

VOLUNTARY ADMISSION BY MERCK SHARP & DOHME

Failure to provide prescribing information and certify an advertisement

Merck Sharp & Dohme voluntarily admitted that an advertisement for Keytruda (pembrolizumab) did not contain prescribing information. Keytruda was indicated for, *inter alia*, advanced melanoma in adults.

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.

Merck Sharp & Dohme explained that the advertisement at issue had been displayed at a scientific congress, held in the UK in October 2018. The advertisement had been developed and certified for use with the congress programme app only. As part of the sponsorship package of the congress Merck Sharp & Dohme was also offered the placement of the company logo in the registration area. The congress organisers inadvertently printed the digital advertisement intended for the app instead of the company logo and placed it on a pillar just after the registration area (before the exhibition area). Consequently, the printed advertisement only contained a link to prescribing information, as it was intended to be viewed in digital format, and so full prescribing information was not provided.

At 14:30 on the second day of the conference, an employee noticed the error and immediately informed the Merck Sharp and Dohme team and requested that the congress representative immediately remove and destroy the poster, which was completed by 14.45.

The response from Merck Sharp & Dohme is given below.

The Panel noted that it was a well-established principle that a company was responsible for the acts or omissions of its agents or third parties. Merck Sharp & Dohme was thus responsible for the placement of the Keytruda advertisement at issue in the congress registration area by the congress organisers.

The Panel noted that the advertisement in question did not include prescribing information as required by the Code and a breach was ruled accordingly as acknowledged by Merck Sharp & Dohme.

The Panel further noted that the advertisement had not been certified for such use and a breach of the Code was ruled as acknowledged by Merck Sharp & Dohme.

The Panel noted that Merck Sharp & Dohme had clearly stated in emails to the congress organisers that only the Merck Sharp & Dohme logo was to be placed on the pillar. The Panel noted the corrective

action promptly taken by Merck Sharp & Dohme once it became aware of the error. The Panel considered that Merck Sharp & Dohme had been badly let down by the congress organisers. Overall the Panel considered that Merck Sharp & Dohme had not failed to maintain high standards and no breach of the Code was ruled.

Merck Sharp & Dohme voluntarily admitted that an advertisement (ONCO-1269798-0000) for Keytruda (pembrolizumab) displayed in a conference registration area, did not contain prescribing information. Keytruda was indicated for, *inter alia*, advanced melanoma in adults.

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 advertisement at issue had been displayed at a global melanoma scientific congress held in the UK in October 2018. The advertisement had been developed and certified for use with the congress programme app only. The congress programme was only available as an app and access was only provided during registration. As part of the sponsorship package of the congress Merck Sharp & Dohme was also offered the placement of the company logo in the registration area. The congress organisers inadvertently printed the digital advertisement intended for the app instead of the company logo and placed it on a pillar just after the registration area (before the exhibition area). Consequently, the printed advertisement only contained a link to prescribing information, as it was intended to be viewed in digital format, and so full prescribing information was not provided.

Merck Sharp & Dohme explained that it was a sponsor of the congress which included in the offering: a full-page colour advertisement for mobile app and a company branded pillar. Merck Sharp & Dohme Global was responsible for the development of materials and all required documentation was provided to Merck Sharp & Dohme UK for review and approval, together with a checklist of all materials. On 24 October 2018 Merck Sharp & Dohme Global emailed the congress organisers to ask them to upload the digital advertisement to the congress programme app and print the Merck Sharp & Dohme logo alone for the pillar. Although the digital advertisement was correctly uploaded to the congress programme app it was also printed in error by the congress organisers and placed on the pillar which was intended for the Merck Sharp & Dohme logo.

The printed advertisement placed on the pillar stated 'tap here for prescribing information' as per the certified digital advertisement, and therefore, prescribing information could not be accessed. As the Merck Sharp & Dohme logo in isolation did not require certification nor examination under the Code it was not passed back to the medical signatory on site for review and approval of the printed document prior to placement.

The opening session of the congress was at 17:30 on 24 October. From 17:30, all head office staff were engaged in speaker rehearsals and final logistical preparations in relation to a promotional meeting to be held at lunchtime on 25 October 2018. At 14:30 on 25 October, an employee noticed the printing error and immediately informed the Merck Sharp & Dohme internal team and requested that the congress representative immediately remove and destroy the poster. This was completed by 14:45. The congress organisers confirmed by email that the poster had been removed and destroyed as soon as it had been brought to their attention and acknowledged responsibility for the incorrect printing.

With regards to possible breaches of the Code, Merck Sharp & Dohme referred to the following: Clause 4.1 – no prescribing information was available on a printed advertisement. The intention was that this was a digital advertisement for use on a mobile app and the prescribing information was available one-click away, in digital form. The digital advertisement was incorrectly printed by the congress organisers and placed on the pillar instead of the Merck Sharp & Dohme corporate logo.

Clause 14.1 – the pillar wrap was not certified in printed final form. As per the description of the job bag, there was no intention to print the digital advertisement for the app. The description of the job bag for the digital advertisement (ONCO-1269798-0000) stated: 'MSD advert for [congress] program which will be available to all attendees. The program will be available as an app and will not be printed'.

Clause 9.1 – as no prescribing information had been provided, the Panel might wish to consider whether high standards had been maintained. However, Merck Sharp & Dohme firmly believed that high standards had been maintained throughout and that this was an isolated incident caused by an unfortunate error in printing by the congress organisers, which they freely admitted. Merck Sharp & Dohme acknowledged that the actions by third parties still fell under its responsibility, however the company had operated responsibly, ethically and professionally throughout and had taken corrective

action as soon as the mistake was identified.

In summary, Merck Sharp & Dohme considered that its internal processes were not at fault. The digital form was certified, and it was clear from the job summary that it was for a digital advertisement and not to be printed. There was clear documentation that only the corporate logo, which did not require certification or examination, should be on the pillar.

RESPONSE

Merck Sharp & Dohme had no further comments.

PANEL RULING

The Panel noted that it was a well-established principle that a company was responsible for the acts or omissions of its agents or third parties. If this were not the case companies would be able to rely on such acts or omissions as a means of circumventing the requirements of the Code. Merck Sharp & Dohme was thus responsible for the placement of the Keytruda advertisement at issue in the congress registration area by the congress organisers.

The Panel noted that the advertisement in question did not include prescribing information as required by Clause 4.1 and a breach was ruled accordingly as acknowledged by Merck Sharp & Dohme.

The Panel further noted that the advertisement had not been certified for such use and a breach of Clause 14.1 was ruled as acknowledged by Merck Sharp & Dohme.

The Panel noted that the congress organisers had inadvertently printed the digital advertisement intended for the congress programme app instead of the company logo and placed it on a pillar just after the registration area. The Panel noted that Merck Sharp & Dohme had clearly stated in emails to the congress organisers that only the Merck Sharp & Dohme logo was to be placed on the pillar. The Panel noted the corrective action promptly taken by Merck Sharp & Dohme once it became aware of the error. The Panel considered that Merck Sharp & Dohme had been badly let down by the congress organisers. Overall the Panel considered that Merck Sharp & Dohme had not failed to maintain high standards and no breach of Clause 9.1 was ruled.

Voluntary admission received	30 November 2018
Case completed	21 February 2018