CASE AUTH/2817/12/15

ALK-ABELLÓ/DIRECTOR v BAUSCH & LOMB

Breach of undertaking

ALK-Abelló alleged that Bausch & Lomb UK had failed to comply with the undertaking given in Case AUTH/2802/11/15 regarding use of the word 'new' in relation to the promotion of Emerade (adrenaline auto-injector). The claim now at issue appeared on a website.

As the complaint concerned an alleged breach of undertaking it was taken up by the Authority in the name of the Director as the Authority was responsible for ensuring compliance with undertakings.

The detailed response from Bausch & Lomb is given below.

The Panel noted that Bausch & Lomb had accepted the ruling of a breach in Case AUTH/2802/11/15 in relation to the claim 'new higher dose' for Emerade which appeared in a Pulse Quick Guide. The company's undertaking was signed on 10 December and stated that the last date the material was used or appeared was September 2015.

The Panel noted that a form of undertaking and assurance was an important document. Companies had to give an undertaking that the material in question and any similar material, if not already discontinued or no longer in use would cease forthwith and give an assurance that all possible steps would be taken to avoid similar breaches of the Code in future. It was very important for the reputation of the industry that companies complied with undertakings.

The Panel noted Bausch & Lomb's submission that following its provision of the undertaking it ensured that all references to the word new had been removed from printed material. The Panel further noted that in March 2015, and unconnected to the previous complaint, Bausch & Lomb had instructed the website administrator to remove all reference to the word new from the Emerade website. Bausch & Lomb submitted that it understood that that had been actioned and its checks confirmed this to be so. The webpage now at issue was on the section of the Emerade website for health professionals and was the second page that they were likely to click on. In that regard the Panel queried the robustness of the checks carried out by Bausch & Lomb. Regardless of why, the Panel considered that as the Emerade website continued to describe Emerade as 'new', after Bausch & Lomb had given its undertaking in Case AUTH/2802/11/15, it had failed to comply with that undertaking. Thus the Panel ruled a breach of the Code. High standards had not been maintained and a breach of Code was ruled. The Panel considered that Bausch & Lomb's failure to comply with its undertaking brought discredit upon and reduced confidence in, the pharmaceutical industry. A breach of Clause 2 was ruled.

ALK-Abelló Ltd alleged that Bausch & Lomb UK Ltd had failed to comply with the undertaking given in Case AUTH/2802/11/15 regarding use of the word 'new' in relation to the promotion of Emerade (adrenaline auto-injector). A breach of Clause 7.11 was ruled in that case.

As the complaint concerned an alleged breach of undertaking it was taken up by the Authority in the name of the Director as the Authority was responsible for ensuring compliance with undertakings.

COMPLAINT

ALK-Abelló alleged that the claim 'The new adrenaline auto-injector for emergency treatment of anaphylaxis' which appeared on an Emerade website breached the undertaking given in Case AUTH/2802/11/15.

ALK-Abelló noted that the top of the webpage clearly stated 'Information for healthcare professionals only in the UK'. The website was promotional and should comply with the Code. ALK-Abelló was concerned that the webpage referred to Emerade as new. It noted the title of the page 'The new adrenaline auto-injector for emergency treatment of anaphylaxis', and further down the page 'New Emerade'. The references to 'new' were despite the ruling in Case AUTH/2802/11/15; a breach of Clause 29 was alleged.

When writing to Bausch & Lomb, the Authority asked it to respond in relation to Clauses 9.1 and 2 of the 2015 Code in addition to Clause 29 cited by ALK-Abelló.

RESPONSE

Bausch & Lomb submitted that as per its undertaking in Case AUTH/2802/11/15 to remove all references to the word 'new' in its promotional materials, it had taken great care with all printed materials to ensure that that was so and submitted that it was fully compliant.

Case AUTH/2802/11/15 referred to an article published in Pulse, Bausch & Lomb notified the publishers that no further distribution or copies of the inserts should be made which the publishers agreed. Bausch & Lomb's sales teams did not have any copies of the insert to distribute so no withdrawal was required.

At the end of February 2015, Bausch & Lomb assumed the sales and marketing of Emerade from the previous distributor. One of its first actions on 2 March 2015 was to request the removal of all references to the word 'new' from the Emerade.com website by the website administrator. Bausch & Lomb understood that this had been done and its checks confirmed this to be so. Turning to

Case AUTH/2817/12/15 Bausch & Lomb was very concerned that one of the webpages had been overlooked and still included the word 'new'. In mitigation Bausch & Lomb submitted that it was not a deliberate action to deviate from its undertaking and it would implement better processes to avoid similar issues going forward.

PANEL RULING

The Panel noted that in the previous case, Case AUTH/2802/11/15, ALK-Abelló had complained in November 2015 about the claim 'Emerade offers a new higher dose …' which appeared in a Pulse Quick Guide and implied that a new higher dose of Emerade had been launched within the last 12 months. The Panel noted that the Emerade 500mcg summary of product characteristics (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 had been available for over 12 months. A breach of Clause 7.11 was ruled which was accepted by Bausch & Lomb; the company's undertaking signed on 10 December 2015 stated that September 2015 was the last date the material was used or appeared.

The Panel noted that a form of undertaking and assurance was an important document. Companies had to give an undertaking that the material in question and any similar material, if not already discontinued or no longer in use would cease forthwith and give an assurance that all possible steps would be taken to avoid similar breaches of the Code in future (Paragraph 7.1 of the Constitution and Procedure). It was very important for the reputation of the industry that companies complied with undertakings.

The Panel noted Bausch & Lomb's submission that following its provision of the undertaking it had taken great care with all printed materials to ensure that all references to the word new had been removed. The Panel further noted that in March 2015, and unconnected to the previous complaint, Bausch & Lomb had instructed the website administrator to remove all reference to the word new from the Emerade website. Bausch & Lomb submitted that it understood that that had been actioned and its checks confirmed this to be so. No copies of the correspondence between the parties etc were provided. The webpage now at issue was on the section of the Emerade website for health professionals and was the second page that they were likely to click on. In that regard the Panel queried the robustness of the checks carried out by Bausch & Lomb. Regardless of why, the Panel considered that as the Emerade website continued to refer to 'New Emerade' and 'The new adrenaline auto-injector for emergency treatment of anaphylaxis' after Bausch & Lomb had given its undertaking in Case AUTH/2802/11/15, it had failed to comply with that undertaking. Thus the Panel ruled a breach of Clause 29. High standards had not been maintained and a breach of Clause 9.1 was also ruled. The Panel noted the importance of complying with undertakings and considered that Bausch & Lomb's failure to comply with its undertaking brought discredit upon and reduced confidence in, the pharmaceutical industry. A breach of Clause 2 was ruled.

During its consideration of this case the Panel was concerned that Bausch & Lomb had only stated that it reviewed printed materials after providing its undertaking in Case AUTH/2802/11/15 in December 2015. The undertaking covered all closely similar materials and so, regardless of their format, all materials should have been examined. The Panel requested that its concerns be drawn to Bausch & Lomb's attention.

Complaint received **23 December 2015**

Case completed **2 February 2016**