

HEALTH PROFESSIONAL v CONCORDIA

Promotion of Morphgesic SR

An anonymous 'concerned UK health professional' complained about a journal advertisement for Morphgesic SR 10mg tablets (modified release morphine sulphate) placed by Concordia International Rx (UK) Limited and published in Pulse, April 2018.

The complainant alleged that the prescribing information on the advertisement was from May 2013 which seemed unusually old. In an update in 2014 there was additional information on medicines and driving warnings and in 2015 most of the summary of product characteristics (SPC) was updated as were corresponding sections of the patient information leaflet. The complainant alleged that the disparity between the prescribing information in the advertisement and what was currently known, could put patients at risk.

The detailed response from Concordia appears below.

The Panel noted that the Code required prescribing information to include the date that the prescribing information was drawn up or last revised. The prescribing information in the advertisement in question gave the date of preparation as May 2013 and the date of revision as December 2017. The date of preparation for the advertisement as a whole was given as February 2018. The Panel noted, as stated by Concordia that the complainant was incorrect when stating that the prescribing information dated from May 2013. That was not so. May 2013 was when the prescribing information was originally created. The Panel noted Concordia's submission that the advertisement contained the latest certified prescribing information which was in accordance with the current SPC and ruled no breaches of the Code including Clause 2.

An anonymous 'concerned UK health professional' complained about a journal advertisement (ref Con/MOR/PM/0021) for Morphgesic SR 10mg tablets (modified release morphine sulphate) placed by Concordia International Rx (UK) Limited and published in Pulse, April 2018. Morphgesic was indicated for the prolonged relief of severe pain in adults.

COMPLAINT

The complainant alleged that the prescribing information on the advertisement was from May 2013 which seemed unusually old. In an update in 2014 there was additional information on medicines and driving warnings and in 2015 most of the summary of product characteristics (SPC) was updated. The complainant stated that sections 1, 3, 4.1-4.9, 5.1-5.3, and 6.1-6.6 were updated together with corresponding sections of the patient information leaflet. The complainant alleged that the disparity between the prescribing information in the advertisement and what was currently known, could put patients at risk.

When writing to Concordia, the Authority asked it to consider the requirements of Clauses 2, 4.1 and 9.1.

RESPONSE

Concordia submitted that the prescribing information was last updated in December 2017 and was in line with the latest Morphgesic SR 10mg tablets SPC, which was last updated in May 2015. The prescribing information was accurate and was in line with the Code; the 'Date of revision' was correctly stated as December 2017'. Concordia assumed that the complainant must have read the line above which stated 'Date of Preparation: May 2013'. The stated 'Date of Preparation' was when the prescribing information was first created and the 'Date of revision' was the last time the prescribing information was revised which was in accordance with latest SPC. Concordia denied a breach of Clause 4.1.

Concordia submitted that high standards has been maintained as the advertisement in question included the date of revision within the prescribing information, as required by the Code. The company denied a breach of Clause 9.1.

Given that the advertisement included the latest certified prescribing information with a date of revision of December 2017 Concordia did not consider that patient safety was compromised. The company denied a breach of Clause 2.

PANEL RULING

The Panel noted that Clause 4.2 (viii) required prescribing information to include the date that the prescribing information was drawn up or last revised. The Panel noted that the prescribing information in the advertisement in question gave the date of preparation as May 2013 and the date of revision as December 2017. The date of preparation for the advertisement as a whole was given as February 2018. The Panel noted, as stated by Concordia that the complainant was incorrect when stating that the prescribing information dated from May 2013. That was not so. May 2013 was when the prescribing information was originally created. The Panel noted Concordia's submission that the advertisement contained the latest certified prescribing information which was in accordance with the current SPC and ruled no breach of Clauses 4.1, 9.1 and 2.

Complaint received **25 April 2018**

Case completed **12 July 2018**