

**CASE AUTH/3398/10/20**

## **VOLUNTARY ADMISSION BY MERCK SHARP & DOHME**

**Promotion of Steglatro to the public via exposed promotional material sent with a journal**

**Merck Sharp & Dohme Limited voluntarily 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, a formulary decision guide for Steglatro (ertugliflozin) sent out with 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 Merck Sharp & Dohme.**

**Further details from Merck Sharpe & Dohme are given below.**

**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 formulary decision guide for Steglatro, a prescription only medicine, had been visible to the public. A breach of the Code was ruled as acknowledged by Merck Sharp & Dohme.**

**The Panel noted that the journal was printed for the publisher by a third party and whilst the publisher had provided clear instructions to the printer, stressing the need for the wrapper to be opaque, it was decided by one of the printer's employees to complete the task using a transparent wrapper when supplies of the opaque wrap ran out.**

**The Panel considered that Merck Sharp & Dohme had been badly let down by the printer which had not followed the agreed procedures and clear instructions from the publisher regarding use of an opaque wrap when distributing the journal at issue. The Panel considered that the printer's error meant that a prescription only medicine had been promoted to the public and therefore high standards had not been maintained; a breach of the Code was ruled.**

**Whilst an error of judgement by the printer had resulted in a prescription only medicine being promoted to the public, the Panel did not consider that Merck Sharp & Dohme had, through an act of commission or omission, promoted Steglatro to the public. The Panel did not consider that the particular circumstances of this case thus warranted a ruling of a breach of Clause 2 a sign of particular censure and reserved for such use. No breach of the Code was ruled.**

**Merck Sharp & Dohme Limited voluntarily admitted that as copies of the September 2020 edition of Guidelines in Practice had been sent out in transparent wrappers, a formulary decision guide for Steglatro (ertugliflozin) (ref GB-STE-00367) would have been visible to the general public, in breach of the Code.**

Steglatro was indicated in certain adults aged 18 years and older with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control.

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 Merck Sharp & Dohme.

## **VOLUNTARY ADMISSION**

Merck Sharp & Dohme explained that the formulary decision guide for Steglatro was developed as a promotional tool to articulate the medicine's clinical data and its cost-effectiveness in the treatment of adult type 2 diabetes. The intended audience were health professionals and other relevant decision makers responsible for local formularies and clinical guidelines. The guide, presented as a hardcopy leaflet, was certified in accordance with the requirements of the Code.

Merck Sharp & Dohme explained that its media buyer purchased a promotional slot with the publisher of Guidelines in Practice which allowed the guide to be placed inside the September 2020 distribution of the journal.

Guidelines in Practice was for health professionals and particularly for those involved in the development of local formularies and clinical guidelines to treat chronic medical conditions such as type 2 diabetes. The journal was distributed monthly to approximately 18,000 subscribers in a hardcopy format.

The journal was printed for the publisher by a third party. The addressee's details were printed on an opaque bespoke wrapper by the printer to ensure that, when posted to the subscriber, the contents could not be seen by the general public. The publisher had provided clear instructions to the printers, stressing the need for the wrapper to be opaque. During the print run, supplies of the opaque wrap ran out. One of the printer's employees on site decided to complete the task using a transparent wrapper. Due to this error, around 3,300 health professional's (around 18% of the total circulation) and one or more contacts at media buying agencies received the journal in a transparent wrapper.

Merck Sharp & Dohme stated that, immediately after being notified by the publishers of the error on 21 September, it launched an investigation. All copies of the journal had been posted before Merck Sharp & Dohme had been notified, hence after an initial investigation it was deemed that there was no corrective course of action that could be taken.

Merck Sharp & Dohme acknowledged that as the journal was in a transparent wrapper, the formulary decision guide would have been visible to some members of the general public (eg postal service employees) whilst in transit to the intended recipients. The medicine's brand name and indication would have been readable. As Merck Sharp & Dohme was indirectly liable for the actions of the publishers and its printers having procured the promotional slot through the company's media and advertising purchaser, the company believed that this error constituted a breach of Clause 26.1 and as a consequence a breach of Clause 9.1 should also be considered. Merck Sharp & Dohme stated that it took the Code very seriously and was very disappointed that this error had occurred. Whilst the company acknowledged that it was responsible for the actions of agencies working on its behalf, its internal investigations had confirmed that the company had followed all correct procedures and clear instructions were provided to the agency. Merck Sharp & Dohme followed up immediately with the agency to ensure that preventative measures were implemented.

Merck Sharp & Dohme stated that although there was a process failure by the third-party, exposing members of the public to promotional material intended for health professionals, patient safety was not compromised. Merck Sharp & Dohme therefore did not consider that it had failed to maintain high standards.

The publisher had already instigated corrective action to prevent this scenario occurring again. These actions included notifying all key personnel and managers at the printing company of the error and asking them to ensure their relevant departments were aware so that it could not happen again. In addition, all employees of the printing company had been briefed that any queries must be directed to the publisher and they could not make any decisions or changes to the publisher's express specifications on their behalf. Finally, the publisher had updated its overall service level agreement with its printers to include the wrapper requirements. The publishers had provided its printers with standard operating procedures (SOPs) covering the nature of its business and the importance of journals and inserts not being visible to anyone other than the intended recipient.

In summary, Merck Sharp & Dohme was dismayed that due to the decision by a third-party organization, a breach of Clause 26.1 had occurred. Merck Sharp & Dohme acknowledged that the third-party organization was indirectly acting on its behalf and hence the company was liable for its actions. Due to the nature of the breach, Merck Sharp & Dohme considered whether there had been a failure on its behalf to maintain high standards and therefore a breach of Clause 9.1. Merck Sharp & Dohme concluded that as all of its procedures had been correctly followed and patient safety had not been compromised there had not been a breach of Clause 9.1. However, Merck Sharp & Dohme would use this case to reiterate to its employees the importance of clearly contracting with, and managing, third-party suppliers.

When writing to confirm that the matter would be taken up under the Code, the Authority asked Merck Sharp & Dohme to provide any further comments it might have in relation to Clause 2 in addition to Clauses 26.1 and 9.1.

## **RESPONSE**

Merck Sharp & Dohme reiterated its comments above and stated that although there was a process failure by the third-party, exposing members of the public to promotional material intended for health professionals, this did not compromise patient safety. All possible steps had been taken to ensure that exposure of the promotional item to the general public did not occur. Merck Sharp & Dohme therefore did not consider that it had failed to maintain high standards or that it had brought discredit upon the industry. Merck Sharp & Dohme denied a breach of Clauses 9.1 and 2.

Whilst no Merck Sharp & Dohme process failings occurred, and the publishers had provided clarity as to the requirements for this activity with the printing company, the incident highlighted the need for constant vigilance. Merck Sharp & Dohme stated that it had used this case as an opportunity to remind and reinforce with its employees the need to manage third parties diligently in accordance with its SOPs.

In summary, Merck Sharp & Dohme was dismayed that a decision by a third-party organization had resulted in a breach of Clause 26.1. Merck Sharp & Dohme acknowledged that the third-party organization was indirectly acting on its behalf and hence the company was liable for its actions. Due to the nature of the breach, Merck Sharp & Dohme agreed that consideration must

be given as to whether it had failed to maintain high standards and thus brought the industry in to disrepute. After investigating the incident, and careful consideration, it was evident that there had not been a failure of Merck Sharp & Dohme procedures, that the third party from which it had procured the promotional space was aware of its obligations in relation to the Code and it had, in turn, instructed its service providers of those obligations. Merck Sharp & Dohme concluded, based on these findings, and the fact that throughout patient safety had not been compromised, that a breach of Clauses 9.1 and 2 had not occurred.

## **PANEL RULING**

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 formulary decision guide for Steglatro, a prescription only medicine, had been visible to the public. A breach of Clause 26.1 was ruled as acknowledged by Merck Sharp & Dohme.

The Panel noted that the journal was printed for the publisher by a third party and whilst the publisher had provided clear instructions to the printers, stressing the need for the wrapper to be opaque, one of the printer's employees decided to complete the task using a transparent wrapper when supplies of the opaque wrap ran out.

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 Merck Sharp & Dohme had been badly let down by a sub-contractor to its third-party publisher who had not followed the agreed procedures and clear instructions from the publisher regarding use of an opaque wrap when distributing the journal at issue. The Panel considered that the printer's error meant that a prescription only medicine had been promoted to the public and therefore high standards had not been maintained; a breach of Clause 9.1 was ruled.

Whilst an error of judgement by a sub-contractor to Merck Sharp & Dohme's third party had resulted in a prescription only medicine being promoted to the public, the Panel did not consider that Merck Sharp & Dohme had, through an act of commission or omission, promoted Steglatro to the public. The Panel did not consider that the particular circumstances of this case thus warranted a ruling of a breach of Clause 2 which was a sign of particular censure and reserved for such use. No breach of Clause 2 was ruled.

**Complaint received**      **8 October 2020**

**Case completed**        **15 March 2021**