

CASE AUTH/2094/1/08

PRESCRIBING ADVISOR v SERVIER

Provision of samples and heart rate monitors

A prescribing advisor, on one of the Channel Islands, complained about the provision of samples of Procoralan and heart rate monitors by Servier.

The complainant stated that early last year Procoralan was turned down for inclusion on the island's prescribing list, which meant that it could not be prescribed at public expense. Servier representatives, however, offered a consultant cardiologist samples of Procoralan. A copy of the correspondence and paperwork was provided. The hospital's policy was that all samples must be received via pharmacy. Only medicines already on the formulary would be accepted. The pharmacy department was not asked by Servier's representative to handle these samples. The complainant alleged a breach of the Code because this attempt to supply samples did not comply with the hospital's requirements. It was an ill-disguised attempt to circumvent the approval process for new medicines. It was inconceivable that the Servier representative would not have known that Procoralan was turned down for use on the island.

The complainant further alleged that Servier had offered the consultant cardiologist heart rate monitors as an inducement to start patients on Procoralan.

The Panel noted Servier's submission that, to date, the samples had not been provided; there thus could be no breach of the Code and the Panel ruled accordingly.

With regard to the provision of heart rate monitors, the Panel noted that the representatives' briefing material stated '[The heart rate monitors] are not a promotional aid and therefore must be delivered in a separate call to a promotional call. You should not enter into a promotional discussion with the doctor when delivering the monitors'. The briefing notes were signed by 'The Procoralan Team' which the Panel considered could link the monitors to the promotion of Procoralan.

An email from the representative to the doctor provided by the complainant referred to the Procoralan samples and also stated 'I would like to thank you for your time..... You should also be receiving your heart rate monitors by next week, let me know if they are useful to you'. The email concluded with a request for the name of another doctor so that the representative could '... keep him updated about Procoralan and Coversyl'. The Panel did not know what was said at the meeting. Nevertheless the email gave a poor impression. It referred to a promotional discussion and the provision of a medical good and implied that both had been discussed at the meeting. This was unacceptable as the provision of medical and educational goods and services must not be linked to the promotion of a medicine. The Panel considered that in the email the representative had not separated the

provision of the heart rate monitors from the promotion of Procoralan. The representative had not maintained a high standard of conduct and thus a breach of the Code was ruled.

The Panel considered that heart rate monitors would enhance patient care and would be acceptable as long as their provision met the requirements of the Code. The Panel noted its comments about the email and the meeting. It also noted Servier's submission about the provision of the monitors and the instructions to representatives. There was no evidence that the monitors had been used as an inducement to prescribe. No breach of the Code was ruled.

A prescribing advisor, on one of the Channel Islands, complained about the provision of samples of Procoralan (ivabradine) and heart rate monitors by Servier Laboratories Ltd. Procoralan was indicated for the symptomatic treatment of chronic stable angina pectoris in patients with normal sinus rhythm, who had a contraindication or intolerance to beta-blockers.

COMPLAINT

The complainant stated that early last year Procoralan was turned down for inclusion on the island's prescribing list, which meant that it could not be prescribed in either primary or secondary care at public expense. A GP and a consultant cardiologist had requested its approval. Neither appealed this decision, although they were permitted to do so.

In November 2007 Servier representatives met the consultant cardiologist and offered him samples of Procoralan to trial on some of his patients. A copy of the correspondence and paperwork was provided. However the island's hospital pharmacy was not asked to receive, store or dispense these samples. The hospital's policy on medicines was that all samples must be received via pharmacy. Only medicines already on the formulary would be accepted. The chief pharmacist and his deputy were never asked by Servier's representative to handle these samples.

The complainant alleged a breach of the Code because the Code stated that the offering of samples must comply with individual hospital requirements. This attempt to supply samples did not comply with the hospital's requirements and was in clear breach of the hospital's policy. It was an ill-disguised attempt to circumvent the approval process for new medicines. It was inconceivable that the Servier representative would not have known that Procoralan was turned down for use on the islands.

The complainant further alleged that Servier had offered the consultant cardiologist heart rate monitors as an inducement to start patients on Procoralan.

When writing to Servier the Authority asked it to respond in relation to Clauses 2, 9.1, 15.2, 17.8 and 18.1 of the Code.

RESPONSE

Servier submitted that, to date, the samples referred to by the complainant had not been provided to the consultant cardiologist. Correspondence between the representative and the cardiologist regarding the samples was via the doctor's personal/private email. In addition, the address provided by the cardiologist for receipt of the samples was the cardiologist's private clinic. Subsequently the cardiologist had independently, without Servier's knowledge, taken Procoralan to the hospital Drugs and Therapeutics Committee. The representative had not intended to supply the samples to the cardiologist for hospital use. In view of this Servier submitted that there was no breach of Clause 17.8 as the samples were not intended for the hospital; the representative knew that Procoralan had not been accepted on to the hospital's formulary. Therefore overall, Servier submitted that the representative had maintained high standards and was not in breach of Clause 15.2.

Servier submitted that it took pride in maintaining the highest standards at all times, and the representative faithfully adhered to this principle. There was thus no breach of Clause 9.1 of the Code.

Servier submitted that elevated heart rate had been associated with an increased risk of all-cause mortality and cardiovascular mortality in patients with pre-existing coronary artery disease and was recognised as an important factor in the management of angina pectoris (Graham *et al* 2007). Yet its value seen by cardiologists remained low. With respect to this Servier offered heart rate monitors as medical goods for patient use in the monitoring and management of heart rate in angina pectoris. The heart rate monitors were offered via a reply paid card, which was mailed to consultant cardiologists in the UK thus providing them all with the opportunity to request the item. The heart rate monitors were delivered by representatives in a non-promotional call as per the briefing notes; a procedure followed in this case. In addition, each heart rate monitor was provided with a 'Heart Rate Monitoring Form' for patient use, and an 'Angina Patient Heart Rate Follow-Up Form' for use by the doctor to allow appropriate heart rate recording and management of patients. The heart rate monitors were provided as an aid to patient care; there was no link between them and any Servier product. Servier had received spontaneous positive feedback about the provision of the monitors and their use in the management of patients with cardiac disease. Overall therefore, Servier submitted that there was no breach of Clause 18.1.

Servier stated that it was clear that none of this activity had brought discredit upon, or reduced confidence in, the pharmaceutical industry and thus there was no breach of Clause 2.

PANEL RULING

The Panel noted Servier's explanation about the

arrangements between the representative and the doctor in relation to the samples. It did not know where the meeting had taken place. The delivery address was not the hospital. It might have been helpful if the sample request form was clear that the samples were to be provided for use with private patients and not NHS hospital use. Procoralan had a marketing authorization and could be promoted. It was not on the island's prescribing list which meant it could not be prescribed at public expense. It could however be prescribed for private patients. The Panel noted Servier's submission that, to date, the samples had not been provided to the requesting doctor for use in his private practice. Thus there could be no breach of Clause 17.8 and the Panel ruled accordingly.

With regard to the provision of heart rate monitors, the Panel noted that representatives' briefing material stated '[The heart rate monitors] are not a promotional aid and therefore must be delivered in a separate call to a promotional call. You should not enter into a promotional discussion with the doctor when delivering the monitors'. The briefing notes were signed by 'The Procoralan Team' which the Panel considered could link the monitors to the promotion of Procoralan.

The Panel examined the email from the representative to the doctor provided by the complainant. The email referred to the Procoralan samples to be used as a trial in patients over the forthcoming months. It also stated 'I would like to thank you for your time..... You should also be receiving your heart rate monitors by next week, let me know if they are useful to you'. The email concluded with a request for the name of another doctor so that the representative could '... keep him updated about Procoralan and Coversyl'. The Panel did not know what was said at the meeting. Nevertheless the email gave a poor impression. It referred to a promotional discussion and the provision of a medical good and implied that both had been discussed at the meeting. This was unacceptable as the provision of medical and educational goods and services must not be linked to the promotion of a medicine. The Panel considered that in the email the representative had not separated the provision of the heart rate monitors from the promotion of Procoralan. The representative had not maintained a high standard of conduct and thus a breach of Clause 15.2 was ruled.

The Panel considered that heart rate monitors would enhance patient care and would be acceptable as long as their provision met the requirements of Clause 18 of the Code. The Panel noted its comments of about the email and the meeting. It also noted Servier's submission about the provision of the monitors and the instructions to representatives. There was no evidence that the monitors had been used as an inducement to prescribe. No breach of Clauses 18.1 and 18.4 was ruled.

The Panel did not consider that the circumstances amounted to a breach of either Clause 9.1 or Clause 2 and ruled accordingly.

Complaint received 31 January 2008

Case completed 5 March 2008