NURSE v SYNER-MED

Question at a meeting

A nurse complained about a meeting organised by Syner-Med at the recent British Renal Society meeting.

The complainant stated that one of the speakers gave a talk on giving Syner-Med's product Venofer, an injectable iron preparation (iron sucrose), in the community. A delegate asked about the safety issues of giving intravenous (iv) iron in the community. In reply another delegate from the audience stated that they had got around this by sending people away with an EpiPen (adrenaline injection). The speaker and several representatives from Syner-Med made no comment which gave the impression that cardio-pulmonary resuscitation procedures could be replaced with an EpiPen.

The detailed response from Syner-Med is given below.

The Panel noted that Syner-Med had sponsored the meeting in question; one of the speakers acted as a consultant to Syner-Med on a part-time basis. Syner-Med had supplied two of the speakers with slide templates and ten of Syner-Med's staff had attended the meeting. Syner-Med submitted that although the meeting was about chronic renal disease and the future of iv iron treatment, it was not about Venofer in particular. One of a speaker's slides referred to iv iron sucrose but the presentation appeared to be about anaemia management and not Venofer *per se*. The question and answer at issue had occurred in the open session of the meeting. It appeared that in response to a question from a delegate about the safety issues of giving iv iron in the community another delegate had referred to the use of an EpiPen. It was impossible for the Panel to know the exact question and answer or the context in which they had occurred. Nonetheless it appeared that the discussion was general and not about Venofer in particular. Syner-Med had submitted that the question was not specifically directed at Syner-Med's consultant and so she had had no reason to intervene.

The Panel noted that the Venofer summary of product characteristics (SPC) stated that parenterally administered iron preparations could cause allergic or anaphylactoid reactions which might be potentially fatal. Therefore treatment for serious allergic reactions and facilities with the established cardio-pulmonary resuscitation procedures should be available.

Given the implications for patient safety the Panel considered that it might have been helpful if someone had reminded the audience about cardio-pulmonary resuscitation during the discussion of the EpiPen. (EpiPen was injectable adrenalin for use in allergic emergencies). Given the lack of details, however, the Panel was satisfied that, on the balance of probabilities, the audience was not left with the impression that EpiPen could replace cardio-pulmonary resuscitation as alleged. No breach of the Code was ruled.

A nurse complained about a meeting organised by Syner-Med (Pharmaceutical Products) Limited at the recent British Renal Society (BRS) meeting.

COMPLAINT

The complainant stated that one of the speakers gave a talk on giving Syner-Med's product Venofer, an injectable iron preparation (iron sucrose), in the community. A delegate asked about the safety issues of giving intravenous (iv) iron in the community. In reply another delegate from the audience stated that they had got around this legality by sending people away with an EpiPen (adrenaline injection). The speaker and several representatives from Syner-Med made no comment which gave the impression that cardio-pulmonary resuscitation procedures could be replaced with an EpiPen.

When writing to Syner-Med, the Authority asked it to respond in relation to Clauses 7.2, 7.9 and 7.10 of the 2006 Code. The case was considered under the 2008 Constitution and Procedure.

RESPONSE

The Syner-Med symposium (100 plus delegates) was listed in the programme of the BRS Conference on Thursday,15 May. The lunchtime educational meeting, entitled 'Anaemia in chronic kidney disease: The future of iv iron treatment', lasted 60 minutes and was chaired by a leading UK renal consultant. Three presentations of approximately 15 minutes were given, followed by questions.

The presentations were: anaemia in chronic kidney disease (renal consultant); prediction of iron requirements in pre-dialysis patients (clinical scientist) and how the latest evidence can support changes in clinical practice (nurse advisor). The last presentation was given by a former nurse consultant at a London hospital who had worked as a research nurse in anaemia management. She was well qualified to lecture on the subject and to answer relevant questions. Her talk covered aspects of her work at the hospital.

There were Syner-Med representatives in the audience as noted by the complainant.

Syner-Med explained that in the open session (last 10 minutes of meeting) there were a number of questions that were answered by different members of the panel under the direction of the chairman. The panel members were sat together at the front of the meeting. The speaker in question was not at the podium, but sat with the panel members and took questions as requested of her.

During the open discussion, the chairman raised the issue with the audience that the Department of Health agenda for future chronic kidney disease management required that consideration should be given to the administration of iv iron nearer to the patient's home. This prompted a very general question from a delegate 'What about safety issues of giving iv iron in the community?' As noted by the complainant the questioner did not specify a product and it was not directed to anyone specifically. Also as noted a nurse delegate answered the question and referred to her own experience relating to the provision of EpiPens to patients on home haemodialysis. Her answer went no further than providing a short headline statement about a product used locally in the home haemodialysis setting, and a statement that there had not been any problems over a number of years. The answer did not explain the details of this practice but it was a valid interjection and an appropriate response to the question. The complainant was of the opinion that the statement regarding the use of an EpiPen was inadequate and that either the nurse advisor in question or Syner-Med personnel should have intervened. The company disagreed. The original question was not addressed to the nurse advisor so she had no reason to intervene. The provision of an EpiPen in the community was not inappropriate as it was first line treatment in the event of an anaphylactic reaction in the community in line with the Resuscitation Council's Guideline 2008, so Syner-Med had no reason to intervene. Also, it was not appropriate for Syner-Med to comment either on other medicines or the clinical practice of health professionals.

If the complainant, or any other delegate, thought that the meeting would have benefited from a more detailed explanation on the use of an EpiPen or of cardio-pulmonary resuscitation then there was opportunity to ask a follow-up question. To suggest that the meeting was left with the impression that cardio-pulmonary resuscitation could be replaced with an EpiPen was a subjective interpretation which the company refuted. There was no discussion about cardio-pulmonary resuscitation.

Syner-Med rejected the view that it had been negligent, or that it had a duty to supply additional corrective information to the meeting. There was nothing that required correction and the audience requested no additional information. All the information, claims and comparisons at the meeting over which the company had control were accurate, balanced and fair and did not mislead. Syner-Med strenuously refuted the allegation that it had breached Clauses 7.2, 7.9 or 7.10.

Syner-Med provided details of the three speakers and their presentations and of the company employees who were present.

None of the slides presented by the speakers were provided by the company. A background template was supplied that was used by two speakers. Each speaker's presentation represented their own area of experience, knowledge or clinical research. The company did not contribute to the content of the presentations. Each presenter was invited to speak at the symposium based on the expert knowledge they could share with the audience.

As was very evident from the slides, the symposium was educational and not promotional. The focus was on iv iron management and was not product specific. There were no brand names used in any of the three sets of slides.

The presentation referred to by the complainant was entitled 'Using evidence to inform change in practice: Anaemia management' and covered recognition that evidence was required to change clinical practice and identification of the need to change current practice to facilitate a growing need to treat patients with iv iron infusions. All data referred to by the speaker was collected whilst she was employed as a nurse consultant. The tone of the presentation was educational with emphasis on changing practice to meet the needs of patients and changing service delivery.

PANEL RULING

The Panel noted that Syner-Med had sponsored the lunchtime meeting in question; one of the speakers acted as a consultant to Syner-Med on a part-time basis. Syner-Med had supplied two of the speakers with slide templates and ten of Syner-Med's staff had attended the meeting. Syner-Med submitted that although the meeting was about chronic renal disease and the future of iv iron treatment, it was not about Syner-Med's product Venofer in particular. One of a speaker's slides referred to iv iron sucrose but the presentation appeared to be about anaemia management and not Venofer *per se*. The question and answer at issue had occurred in the open session of the meeting in the last 10 minutes. It appeared that a delegate had asked about the safety issues of giving iv iron in the community and another delegate had stated that they had got around this legality by sending people away with an EpiPen. It was impossible for the Panel to know the exact question and answer or the context, ie the wider discussion, in which they had occurred. Nonetheless it appeared that the discussion was a general one and not about Venofer in particular. Syner-Med had submitted that the question was not specifically directed at Syner-Med's consultant and so she had had no reason to intervene.

The Panel noted that the Venofer summary of product characteristics (SPC) stated in Section 4.4, Special warnings and precautions for use, that parenterally administered iron preparations could cause allergic or anaphylactoid reactions which might be potentially fatal. Therefore treatment for serious allergic reactions and facilities with the established cardio-pulmonary resuscitation procedures should be available.

Given the implications for patient safety the Panel considered that it might have been helpful if someone had reminded the audience about cardio-pulmonary resuscitation during the discussion of the EpiPen. (EpiPen was injectable adrenalin for use in allergic emergencies). Given the lack of details, however, the Panel was satisfied that, on the balance of probabilities, the audience was not left with the impression that EpiPen could replace cardio-pulmonary resuscitation as alleged. No breach of Clauses 7.2, 7.9 and 7.10 was ruled.

Complaint received **17 July 2008**

Case completed **16 September 2008**