### **CASE AUTH/3323/3/20**

### **COMPLAINANT v TEVA**

# Legibility of DuoResp Spiromax prescribing information

A complainant, who described him/herself as a concerned UK health professional, complained that the DuoResp Spiromax (budesonide/formoterol) prescribing information in a webinar (ref UK/DUO/17/0047w) commissioned by Teva UK Limited and hosted on the Guidelines in Practice website was difficult to read due to the small size of the text, the dark background and the extremely long lines.

The detailed response from Teva is given below.

The Panel noted that the prescribing information was printed in black font on a flesh coloured background and, in that regard, considered that the contrast between the colour of the text and the background was not unacceptable and did not render the text illegible. The Panel did not know upon what device the complainant had viewed the material and so in what size the text of the prescribing information had appeared. It was thus impossible for the Panel to make a decision about the legibility of the prescribing information based on the font size of the text. The line length was, however, approximately 150 characters including spaces. The Panel considered that that was excessive and made the prescribing information difficult to read. A breach of the Code was ruled as acknowledged by Teva.

A complainant, who described him/herself as a concerned UK health professional, complained about the legibility of the DuoResp Spiromax (budesonide/formoterol) prescribing information in a webinar (ref UK/DUO/17/0047w) commissioned by Teva UK Limited and hosted on the Guidelines in Practice website. The webinar was about the implementation of the asthma quidelines issued by the National Institute for Health and Care Excellence (NICE).

#### **COMPLAINT**

The complainant submitted that he/she had viewed the webinar 'Introduction and Implementation of the NICE Asthma Guidelines' and had found the prescribing information for DuoResp Spiromax extremely difficult to read due to the small size of the text, the dark background and the extremely long lines; it was neither clear nor legible.

When writing to Teva, the Authority asked it to consider the requirements of Clause 4.1.

### **RESPONSE**

Teva explained that the material in question was a webpage hosting a recorded Teva sponsored webinar hosted on the Guidelines in Practice website around asthma guidance that included prescribing information for DuoResp Spiromax and Cingaero (reslizumab).

Teva noted that Clause 4.1 and its supplementary information required that prescribing information as listed in Clause 4.2 must be provided in a clear and legible manner which assisted readability.

Teva was surprised and concerned that any health professional would interpret that the prescribing information in this case had not been provided in a clear and legible manner. However, as this health professional had advised that he/she had found the prescribing information for DuoResp Spiromax extremely difficult to read, Teva recognised that, in this instance, acknowledging the complainant's concerns, the prescribing information provided could be deemed as being inconsistent with Clause 4.1 and in breach of the Code.

## **PANEL RULING**

The Panel noted that the DuoResp Spiromax prescribing information was printed in black font on a flesh coloured background. In that regard, the Panel considered that the contrast between the colour of the text and the background was not unacceptable and did not render the text illegible. The Panel did not know upon what device the complainant had viewed the material and so in what size the text of the prescribing information had appeared. It was thus impossible for the Panel to make a decision about the legibility of the prescribing information based on the font size of the text. The line length was, however, approximately 150 characters including spaces. The Panel considered that that was excessive and made the prescribing information difficult to read. A breach of Clause 4.1 was ruled as acknowledged by Teva.

Complaint received 12 March 2020

Case completed 8 June 2020