

CASE AUTH/3223/7/19

VOLUNTARY ADMISSION BY BOEHRINGER INGELHEIM

More than two pages bearing advertising

Boehringer Ingelheim Limited voluntarily admitted that the June 2019 issue of MIMS bore advertising for Spiolto Respimat (tiotropium and olodaterol) on more than two pages – a whole page advertisement and a double-sided bookmark. Spiolto Respimat was indicated as a maintenance bronchodilator treatment to relieve symptoms in adults with chronic obstructive pulmonary disease (COPD).

As Paragraph 5.6 of the Constitution and Procedure required the Director to treat a voluntary admission as a complaint, the matter was taken up with Boehringer Ingelheim.

The detailed response from Boehringer Ingelheim is given below.

The Panel noted that the Code required that no issue of a print journal may bear advertising for a particular product on more than two pages. The supplementary information, Limitations on Number of Pages of Print Advertising, stated, *inter alia*, that advertisements in the form of inserts, whether loose or bound in, counted towards the two pages allowed and that an insert printed on both sides counted as two pages.

The Panel noted Boehringer Ingelheim's submission that although the placement of the advertisement had been planned since December 2018, the bookmark was only commissioned in May 2019 and that both the advertisement and bookmark were certified in May 2019, within 2 days of each other, as standalone items for use in MIMS; however, there was no alert to the certifier that these would appear in the same edition of MIMS. The Panel noted that there did not appear to be any journal publication schedule provided to the certifier in the copy approval system and, in its view, there appeared to be a general lack of company oversight in this regard.

The June 2019 edition of MIMS bore advertising for Spiolto Respimat on three pages. A breach of the Code was ruled.

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VOLUNTARY ADMISSION

Boehringer Ingelheim explained that on 25 June 2019 a third-party agency, which it had previously worked with, alerted it to the fact that the June 2019 issue of MIMS contained a

whole page advertisement for Spiolto Respimat in addition to a double-sided bookmark insert for the same product. The agency was concerned that together, the advertisement and bookmark might exceed the page allowable limit for journal advertising in a single issue, in breach of Clause 6.1. Boehringer Ingelheim stated that it immediately contacted its media buyer which placed the whole page advertisement and bookmark to ask how they were placed within the same MIMS edition.

By way of background, Boehringer Ingelheim explained that it planned a standalone one page abbreviated advertisement for publication on the back page of the June 2019 MIMS in consultation with the media buyer. The media buyer liaised with the publisher of MIMS in relation to the advertisement. The publisher subsequently offered to Boehringer Ingelheim, via the media buyer, a bookmark to also be included in MIMS. The media buyer checked with the publisher if this was acceptable under the Code to which the publisher confirmed compliance. Boehringer Ingelheim commissioned an agency to provide the artwork for the bookmark, which it sent direct to the publisher. The bookmark, as certified and printed in hard copy, was double sided and therefore counted as two pages according to the supplementary information of Clause 6.1. Including this in the same edition of MIMS as the advertisement resulted in a breach of Clause 6.1. The media buyer in a call with the publisher accepted that the publisher had made a 'production error' in not checking that the bookmark print format was acceptable in the same publication as the single page advertisement, this was confirmed in email.

Boehringer Ingelheim stated that a formal investigation into the non-compliance had begun. This was a formal HR process where consequences included termination of employment in the case of Boehringer Ingelheim staff non-compliance. The process was ongoing. In addition, initial root causes had been considered and corrective actions and preventative actions (CAPA) had been initiated as explained below. These might be adjusted depending on the conclusions of the formal investigation.

The initial root causes were considered as follows:

- A misunderstanding involving the media buyer and the publisher which resulted in placement of both the advertisement and bookmark in the same journal, failing to take into account the requirement of Clause 6.1.
- With the benefit of hindsight, there was an opportunity to improve internal checks on journal-related job bags as highlighted below in the draft CAPA. The advertisement and double-side bookmark were approved as standalone items for use in MIMS with no mention that they would appear in the same edition and a member of staff failed to realise the connection.

The provisional CAPA related to this initial root cause had been initiated as follows:

- The brand team had checked and confirmed that this was the only job where this bookmark had been used and that no other similar publications were imminent using the bookmark at present.
- A recommendation for the brand team to include in their regular meetings oversight of all pending jobs and recently certified jobs awaiting print as a means of the team double checking that content of any journal advertisement was compliant.

- Although the material approval standard operating procedure (SOP) was considered robust, it would be updated to ensure that if there was an intention to publish more than one item in a journal, that the item should be linked in the copy approval system to enable the brand team and reviewers/certifier to have full oversight.
- Further, at the next Code Review Forum on 25 July, the brand team would present this case for companywide learning.

This initial CAPA might be adjusted/extended on conclusion of the formal internal investigation.

Boehringer Ingelheim submitted that it took compliance with the Code very seriously. The company was committed to enhancing the quality and compliance of its interactions with third parties and with health professionals, and it believed that robust certification underpinned effective self-regulation.

Although Boehringer Ingelheim accepted responsibility for all parties acting on its behalf, it was disappointed that neither the media buyer nor the publisher spotted the error. Boehringer Ingelheim also recognised that it missed an opportunity to detect the error. As soon as it knew about the matter, it put in place immediate CAPA pending the formal investigation outcome.

When writing to Boehringer Ingelheim to acknowledge its voluntary admission, the Authority asked it to provide any further comments it might have in relation to the requirements of Clause 6.1.

RESPONSE

Boehringer Ingelheim had no further substantive comments to add to the above save to state that it was alerted to the matter on 24 June, not 25 June as stated above.

Boehringer Ingelheim provided a copy of the June 2019 issue of MIMS containing the one page abbreviated advertisement on its outside back cover and the bookmark printed on both sides. The certificates for both items were provided together with the details of the signatories. Boehringer Ingelheim explained that the abbreviated advertisement had been planned in December 2018 but that artwork for the bookmark was not generated until May 2019, after the publisher had offered both placements to Boehringer Ingelheim, via its media buyer.

PANEL RULING

The Panel noted that Clause 6.1 required that no issue of a print journal may bear advertising for a particular product on more than two pages. The supplementary information, Limitations on Number of Pages of Print Advertising, stated, *inter alia*, that advertisements in the form of inserts, whether loose or bound in, counted towards the two pages allowed by Clause 6.1 and that an insert printed on both sides counted as two pages.

The Panel noted that the June 2019 edition of MIMS bore an abbreviated advertisement for Spiolto Respimat on its outside back cover and contained a bookmark, printed on both sides, for the same medicine.

The Panel noted Boehringer Ingelheim's submission that although the placement of the abbreviated advertisement had been planned since December 2018, the bookmark was only

commissioned in May 2019 and that both the abbreviated advertisement and bookmark were certified in May 2019, within 2 days of each other, as standalone items for use in MIMS; however, there was no alert to the certifier that these would appear in the same edition of MIMS. The Panel noted that there did not appear to be any journal publication schedule provided to the certifier in the copy approval system and, in its view, there appeared to be a general lack of company oversight in this regard.

The June 2019 edition of MIMS bore advertising for Spiolto Respimat on three pages. A breach of Clause 6.1 was ruled.

Complaint received **12 July 2019**

Case completed **19 December 2019**