NO BREACH OF THE CODE

CASE AUTH/3475/2/21

COMPLAINANT v LUNDBECK

Alleged promotion of Vyepti

An anonymous, contactable complainant who described him/herself as a health professional, complained about the promotion of Vyepti (eptinezumab) which did not have a UK marketing authorisation. The US Food and Drug Administration (FDA) had approved Vyepti.

The complainant alleged that Lundbeck UK had updated the reference to the US status of Vyepti on the UK Specialist Pharmacy Service (SPS) website where launch and approval in the US for Vypeti was documented although SPS NHS was UK based. The complainant submitted that this demonstrated a clear intent in discussing the US market.

The detailed response from Lundbeck is given below.

The Panel noted the eptinezumab 'New Medicines' monograph on the Specialist Pharmacy Service website from the screenshot of the link provided by the complainant. It appeared that the monograph was created in June 2017 and had last been updated in November 2020. It was stated that in the UK and Europe the developmental status was 'Pre-registration (Filed)' and the US developmental status was listed as 'Launched'. Key dates in the development of the medicine were noted and a brief summary of trial data was given.

The Specialist Pharmacy Service, according to its website, was described as joining together experts to create a source of impartial advice for pharmacists, GPs and clinicians to use free of charge. The SPS was commissioned and funded by NHS England and there was no mention on the website about any involvement of the pharmaceutical industry. The website included details about regional medicines optimisation committees (RMOC). It appeared from a very brief look at the website that the information for Vyepti was not different in tone or content to information for other medicines.

The Panel noted Lundbeck's submission that it did not proactively or reactively provide input into the UK SPS website and that Lundbeck UK had never had any involvement in updating the SPS website as alleged, and this was also confirmed by Lundbeck US.

The Panel noted that the complainant bore the burden of proof and did not consider that he/she had established that, on the balance of probabilities, Lundbeck had had any involvement with regard to the SPS website. The Panel therefore ruled no breaches of the Code.

An anonymous, contactable complainant who described him/herself as a health professional, complained about the promotion of Vyepti (eptinezumab) which did not have a UK marketing authorisation. The US Food and Drug Administration (FDA) had approved Vyepti.

Vyepti was an intravenous preventative treatment for migraine being developed by Lundbeck.

COMPLAINT

The complainant noted that Vyepti did not have a UK marketing authorisation. The complainant alleged that Lundbeck UK had updated the reference to the US status of Vyepti on the UK Specialist Pharmacy Service (SPS) website (link provided) where launch and approval in the US for Vypeti was documented although SPS NHS was UK based. The complainant submitted that this demonstrated a clear intent in discussing the US market.

When writing to Lundbeck, the Authority asked it to consider the requirements of Clauses 2, 3.1, 9.1 and 11.1 of the Code.

RESPONSE

Lundbeck noted that the complainant referred to the UK Specialist Pharmacy Service (SPS) NHS website which was an independent website that pharmaceutical companies would not input into; it was a third-party horizon scanning website. Lundbeck or any other pharmaceutical company did not proactively or reactively provide input into the UK SPS website, which was therefore outwith the scope of the Code.

Lundbeck submitted that the complainant did not provide any evidence to support the allegation that Lundbeck UK updated information on the UK SPS NHS website. Lundbeck reiterated that the SPS NHS website was an independent website that pharmaceutical companies would not typically input into (it did not ensure confidentiality), it was a third-party independent horizon scanning website. Lundbeck did not proactively or reactively provide input into the UK SPS website as confirmed by UK staff responsible for updating the company's nominated, restricted access, confidential horizon scanning database used across the industry in the UK. Lundbeck had never had any involvement in updating the SPS website as alleged, and this was also confirmed by the Lundbeck US counterpart.

Lundbeck submitted therefore, the updating of the SPS website was outwith Lundbeck's responsibility and the scope of the Code and therefore it refuted any breaches with regard that allegation. Lundbeck submitted that it had no involvement in the updating of the UK independent SPS horizon scanning website which had been confirmed through Lundbeck's internal investigations.

PANEL RULING

The Panel noted that the Constitution and Procedure stated that the complainant had the burden of proving his/her complaint on the balance of probabilities. All complaints were judged on the evidence provided by the parties.

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The Panel noted Lundbeck's submission that it did not proactively or reactively provide input into the UK SPS website and that Lundbeck UK had never had any involvement in updating the SPS website as alleged, and this was also confirmed by Lundbeck US.

The Panel noted that the complainant bore the burden of proof and did not consider that he/she had established that, on the balance of probabilities, Lundbeck had had any involvement with regard to the SPS website. The Panel therefore ruled no breach of the Clauses 2, 3.1, 9.1 and 11.1 of the Code.

Complaint received **15 February 2021**

Case completed **25 August 2021**