

CASE AUTH/3389/9/20

VOLUNTARY ADMISSION BY SANDOZ

Promotion of Reletrans to the public via an exposed journal advertisement

Sandoz Ltd voluntary admitted that as a number of copies of the September 2020 edition of Guidelines in Practice had been sent out in transparent wrappers instead of the standard opaque wrappers, an advertisement for Reletrans (buprenorphine 7-day transdermal patch), on the front cover of the journal would have been visible to the general public, in breach of the Code.

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 Sandoz.

Further details from Sandoz are given below.

The Panel noted that the Code stated that postcards, other exposed mailings, envelopes or wrappers must not carry matter which might be regarded as advertising to the public.

The Panel noted that because some copies of the September 2020 edition of Guidelines in Practice had been sent through the post in a transparent wrapper, a promotional outsert for Reletrans, a prescription only medicine, had been visible to the public. Breaches of the Code were ruled as acknowledged by Sandoz.

The Panel noted that Sandoz's publisher engaged a third-party printing company to print and distribute the journal. The publisher's investigation had identified that the error occurred because the printer ran out of the bespoke, Guidelines in Practice opaque polywrap during the print run and completed the task using a transparent polywrap, despite the instructions from the publisher that the Guidelines in Practice bespoke polywrap be applied.

The Panel considered that Sandoz had been badly let down by the printer which had not followed the agreed procedures regarding use of an opaque polywrap when distributing the journal at issue. The Panel considered that the printer's error had resulted in a prescription only medicine being promoted to the public and therefore high standards had not been maintained; a breach of the Code was ruled.

Sandoz Ltd voluntary admitted that as copies of the September 2020 edition of Guidelines in Practice had been sent out in transparent wrappers, an advertisement for Reletrans (buprenorphine 7-day transdermal patch), on the front cover of the journal would have been visible to the general public, in breach of the Code.

Reletrans was indicated for the treatment of non-malignant pain of moderate intensity when an opioid was necessary for obtaining adequate analgesia.

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 Sandoz.

VOLUNTARY ADMISSION

Sandoz explained that Guidelines in Practice was sent directly to health professionals via Royal Mail and was required to be in an opaque wrapper. However, a number of copies of the September 2020 edition were sent out in a transparent wrapper. The advertisement for Reletrans on the front cover was thus visible (photograph provided). As such, Sandoz believed there had been a breach of Clauses 9.8 (Postcards, other exposed mailings, envelopes or wrappers must not carry matter which might be regarded as advertising to the public, contrary to Clause 26.1) and 26.1 (Prescription only medicines must not be advertised to the public).

Sandoz stated that as soon as the publisher informed it of the situation on 22 September 2020, an internal investigation was initiated. The publisher had informed Sandoz that the error occurred because the printer ran out of the opaque wrappers for the whole print run and, without consulting or informing the publisher, used transparent wrappers instead. Sandoz stated that its internal investigation was still ongoing.

When writing to Sandoz, the Authority asked it to consider the requirements of Clause 9.1 in addition to Clauses 9.8 and 26.1 of the Code.

RESPONSE

Sandoz completed its investigation and explained that the advertisement at issue was a bound outsert (ie wrapped around the journal) containing advertisements for Reletrans and Mezolar Matrix (fentanyl transdermal patch) (ref UK/P/PAIN/20-0025, copy provided). The outsert was included with the September 2020 print edition of Guidelines in Practice. The Reletrans advertisement was bound to the lower half of the front cover, and the Mezolar Matrix advertisement was bound to the lower half of the back cover. Each page had two sides (front and back); the front contained the artwork/messages and the back contained the prescribing information and references.

The placement of the Sandoz bound outsert into Guidelines in Practice was booked on behalf of Sandoz by a media buying company which then purchased the advertisement with the publishers in May 2020. Only the advertisement booking occurred through the media buying company; the advertisement proofing, printing and mailing of the journal was arranged through the publisher with which Sandoz had a contractual relationship (details were provided). In early September the publishers instructed the printers (with which Sandoz had no contractual relationship) to print and distribute the journal and the affected copies of Guidelines in Practice copies were distributed by the printers from Monday, 14 September 2020 (copy of order dispatch summary provided).

Guidelines in Practice was usually wrapped in an opaque journal polywrap which had the mailing address and information printed on it and was used to carry both the journal and any inserts/supplements. The publishers had confirmed that the opaque journal polywrap met the Code requirements.

For the September 2020 edition of Guidelines in Practice, the publishers had reported that out of nearly 18,000 copies printed, around 3,300 copies were wrapped in a transparent polywrap

through which the promotional bound insert was visible through the front of the wrapper. The insert was not visible through the back of the wrapper as an insert for another company had been placed over the back cover.

In addition to health professionals, media buying agencies and pharmaceutical companies who had placed advertisements in Guidelines in Practice were typically sent complementary copies of the journal and thus might have received affected copies. Due to general data protection regulation, Sandoz could not find out who received the affected copies.

The publishers first knew on Saturday, 19 September 2020 that transparent polywrap had been used when some of its staff received their complementary copies of the journal in the transparent wrappers. The publishers investigated the matter on 19-21 September and informed Sandoz on Tuesday, 22 September.

Outcomes of internal investigation

Material that required certification was reviewed and certified by Sandoz using Zinc. The advertisement was certified appropriately as complying with the Code.

Sandoz's contractual relationship with the publisher was as an authorised recipient of services under an agreement between Novartis Pharmaceuticals UK Limited (Sandoz was a Novartis Division) and the publisher. The agreement between Novartis and the publisher required the publisher to comply with the Code when carrying out any activity covered by the Code, stating in this regard:

'21. ABPI Code and Novartis Professional Practices Policy

21.1 The Supplier shall comply with:

21.1.1 The latest version of the Code when carrying out any activity which was regulated under the same, including but not limited to providing marketing or medical education services, medical communications, digital communications, events, training, patient advocacy services, government affairs policy work, media relations, contract sales representative personnel;'

The agreement with the publisher also stated that:

'5.4. The Supplier was solely responsible for the management of all Personnel and for the acts and omissions of the Personnel and of any sub-contractors and shall ensure that any such Personnel and/or sub-contractors comply with the terms of a Work Contract. If any Personnel or sub-contractors did not comply with the terms of a Work Contract then the supplier shall be liable for such non-compliance as if the non-compliance was the supplier's.'

Sandoz noted that the publisher discharged its obligations under the Code by instructing the printers to apply the opaque journal polywrap. The publisher understood the Code as demonstrated by its proactive investigation and communication of the matter. The publisher had confirmed that the order dispatch summary (copy provided) between it and the printers instructed that the Guidelines in Practice bespoke polywrap be applied, which was opaque. This was referred to in the notes section of the order dispatch and details were provided.

Additionally, it was stated in the notes section of the order dispatch that: 'under no circumstances must the back cover show through the polywrap, & inserts must not cover the front cover'. The publishers explained that the back cover of the September edition of Guidelines in Practice had a promotional insert from another company, thus highlighting in the order dispatch that the back cover must not show through the polywrap. Also, the words 'Guidelines in Practice' on the upper half of the front cover were partially visible through the opaque journal polywrap, thus highlighting in the order dispatch that inserts must not cover the front cover (photographs of the front and back of the correct Guidelines in Practice journal polywrap were provided).

The publisher's investigation had identified that the root cause lay with the printers running out of the opaque journal polywrap during the print run, then proceeding with the print run using a transparent journal polywrap, despite the order dispatch summary requiring that an opaque polywrap be applied. The printers did not consult with, or inform, the publisher of this change at the time or subsequently until the issue was raised by the publishers. An explanation from the printers was provided.

Sandoz accepted that the root cause of this matter was due to an action taken by the printers that directly contravened a clear instruction from the publishers.

Sandoz stated that as part of its internal investigation, it had assessed whether immediate action would reduce the risks associated with the matter. A recall of the affected copies was considered. Given the copies were sent out via Royal Mail, by the time Sandoz was informed by the publishers, the postal service workers handling the copies were already exposed. Sandoz deemed attempting to recall the affected copies an additional risk, given the recall of these affected copies would cause further exposure to postal service workers.

Sandoz explained that following an investigation by the publishers, the publishers had notified all key personnel and managers at the printers of the matter. The printers had committed to ensuring that all relevant departments were aware so that the error could not happen in the future. Further, all printer personnel and managers would be briefed that any changes or variation to the specification or requirements of an order dispatch summary must be raised with the publishers for discussion and prior approval.

Sandoz committed to reinforce Code requirements with the publishers, to ensure it was fully aware of the need to ensure adherence to the Code.

Sandoz considered that there had been breaches of Clauses 9.8 and 26.1. Given the error that had taken place with the journal polywrap, the affected copies could be considered 'other exposed mailings'. The September 2020 edition of Guidelines in Practice had an advertisement for a prescription only medicine as a bound outsert, which was visible on the front of the affected copies. The advertisement at issue was not related to a vaccination campaign.

Sandoz submitted that the exposure of the public to the affected copies of Guidelines in Practice (18% of the total print run) would be minimal. As the journal was sent directly to health professionals/media buying agencies/pharmaceutical companies via Royal Mail, it was likely that only postal service workers would have been exposed to the affected copies.

Sandoz submitted that it had maintained high standards regarding the matter and thus it denied a breach of Clause 9.1. The advertisement itself was in line with the Code, the contract with the

publishers clearly required adherence to the Code, and the printers were informed to use opaque journal polywrap.

As a global organisation, Novartis partnered with a large number of suppliers of goods and services from multiple sectors across the world. Due diligence was conducted on those suppliers and led to an assessment of the risk of partnering with the supplier. The outcome of any partner risk assessment determined the degree to which that partner would be monitored during the provision of services. The publisher in question was well established in the UK and was classified into the lowest risk category available for suppliers and so was not required to undergo regular auditing or be subjected to any other special monitoring requirements. The standard contractual provisions for such a supplier gave Novartis the power to audit the publisher and required it to conduct activities performed for Novartis (and therefore Sandoz) in accordance with the Code. During the course of the relationship with the publisher, no flags or other indicators had arisen that would give reasonable cause for Novartis to re-evaluate the risk level of engaging the publishers or suggested that particular monitoring steps should be taken. In that regard Sandoz noted that specific monitoring and/or auditing of the publisher would not have picked up the matter in hand. As before, Sandoz was content that the publisher had discharged its obligations under the Code diligently and correctly. The matter had arisen because a specific employee at a third party had chosen to ignore a direct and clear instruction.

Sandoz regarded breaches of the Code very seriously and it was important for the company to submit a voluntary admission as quickly as reasonably possible. As could be seen from the timeline of events, it took just over a week from the moment Sandoz was notified to the submission of the company's voluntary admission.

In the circumstances, Sandoz considered that it had upheld its commitment to maintain high standards and that there had been no breach of Clause 9.1.

In conclusion, Sandoz was very disappointed that it had been placed in a position to require a voluntary admission in this matter. Sandoz submitted that the advertisement itself was in line with the Code, and the company worked with the publisher to ensure the correct placement of its advertisement. There was never any intention to advertise to the public.

Maintaining high standards was very important to Sandoz and the company took any matters such as this very seriously. Sandoz stated that it had used this as an opportunity to examine its relevant internal processes rigorously and was satisfied that they were thorough and that they had been followed correctly in this instance.

Sandoz stated that it believed that the information set out here was sufficient to demonstrate that high standards had been maintained.

PANEL RULING

The Panel noted that Clause 9.8 stated that postcards, other exposed mailings, envelopes or wrappers must not carry matter which might be regarded as advertising to the public, contrary to Clause 26.1.

The Panel noted that because some copies of the September 2020 edition of Guidelines in Practice had been sent through the post in a transparent wrapper, a Sandoz promotional outsert

for Reletrans, a prescription only medicine, had been visible to the public. Breaches of Clauses 9.8 and 26.1 were ruled as acknowledged by Sandoz.

The Panel noted that Sandoz's publisher engaged a third-party printing company to print and distribute the journal. The publisher's investigation had identified that the root cause of the error was that the printers ran out of the bespoke, Guidelines in Practice opaque polywrap during the print run and completed the task using a transparent polywrap, despite the publisher confirming that the order dispatch summary between it and the printers instructed that the Guidelines in Practice bespoke polywrap be applied.

The Panel noted Sandoz's submission that Novartis' contract with the publisher stated that it was solely responsible for, *inter alia*, any sub-contractors and should ensure that any such sub-contractors complied with the terms of a work contract. If any sub-contractors did not comply with the terms of a work contract, then the supplier should be liable for such non-compliance as if the non-compliance was the suppliers. In that regard, however, the Panel noted that it was a well-established principle under the Code that a company was responsible for the actions of third parties employed on the company's behalf even if that third party acted outside the instructions from the pharmaceutical company. That principle also applied to the actions of sub-contractors to the third party.

The Panel considered that Sandoz had been badly let down by a sub-contractor to its third-party publisher who had not followed the agreed procedures regarding use of an opaque polywrap when distributing the journal at issue. The Panel considered that the printer's error had resulted in a prescription only medicine being promoted to the public and therefore high standards had not been maintained and a breach of Clause 9.1 was ruled.

Complaint received **30 September 2020**

Case completed **12 March 2021**