COMPLAINANT v ALEXION

Conference programme booklet

A contactable complainant alleged that Alexion Pharma UK's entry in the programme booklet for a UK medical society meeting, held in Sheffield in November 2015, promoted an unlicensed medicine.

The detailed response from Alexion is given below.

The Panel noted that the programme booklet included a list of the pharmaceutical companies and other organisations which had exhibited at or sponsored the event together with a paragraph about each. The paragraph about Alexion referred to the establishment of a premier global metabolic rare disease franchise with the development of two late-stage therapies, Strensiq for hypophosphatasia and Kanuma for lysosomal acid lipase deficiency. In the Panel's view some readers might consider that the wording implied that Strensiq and Kanuma were still in the late stages of development and that was not so. The Panel, however, noted Alexion's submission that the wording referred to the global development stage of the medicines and that both Strensiq and Kanuma had received a UK marketing authorization in August 2015 and therefore no pre-licence promotion had taken place at the meeting in November 2015. The Panel thus ruled no breaches of the Code including no breach of Clause 2.

A contactable complainant, who wished to remain anonymous, complained about Alexion Pharma UK's entry in the programme booklet for the British Society for Paediatric Endocrinology and Diabetes (BSPED) meeting, held in Sheffield from 25-27 November 2015. Alexion was one of a number of pharmaceutical companies that had sponsored the meeting.

COMPLAINT

The complainant alleged that Alexion had promoted an unlicensed medicine and he provided pictures of the programme and text that was of concern. The complainant did not state which unlicensed medicine was at issue but text from the programme provided by him stated, *inter alia*, that 'Alexion is also establishing a premier global metabolic rare disease franchise with the development of two late-stage therapies, Strensiq (asfotase alfa) for hypophosphatasia (HPP) and Kanuma (sebelipase alfa) for Lysosomal Acid Lipase Deficiency (LAL-d)'.

When writing to Alexion, the Authority asked it to respond in relation to Clauses 2, 3.1, 3.2, and 9.1 of the Code.

RESPONSE

Alexion submitted that its exhibition stand at the BSPED meeting had contained educational material designed to improve disease awareness of hypophosphatasia. Alexion submitted that it also had a corporate statement in the programme booklet which described the company and included a statement on the global development status of Strensiq and Kanuma. Alexion submitted that both medicines had received marketing authorizations on 28 August 2015 so there was no pre-licence promotion at the meeting in November 2015; a link to the electronic Medicines Compendium (eMC) website was provided.

Alexion submitted that it had taken into account Clauses 2, 3.1, 3.2 and 9.1 and considered that the documents provided proved that there was no promotion of any unlicensed medicines at the meeting and therefore no breaches of the Code. Alexion provided copies of the approved materials used at the meeting.

In response to a request from the case preparation manager for further information, Alexion provided copies of the Kanuma and Strensiq summaries of product characteristics (SPCs) and an original copy of the programme booklet. Alexion submitted that the programme booklet was given to each delegate upon arrival as part of an information pack distributed by BSPED at the registration desk.

PANEL RULING

The Panel noted the complainant's allegation that Alexion had promoted an unlicensed medicine. The Panel noted that the programme booklet included a list of the pharmaceutical companies and other organisations which had exhibited at or sponsored the event together with a paragraph about each. The paragraph about Alexion referred to the establishment of a premier global metabolic rare disease franchise with the development of two late-stage therapies, Strensiq for hypophosphatasia and Kanuma for lysosomal acid lipase deficiency. In the Panel's view some readers might consider that the wording implied that Strensiq and Kanuma were still in the late stages of development and that was not so. The Panel, however, noted Alexion's submission that the wording referred to the global development stage of the medicines and that both Strensiq and Kanuma had received a UK marketing authorization in August 2015 and therefore no pre-licence promotion had taken place at the meeting in November 2015. The Panel thus ruled no breach of Clause 3.1. The Panel noted that Alexion had been asked to respond in relation to the requirements of Clause 3.2 which required that the promotion of a medicine be in accordance with the terms of its marketing authorization and must not be inconsistent with the particulars listed in its summary of product characteristics. In the Panel's view the complainant has not alleged a breach of that clause and the Panel ruled no breach

accordingly. The Panel subsequently ruled no breach of Clauses 9.1 and 2.

During the consideration of this case, the Panel noted that Alexion's entry into the programme booklet referred to Soliris (eculizumab), Strensiq and Kanuma and the indications for each. It was also stated that the company was evaluating potential indications for Soliris in additional severe and rare disorders. The Panel queried whether the entry went beyond being a corporate piece, as submitted by Alexion, and instead promoted the three medicines cited. The Panel was concerned that as promotional copy the paragraph did not comply with the requirements of the Code such as the need to include prescribing information and avoid exaggerated claims etc; it requested that Alexion be advised of its concerns.

Complaint received **26 November 2015**

Case completed **28 January 2016**