CASE AUTH/2170/9/08

SENIOR HOSPITAL NURSE/DIRECTOR v SYNER-MED

Ferinject brochure

A senior hospital nurse complained about a two page brochure 'Anaemia Service… Redesigning Provision' for Ferinject (ferric carboxymaltose) produced by Syner-Med.

The complainant stated that a colleague had obtained the brochure at a study day in Warwick on 19 September. After reading the brochure concerns were raised that iron had been administered incorrectly. The unit had given CosmoFer [a product marketed by Vitaline Pharma UK] on a second administration of 1,500mg over four hours yet the brochure stated 1,000mg over six hours. The brochure had caused unfounded anxiety and gave incorrect information as CosmoFer had been administered correctly.

The Authority noted that it appeared that the item at issue was identical to that ruled in breach in Case AUTH/2149/8/08 and so it asked Syner-Med to comment in relation to a possible breach of undertaking. It was the Authority's responsibility to ensure compliance with undertakings.

The detailed responses from Syner-Med are given below.

The Panel noted that in Case AUTH/2149/8/08 the brochure at issue had been ruled in breach of the Code as, *inter alia*, it was misleading to only refer to the infusion time for CosmoFer as 6 hours when the summary of product characteristics (SPC) stated that it could be administered over 4-6 hours. The Panel considered that its ruling in that case covered the complainant's allegation in the case now before it, Case AUTH/2170/9/08.

With regard to the undertaking given in the previous case, both parties agreed that the brochure had not been obtained from the company stand on 19 September. There was no evidence that the brochure had been supplied by Syner-Med after it had given its undertaking to withdraw it and thus there could be no breach in that regard.

A senior hospital nurse complained about a two page brochure 'Anaemia Service… Redesigning Provision' (ref F09/07-05-08-045) for Ferinject (ferric carboxymaltose) produced by Syner-Med (Pharmaceutical Products) Limited.

COMPLAINT

The complainant stated that a colleague had obtained the brochure at a study day in Warwick on 19 September. After reading the brochure concerns were raised that iron had been administered incorrectly. The unit had given CosmoFer [a product marketed by Vitaline Pharma UK] on a second administration of 1,500mg over four hours yet the brochure stated 1,000mg over six hours. The brochure had caused unfounded anxiety and gave incorrect information as CosmoFer had been administered correctly.

When writing to Syner-Med, the Authority asked it to respond in relation to Clause 7.2 of the Code. The Authority noted that it appeared that the item at issue was identical to that ruled in breach in Case AUTH/2149/8/08 and so it asked the company to comment in relation to Clause 25 which concerned breaches of undertakings. It was the Authority's responsibility to ensure compliance with undertakings.

RESPONSE

Syner-Med stated that on 18 August it undertook to withdraw, *inter alia*, the brochure at issue with immediate effect. Each hospital sales specialist was requested in writing to stop using the specified items immediately and to return all stock with a detail stock list. All stock of each item held at head office was immediately isolated and removed from the secure storage area to an off site lock-up pending destruction.

The local area hospital sales specialist attended the haematology study day held in Warwick on 19 September. The hospital sales specialist had confirmed that the brochure 'Anaemia Service, Redesigning Provision' was not available on the stand. He also confirmed that two previously unopened boxes of other brochures were opened at the venue, thus eliminating any risk of the box containing an incorrect brochure.

The company respectfully asked if the name of the complainant's colleague could be checked against the study day delegate list which was provided. It was possible that a health professional could have been given the detail aid at a meeting prior to 18 September.

The company had made every effort to ensure the detail aids in question had been recalled and destroyed and denied a breach of Clause 25.

The Authority asked Syner-Med to comment on the complainant's concerns and the complainant to name the colleague who had attended the study day.

FURTHER RESPONSE FROM SYNER-MED

Syner-Med stated that the CosmoFer summary of product characteristics (SPC) recommended that the total amount of CosmoFer, up to 20mg/kg bodyweight, was infused over 4-6 hours.

The brochure at issue compared the currently available iron products and the amount of time that it might take to administer 1,000mg of each. There had been no attempt to provide specific prescribing information regarding the minimum or maximum dosage for any product over a particular time and no attempt to provide specific prescribing information for individual patients.

The information regarding the administration of CosmoFer 1,000mg as a 6 hour infusion was correct and in line with its SPC.

The company was mindful that material should only provide meaningful comparisons between comparative pharmaceutical products when appropriate and should not replace an SPC to provide detailed prescribing information.

The company did not believe that it had provided incorrect or misleading information in breach of the Code or that the brochure at issue had been distributed after Syner-Med had given its undertaking to withdraw it, contrary to Clause 25.

FURTHER COMMENTS FROM THE COMPLAINANT

The complainant stated that the colleague would not allow their name to be revealed and that the leaflet had been obtained from another person at the study day and not from the stand itself.

PANEL RULING

The Panel noted that in a previous case, Case AUTH/2149/8/08 the brochure at issue had been ruled in breach of Clause 7.2 as it was misleading to only refer to the infusion time for CosmoFer as 6 hours when the SPC stated that it could be administered over 4-6 hours. The Panel had also commented that any comparison of the different methods of administration for Ferinject and CosmoFer should make it abundantly clear as to which method and dose was being cited for each. The Panel considered that its ruling in the previous case covered the complainant's allegation in the case now before it, Case AUTH/2170/9/08.

With regard to the undertaking given in the previous case, both parties agreed that the brochure had not been obtained from the company stand on 19 September. There was no evidence that the brochure had been supplied by Syner-Med after it had given its undertaking to withdraw it and thus there could be no breach of Clause 25.

Complaint received **30 September 2008**

Case completed **12 November 2008**