CASE AUTH/2802/11/15

ALK-ABELLÓ v BAUSCH & LOMB

Use of the word 'new'

ALK-Abelló UK complained about a promotional article published in Pulse as a Pulse Quick Guide. The article was entitled 'New approaches in management and treatment of anaphylaxis' and discussed various features of adrenaline auto injectors including Emerade marketed by Bausch & Lomb. Page 1 of the Pulse Quick Guide stated that the material had been initiated, developed, and funded by Bausch & Lomb; an advertisement for Emerade appeared on the reverse.

Emerade was indicated for the emergency treatment of severe acute allergic reactions (anaphylaxis) triggered by allergens in foods, medicines, insect stings or bites, and other allergens as well as for exercise-induced or idiopathic anaphylaxis.

ALK-Abelló alleged that the claim 'Emerade offers a new higher dose…' implied that a new higher dose of Emerade had been launched within the last 12 months. This was not so. The Emerade summary of product characteristics (SPC) stated that the first date of marketing authorization was 3 January 2013. ALK-Abelló alleged a breach of the Code.

The detailed response from Bausch & Lomb is given below.

The Panel noted that the Emerade 500mcg SPC stated that the date of first marketing authorization/ renewal of authorization was 3 January 2013. The Panel further noted Bausch & Lomb's submission that the 500mcg dose referred to in the claim at issue had been available for over 12 months. The Panel ruled a breach of the Code as acknowledged by Bausch & Lomb.

ALK-Abelló UK complained about an article (ref EME-UK-1507-04, prepared July 2015) published in Pulse as a Pulse Quick Guide. The article was entitled 'New approaches in management and treatment of anaphylaxis' and discussed various features of adrenaline auto injectors including Emerade marketed by Bausch & Lomb UK Ltd.

Emerade was indicated for the emergency treatment of severe acute allergic reactions (anaphylaxis) triggered by allergens in foods, medicines, insect stings or bites, and other allergens as well as for exercise-induced or idiopathic anaphylaxis.

COMPLAINT

Page 1 of the Pulse Quick Guide stated that the material had been initiated, developed, and funded by Bausch & Lomb; an advertisement for Emerade appeared on the reverse. In ALK-Abelló's view, the Pulse Quick Guide was promotional and needed to comply with the Code.

ALK-Abelló alleged that a claim in the conclusion section, 'Emerade offers a new higher dose…' implied that a new higher dose of Emerade had been launched within the last 12 months which was not so. The Emerade summary of product characteristics (SPC) stated that the first date of marketing authorization was 3 January 2013. ALK-Abelló alleged a breach of Clause 7.11.

RESPONSE

Bausch & Lomb stated that unfortunately the claim 'Emerade offers a new higher dose...' was not compliant with the requirements of Clause 7.11 as the higher dose had been available for over 12 months. Bausch & Lomb sincerely apologised for the oversight and gave assurance that going forward it would ensure vigilance in checking materials and that particular clause.

Bausch & Lomb submitted that the Pulse Quick Guide was a one-off publication which did not have any on-line coverage, nor were any additional laminated copies made and it had not been circulated by Bausch & Lomb sales teams. The company had written to Pulse to advise that the article must not be reprinted or circulated in any form as it was not in compliance with Clause 7.11. There should not be any further situations where a health professional would be exposed to the material.

PANEL RULING

The Panel noted that Clause 7.11 required that the word 'new' must not be used to describe any product or presentation which had been generally available, or any therapeutic indication which had been generally promoted, for more than twelve months in the UK. The Panel noted that the Emerade 500mcg SPC stated that the date of first marketing authorization/renewal of authorization was 3 January 2013. The Panel further noted Bausch & Lomb's submission that the 500mcg dose referred to in the claim 'Emerade offers a new higher dose…' had been available for over 12 months. The Panel ruled a breach of Clause 7.11 as acknowledged by Bausch & Lomb.

Complaint received **5 November 2015**

Case completed **11 December 2015**