

# PHARMACEUTICAL PHYSICIAN v STIRLING ANGLIAN

## Use of the word 'new'

A pharmaceutical physician, who until recently worked in the industry but now provided oncology consultancy services, complained that on its website for health professionals, Stirling Anglian Pharmaceuticals described Stirlescent (naproxen effervescent tablets) and theiCal-D3 (1000mg/880IU chewable tablet) as 'new' despite both having been on the market for over 12 months. The complainant could see no evidence that any part of the website had been certified.

The detailed response from Stirling Anglian is given below.

The Panel noted that, as acknowledged by Stirling Anglian, theiCal-D3 was still described as 'new' on its health professional website on 2 January 2017, despite the product having been available for more than 12 months. A breach of the Code was ruled.

With regard to Stirlescence, although, as stated on the website, it was licensed in the UK on 3 December 2015, it was not generally available until 25 May 2016. The medicine, however, had been promoted to health professionals from 10 March 2016 and so in that regard it could continue to be described as 'new' until 9 March 2017. The Panel noted that this complaint was received in January 2017 and thus it ruled no breach of the Code.

The Panel noted that the Constitution and Procedure was such that complainants had the burden of proving their complaint on the balance of probabilities. The complainant had alleged that he/she could see no evidence that any part of the Stirling Anglian website had been certified for promotional use. Stirling Anglian stated that although the website had been certified, no certificate could be found. This was highly unsatisfactory. Noting the company's account and that the complainant bore the burden of proof, and given the lack of evidence that the website had not been certified, the Panel ruled no breach of the Code.

A pharmaceutical physician, who until recently worked in the industry but now provided oncology consultancy services, complained about Stirling Anglian Pharmaceuticals Limited's use of the word 'new' on its website for health professionals to describe Stirlescent (naproxen effervescent tablets) and theiCal-D3 (1000mg/880IU chewable tablet).

### COMPLAINT

The complainant stated that both Stirlescent and theiCal-D3 were described as new but both had been on the market for over 12 months. The complainant could not see evidence that any part of the website had been certified for promotional use which probably explained why in both instances it had not been updated in a timely manner.

When writing to Stirling Anglian, attention was drawn to the requirements of Clauses 7.11 and 14.1 of the Code.

### RESPONSE

Stirling Anglian stated that an internal review recognised that the website certification process should be improved. An external agency was undertaking a review of the content and resetting the process and procedures to ensure that the company complied with the Code in future.

Stirling Anglian accepted that in the health professional area of its website the word 'new' was inappropriately used to describe theiCal-D3 when viewed by the complainant on 2 January 2017. This area of the website was intended for health professional use only and not members of the public. Stirling Anglian apologised unreservedly. This area of the website was checked before the end of November 2016 and regretfully this instance was missed.

On receipt of the complaint Stirling Anglian immediately removed the instances of the use of the word and had contracted an external company to undertake a compliance review of the website.

Stirling Anglian submitted that Stirlescent was first made generally available on 25 May 2016 with stock following a notification on 5 January 2016 that it was listed in the Electronic Medicines Compendium (eMC). The company did not accept that the use of 'new' was inappropriate when the complainant viewed the website (2 January 2017). It had however removed the word 'new' from the Stirlescent health professional only area. The company submitted that 'generally available' would start from the moment that the medicine was promoted and available with stock in the market which in this instance was 25 May 2016 but in case the date of the eMC listing was taken as the start of the 12 months it had taken this action.

In response to a request for further information, Stirling Anglian submitted that Stirlescent was first promoted to health professionals on 10 March 2016 and this promotional material was reviewed and certified by its now departed medical department on 29 February 2016. The company was notified by the NHS Business Services Authority (NHSBSA) via eMC In-Demand that Stirlescent was approved as a 'new' product and listed on eMC. 'New' was removed from the relevant page on the company website on 6 January 2017.

All content for the website was discussed and updated on a beta site before signatories verbally agreed to add this to the live website. Although the certification of the website content was made by the two members of staff, due to staff changes unfortunately this could not now be found.

Stirling Anglian stated that as a result of the importance of the key functions in compliance it had reviewed its company structure and performance. Within this, it had replaced its medical department and was introducing new systems and processes with two very experienced pharmaceutical signatories. Although the company considered that its website contained appropriate material, the situation had highlighted shortcomings. Stirling Anglian submitted that it would take its product and clinical website areas down and review every piece of information, update and recertify, using its new process, as a matter of urgency.

#### **PANEL RULING**

The Panel noted that Clause 7.11 stated 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 promoted, for more than 12 months in the UK.

The Panel noted that, as acknowledged by Stirling Anglian, theiCal-D3 was described on its health professional website as 'new' on 2 January 2017, despite the product having been available for more than 12 months (the product was launched on 2 October 2014). A breach of Clause 7.11 was ruled.

With regard to Stirlescence, although, as stated on the website, the product was licensed in the UK on 3 December 2015, it was not generally available until 25 May 2016. The medicine, however, had been promoted to health professionals from 10 March

2016 and so in that regard it could continue to be described as 'new' until 9 March 2017. The Panel noted that this complaint was received in January 2017 when Stirling Anglian could still describe Stirlescence as 'new' and thus it ruled no breach of Clause 7.11. The Panel noted Stirling Anglian's submission that 'new' was removed from the relevant page on the company website on 6 January 2017, three days after the receipt of this complaint.

The Panel noted that the Constitution and Procedure was such that complainants had the burden of proving their complaint on the balance of probabilities. The complainant had alleged that he/she could see no evidence that any part of the Stirling Anglian website had been certified for promotional use. Stirling Anglian stated that the website had been certified but that the signatories had now left the company and no certificate could be found. This was highly unsatisfactory. Clause 14.6 of the Code required companies to keep certificates and the relevant accompanying information for not less than three years after final use of the material. Noting the company's account and that the complainant bore the burden of proof, and given the lack of evidence that the website had not been certified, the Panel ruled no breach of Clause 14.1.

The Panel noted Stirling Anglian's submission that this case had highlighted deficiencies and that it was introducing new systems and processes.

**Complaint received**                      **2 January 2017**

**Case completed**                              **23 February 2017**