.3, 15.4 and 15.9 of the Code.

RESPONSE

As soon as Servier knew of these serious allegations, the representative was suspended pending detailed further investigation and appropriate resolution of the complaint. As a direct result of Servier's investigations, the representative was undergoing a disciplinary procedure. Every aspect of the representative's conduct in this matter had been comprehensively investigated. Servier confirmed that serious disciplinary action would be taken against the representative and that he might be dismissed from the company.

Call frequency

The representative recorded a total of eleven contacts

with the consultant in question in the 12 months prior to being asked not to visit the trust by the complainant. Of these calls six were proactive, three were at the request of the consultant to deliver requested data and two were chance encounters in the corridor of the hospital, with no discussions. Servier accepted that this proactive call rate was more frequent than permitted by the Code and regretted any inconvenience that this and the manner in which they occurred had caused the consultant. As a result, Servier accepted a breach of Clause 15.4 of the Code.

Provision of biscuits and snacks

The representative had in the past provided biscuits and snacks for secretarial staff. Servier knew that this might have been an issue earlier in 2006 and so on 15 March 2006 it told all field based staff that this was not acceptable activity (a copy of the memorandum was provided). Since then the representative had not provided snacks etc and his expense claims had been audited to ensure compliance. In light of this Servier accepted that there had been a breach of Clause 15.3 but that clear direction had ensured that this would not happen again.

Outpatient clinic visit

The representative visited an outpatient clinic at the end of July 2006 in order to see the consultant. He arrived in the clinic after the last patient had left. He gave his card to the nurse and asked to see the consultant to discuss the management of elderly patients on a hospital ward. The nurse passed the card to the consultant who said she did not have time to see the representative. He subsequently left. This happened once. At no time during that visit did he discuss or suggest the discussion of an individual patient's clinical details. Servier therefore denied breaches of Clauses 15.2, 15.3 or 15.4.

Clinical details of a patient

Servier noted that the complainant had twice alleged that the representative had obtained clinical details of inpatients. Servier had questioned the representative in detail and was convinced that he never had requested access to individual patient details. The representative tried to discuss the use of Protelos in general terms with the consultant as it might be relevant to a geriatric inpatient population. This had been prompted at the suggestion of a ward manager but the representative never had access to individual patient details. The representative and Servier were fully aware that it was totally inappropriate for a representative to have or request access to such records. Servier did not consider that there was any evidence to support a breach of Clause 15.2.

Promotion of Protelos to junior medical and ward staff

Servier noted that the complainant did not explain why the promotion of Protelos to junior medical staff and ward staff was unacceptable to the trust. It was legitimate for a representative to promote a product to health professionals that included ward staff and junior medical staff under Clause 1.1 of the Code. There was no evidence that the representative was able or tried to get these staff to pressurise the

consultant. In the absence of such evidence or a clearly written or communicated policy and given that the activity was legitimate, there had been no breach of the Code.

Requests to see the complainant

Servier stated that the representative tried to contact the complainant twice between January 2005 and July 2006. Whilst he was unable to secure an appointment on either occasion he was not told that the complainant did not see representatives. In light of this, two attempts to obtain an appointment with a key health professional in the trust in a 19 month period was not inappropriate and was not of a frequency liable to cause inconvenience. Servier did not believe that there had been a breach of Clauses 15.2 or 15.4.

Entering clinical areas

Neither Servier nor the representative knew of a trust policy or direction that representatives should not enter a clinical area of the hospital without permission. Without such direction it was not inappropriate for this to happen provided that the work of the clinical area or patient care was not interfered with or compromised.

Hospital pharmacists were key health professionals and were important contacts for representatives. Obtaining the names of this key group was important and to ask members of staff in clinical areas was not inappropriate. In addition, contacting pharmacists to arrange appointments was not inappropriate in the absence of a direction or policy to the contrary. Neither direction nor policy existed within the trust to Servier's knowledge.

Servier did not accept that this action was inappropriate or in breach of the Code including Clauses 15.2 and 15.4.

Medicines management pharmacist

The representative attempted to contact the medicines management pharmacist through an enquiry at the pharmacy; he was told that she was on the ward. He subsequently went to the ward to attempt to discuss the possibility of an appointment. Unfortunately the pharmacist was not on the ward and so the representative left having neither talked to nor obtained an appointment. Servier did not believe that there was anything inappropriate in these actions especially in the absence of direction or a clear trust policy. Servier submitted that there had therefore been no breach of the Code, including Clauses 15.2 and 15.4.

Briefing Documents

In the 12 months prior to the complaint the representative's team was asked to have twelve 1:1 calls with rheumatologists. This was reflected in a PowerPoint presentation. During this 12 month period, Protelos was a new medicine in the immediate post launch period with a considerable amount of new evidence being published, including the presentation of bone biopsy data. At this time physician experience with Protelos was extremely limited for a chronically prescribed new chemical

entity with long-term treatment outcomes. In addition, during this period it was anticipated that there would be a number of formulary decisions being made in the field of osteoporosis. In light of these considerations, Servier set the target to include proactive calls as well as calls to deliver new data at the request of the clinician and data to support the formulary process as requested by the clinician.

The briefing material in the form of a PowerPoint presentation told representatives how to behave in hospitals (a copy was provided) in an appropriate manner and to ensure that they complied with hospital regulations.

The representative was under review for under performance primarily as a result of the quality of his interaction with health professionals and not because of call frequency. He was therefore not encouraged to breach the Code with respect to call frequency or through inappropriate behaviour. Servier took the Code with the utmost seriousness and would not encourage or sanction any activity that would be likely to lead to a breach. Servier therefore did not consider that it had breached Clause 15.9.

This representative's activity had not been consistent with Servier's clear instruction given to him to ensure his activity did not breach the Code. Whilst Servier accepted that there had been some failings of this individual, it did not believe that it had failed to maintain high standards and thus did not believe there had been a breach of Clause 9.1. Servier also did not believe that the actions of this individual presented a case for the particular censure for bringing discredit upon or reducing confidence in the pharmaceutical industry and thus there was no breach of Clause 2.

Issues following investigation

Servier had conducted an extensive investigation into the activities of the representative with specific reference to the hospital. As a result of this investigation Servier provided details about the use of emails and letters which were in breach of the Code. Details were provided and these were taken up with Servier as a separate complaint, Case AUTH/1889/9/06.

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The complainant was asked on a number of occasions to comment on the points raised by Servier in its response and to advise whether the hospital had a written policy on the conduct of sales representatives and their access to health professionals, to provide a copy of it and to explain how it was disseminated. The complainant did not respond to these requests for additional information.

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PANEL RULING

The Panel noted that Clause 15 required, *inter alia*, that representatives must at all times maintain a high

standard of ethical conduct (Clause 15.2) and not employ any inducement etc to gain an interview (Clause 15.3). Representatives should ensure that the frequency, timing, duration of calls and the manner in which they were made did not cause inconvenience. The wishes of individuals on whom representatives wished to call and the arrangements in force at any particular establishment, must be observed (Clause 15.4). The supplementary information to Clause 15.4 of the Code stated that the number of calls made on a prescriber each year must not exceed 3 on average, excluding group meetings, a call which was requested by the doctor or other prescriber, a call to respond to a specific enquiry or a visit to follow up a report of an adverse event reaction.

The Panel noted that the number of contacts with the consultant in the twelve months prior to the representative being asked not to visit the trust (6 proactive calls, 3 at the consultant's request and 2 chance encounters) exceeded that permitted by the supplementary information to Clause 15.4 of the Code. A breach of Clause 15.4 of the Code was ruled as acknowledged by Servier.

The provision of biscuits and snacks for secretarial staff in order to gain access to health professionals was contrary to Clause 15.3 which prohibited the use of inducements to gain an interview. The Panel noted that the company had issued a memorandum clearly stating that such conduct was unacceptable. A breach of Clause 15.3 was ruled as acknowledged by Servier.

The Panel noted that the representative had visited an outpatient clinic to see the consultant at the end of July 2006. The Panel noted that the parties' accounts of this visit differed. The complainant stated that the visit was in the middle of an outpatient clinic whilst the company stated that the representative arrived after the last patient had left. The complainant understood that the representative had asked to discuss clinical details of a hospital inpatient. Servier denied this stating that the request was to discuss the management of geriatric inpatients. Given the parties' differing accounts it was impossible to determine where the truth lay. The Panel considered that the evidence before it was such that it was not possible to determine whether on the balance of probabilities the representative's conduct amounted to a breach of Clauses 15.2 and 15.4 of the Code and thus no breach of these clauses was ruled.

With regard to the allegation that the representative had promoted Protelos to junior medical and ward staff who had subsequently pressurised the ward consultant, the Panel noted that the complainant did not identify those grades of ward staff that had been promoted to. The Panel noted that Protelos was indicated for the treatment of postmenopausal osteoporosis to reduce the risk of hip and vertebral fractures. Whilst promotion to health professionals and appropriate administrative staff was permitted the material had to be appropriate and tailored towards the audience (Clauses 1.1 and 12.1). The Panel was concerned that the representatives' training material referred to student nurses, auxiliary nurses and medical students and did not differentiate between contact with these and more senior staff such

as consultants. The Panel queried whether given the product's licensed indication it would be appropriate to promote Protelos to, *inter alia*, an auxiliary nurse. Nonetheless, despite its concerns about the briefing material and in the absence of further information from the complainant, the Panel did not know to whom the product had been promoted or the hospital policy in this regard. The Panel thus ruled no breach of Clauses 15.2 and 15.4 of the Code.

With respect to the allegation that the representative had obtained details of a hospital inpatient, the Panel noted that the parties' accounts differed. Servier denied the allegation. The complainant had not responded to the Panel's request for further information. It was impossible to determine where the truth lay. No breach of Clause 15.2 was ruled.

Similarly, in relation to the allegation that the representative had sought appointments with the complainant despite knowing that she did not see representatives, the parties' accounts differed. The Panel did not know where the truth lay and thus ruled no breach of Clauses 15.2 and 15.4 of the Code.

The Panel noted the allegation that the representative had entered clinical areas of the hospital uninvited and obtained names of pharmacists. In the Panel's view, representatives should take great care when entering clinical areas at a hospital. Whether such conduct was ever acceptable in the absence of a clear invitation to do so would depend, *inter alia*, on the hospital policy. The Panel was concerned that the representatives' briefing document whilst instructing representatives to enter ward areas and such like did not provide any advice on the relevant requirements of Clauses 15.2 and 15.4 of the Code. The Panel noted that the acceptability of the representatives' briefing material was the subject of a separate complaint, Case AUTH/1906/10/06. Nonetheless without the benefit of further comment from the complainant the Panel considered that there was insufficient evidence to establish whether, on the balance of probabilities, such conduct was contrary to either hospital policy or any direction from those health professionals concerned to establish a breach of Clauses 15.2 or 15.4 of the Code. No breach was ruled accordingly.

In relation to the attempts to see the medicines management pharmacist, the Panel noted that the parties' accounts differed. The Panel also noted its comments above about the existence of a hospital policy and activity in clinical areas. It was impossible to determine where the truth lay. The Panel ruled no breach of Clauses 15.2 and 15.4 of the Code.

The Panel noted its rulings of breaches of the Code above in relation to call rates and the provision of biscuits and snacks for secretarial staff. The Panel was concerned about the activities of the representative. High standards had not been maintained. A breach of Clause 9.1 was ruled. Nonetheless the Panel considered that overall, the circumstances did not warrant a ruling of a breach of Clause 2 which was reserved for particular censure.

Complaint received	21 August 2006
Case completed	16 January 2007