CASE AUTH/2261/9/09

VOLUNTARY ADMISSION BY MERCK SHARP & DOHME

Breach of undertaking

Merck Sharp & Dohme voluntarily admitted that it might have breached its undertaking given in Case AUTH/2212/3/09 in that an electronic banner advertisement for Cozaar (losartan) had appeared in MIMS Monthly Update issued on 1 September. The banner advertisement featured a claim similar to that which had previously been ruled in breach of the Code (Case AUTH/2212/3/09). Cozaar was an angiotensin II antagonist (AIIA).

The action to be taken in relation to a voluntary admission by a company was set out in Paragraph 5.4 of the Constitution and Procedure which stated, *inter alia*, that the Director should treat the matter as a complaint if it related to a potentially serious breach of the Code. The breach of an undertaking was a serious matter and the admission was accordingly treated as a complaint.

The detailed response from Merck Sharp & Dohme is given below.

The Panel noted that in Case AUTH/2212/3/09 the claim 'there are no clinically meaningful BP [blood pressure] lowering differences between available [AIIAs]' was ruled to be misleading in breach of the Code. The publisher of MIMS monthly update had been clearly instructed by Merck Sharp & Dohme to 'pull all the Cozaar digital advertisements that are live at the latest by tomorrow [12 June] from any of your websites. We have had a complaint … which has been upheld by the code. Tomorrow is the deadline for these to be taken down'. Updated advertisements were to be provided. The publisher confirmed by email on 11 June that '… all copies of the advert have been deleted from our servers'. Following publication of the advertisement on 1 September the publisher confirmed that one of its employees had retained a copy on their own computer and this was used in error. The publisher had informed staff of its change in policy so that, without exception, advertisements were only stored on one server. The publisher stated that the advertisement appeared because of its error and Merck Sharp & Dohme had done everything in its power to ensure the advertisement did not reappear.

The Panel noted that the advertisement now at issue (Case AUTH/2261/9/09) included the claim 'Evidence from a new independent review by the Cochrane collaboration suggests that there are no clinically meaningful BP lowering differences between available AIIAs'. This was sufficiently similar to the claim at issue in Case AUTH/2212/3/09 for it to be covered by the undertaking given in that case.

The Panel considered that Merck Sharp & Dohme had taken all possible steps to comply with its undertaking and that it had been very badly let down by the publisher. The Panel had no option but to rule a breach of the Code as the publisher's failure to comply with the instructions meant that Merck Sharp & Dohme had breached its undertaking. In the circumstances the Panel did not consider that Merck Sharp & Dohme had failed to maintain high standards or that it had brought discredit upon, or reduced confidence in, the industry. Thus no breaches of the Code, including Clause 2 and were ruled.

Merck Sharp & Dohme Limited voluntarily admitted that it might have breached its undertaking given in Case AUTH/2212/3/09 in that an electronic banner advertisement for Cozaar (losartan) (ref 04-10CZR.09.GB.10269.AV) had appeared in MIMS Monthly Update issued on 1 September. The banner advertisement featured a claim similar to that which had previously been ruled in breach of the Code. Cozaar was an angiotensin II antagonist (AIIA).

The action to be taken in relation to a voluntary admission by a company was set out in Paragraph 5.4 of the Constitution and Procedure which stated, *inter alia*, that the Director should treat the matter as a complaint if it related to a potentially serious breach of the Code. The breach of an undertaking was a serious matter and the admission was accordingly treated as a complaint.

COMPLAINT

Merck Sharp & Dohme noted that Case AUTH/2212/3/09 concerned a complaint about the claim 'A new independent Cochrane review suggests that 'there are no clinically meaningful BP lowering differences between available [AIIAs]" in promotional material for Cozaar. The Appeal Board ruled that the claim was misleading and Merck Sharp & Dohme signed and returned the form of undertaking on 12 June 2009.

After the unsuccessful appeal on 21 May, Merck Sharp & Dohme wrote to all advertisers, including the publisher of MIMS Monthly Update, to notify them of the withdrawal of affected advertisements. At that time an electronic banner was the only Cozaar advertisement in use by the publisher. Withdrawal of this item was requested because it included the claim 'Evidence from a new independent review by the Cochrane collaboration suggests that there are no clinically meaningful BP lowering differences between available AIIAs.'

Merck Sharp & Dohme wrote to the publisher on

the 11 June to ask that it withdraw the banner advertisement from use because of a Code breach, and confirm that the file had been destroyed. The publisher replied the same day to confirm that the banner had been withdrawn and that all file copies of the artwork had been destroyed. A copy of the correspondence was provided.

Merck Sharp & Dohme noted that the Cozaar banner advertisement in question was included in the electronic MIMS Monthly Update, issued on 1 September. Merck Sharp & Dohme understood that the update had been circulated to several thousand health professionals.

Merck Sharp & Dohme had since asked the publisher to ensure that it had destroyed the Cozaar banner advertisement and to investigate how the withdrawn advertisement, allegedly deleted from its archives, had appeared in one of its publications. The publisher had submitted that although the electronic file was destroyed from its central archive, it had been held as a local copy by one of its employees who then used it in the September edition of MIMS Monthly Update. This additional copy had been deleted and steps taken to ensure that there was only ever one copy of all materials in the central archive and that no local copies were made and retained by staff.

The publisher had apologised and accepted full responsibility for the error; it had stated that there was nothing additional that Merck Sharp & Dohme could have done to avoid this problem. A copy of the relevant correspondence was provided.

Merck Sharp & Dohme submitted that it had informed Takeda UK Limited, the complainant in Case AUTH/2212/3/09, of this error.

Merck Sharp & Dohme noted that the Constitution and Procedure (Paragraph 5.4) provided that the Director should treat an admission as a complaint if it related to a potentially serious breach of the Code or if the company failed to take appropriate action to address the matter. Merck Sharp & Dohme considered that it had provided evidence that it took all reasonable steps and appropriate actions to prevent re-use of this withdrawn advertisement (the company asked the publisher to delete all copy, explained the reason why and was specifically notified that the advertisement had been destroyed). Accordingly, Merck Sharp & Dohme hoped that the Director would use the discretion provided by Paragraph 5.4 to decide not to treat this admission as a prima facie complaint and thus a potential breach of Clause 25 of the Code.

Merck Sharp & Dohme submitted that it remained committed to the Code and fully supported the importance of any undertaking it gave following a ruling of a breach. The company was very concerned to discover that, despite its procedures which were adhered to fully by its staff, there were errors at a major medical publisher which caused this unfortunate situation. Nevertheless, Merck Sharp & Dohme was heartened by the fact that, as a result, the publisher had changed its internal procedures to prevent such an occurrence happening again. This would benefit the UK industry and all companies that had a UK presence.

When writing to Merck Sharp & Dohme the Authority asked it to respond in relation to Clauses 2, 9.1 and 25 of the Code.

RESPONSE

Merck Sharp & Dohme stated that the banner advertisement in question was included in MIMS Monthly Update emailed to recipients on 1 September 2009. Although it did not include the claim previously found in breach by the Appeal Board, it was sufficiently similar to warrant its withdrawal. Merck Sharp & Dohme identified the error in this advertisement on 3 September 2009 and immediately investigated and discovered that the publisher had made a mistake.

The detailed facts were as follows:

- 11 June 2009. Following receipt of the Appeal Board's ruling in Case AUTH/2212/3/09, Merck Sharp & Dohme told the publisher that the banner advertisement was effectively in breach of the Code and should be withdrawn. Further, Merck Sharp & Dohme requested that the item should be deleted from the publisher's electronic files and requested confirmation. The publisher subsequently confirmed that the advertisement had been withdrawn and that the electronic files had been deleted.
- 12 June 2009. Merck Sharp & Dohme returned its undertaking to comply with the Appeal Board's ruling.
- July and August 2009. The correct replacement Cozaar banner advertisement was hosted by the publisher on its medical websites.
- 3 September 2009. Merck Sharp & Dohme noted that the September edition of MIMS Monthly Update contained a copy of the advertisement at issue. Investigations were initiated by telephone and email. The publisher, confirmed the deletion of the advertisement from its central files, but discovered that an individual employee had retained a copy on their own computer and accidentally used it instead of the correct advertisement. Merck Sharp & Dohme telephoned the Director, informing her of the situation. The Director advised a written voluntary admission. Takeda, was told about the situation and that Merck Sharp & Dohme would make a voluntary admission.
- 4 September 2009. A formal letter of apology was received from the publisher confirming the facts described above. The letter formally concluded that the error was wholly the responsibility of the publisher and that no blame lay with Merck Sharp & Dohme. A letter containing all of the facts was sent to Authority.

Merck Sharp & Dohme submitted that Cases AUTH/2192/12/08; AUTH/1866/7/06; AUTH/2048/9/07;

AUTH/2049/9/07 and AUTH/2050/9/07; recent voluntary admission cases were relevant to the current case.

Merck Sharp & Dohme gave a brief overview of what it considered important factors leading to the rulings in those cases. It submitted, *inter alia*, that in Case AUTH/2192/12/08, the Appeal Board had ruled no breach of Clause 25 of the Code as well as no breach of Clause 2.

In this current case, Case AUTH/2261/9/09, Merck Sharp & Dohme received written confirmation from the publisher that the advertisement in breach would be withdrawn from further use and that existing copy would be deleted. In addition, Merck Sharp & Dohme informed the publisher of the Code breach as the reason for withdrawal and deletion of the advertisement as referred to in Cases AUTH/2192/12/08 and AUTH/2048/9/07.

Merck Sharp & Dohme believed that its actions in connection with the withdrawal of its advertisement met the criteria used by the Appeal Board in Case AUTH/2192/12/08, including informing the publisher about the breach of the Code which the Appeal Board had considered might have been 'helpful'. Furthermore, in the previous cases breaches were ruled because the companies had failed to do things which Merck Sharp & Dohme did do in this case.

Merck Sharp & Dohme regretted very deeply that this incident has occurred. An undertaking made to the PMCPA was always taken very seriously and would never knowingly be broken. In this case, however, Merck Sharp & Dohme considered that it had done its utmost to meet those obligations.

PANEL RULING

The Panel considered that an undertaking was an important document. It included an assurance that all possible steps would be taken to avoid similar breaches of the Code in the future. It was very important for the reputation of the industry that companies complied with undertakings.

The Panel noted that Merck Sharp & Dohme was wrong in its submission that in Case AUTH/2192/12/08 no breach of Clause 25 was ruled. In Case AUTH/2192/12/08 the respondent company was ruled in breach of Clause 25 for failing to comply with an undertaking. No breach of Clauses 2 and 9.1 was ruled in that case.

The Panel noted that in Case AUTH/2212/3/09 the claim 'there are no clinically meaningful BP [blood pressure] lowering differences between available [AIIAs]' in promotional material for Cozaar was ruled to be misleading in breach of Clauses 7.2 and 7.3 of the Code. The publisher had been clearly instructed by Merck Sharp & Dohme to 'pull all the Cozaar digital advertisements that are live at the latest by tomorrow [12 June] from any of your websites. We have had a complaint … which has been upheld by the code. Tomorrow is the deadline for these to be taken down'. Updated advertisements were to be provided. The publisher confirmed by email on 11 June that '… all copies of the advert have been deleted from our servers'. Following publication of the advertisement on 1 September the publisher confirmed that one of its employees had retained a copy on their own computer and this was used in error. The publisher had changed its policy so that, without exception, advertisements were only stored on one server. Staff had been informed. The publisher stated that the advertisement appeared because of its error and Merck Sharp & Dohme had done everything in its power to ensure the advertisement did not reappear.

The Panel noted that the advertisement now at issue (Case AUTH/2261/9/09) included the claim 'Evidence from a new independent review by the Cochrane collaboration suggests that there are no clinically meaningful BP lowering differences between available AIIAs'. This was sufficiently similar to the claim at issue in the previous case, Case AUTH/2212/3/09, for it to be covered by the undertaking given in that case.

The Panel considered that Merck Sharp & Dohme had taken all possible steps to comply with its undertaking and that it had been very badly let down by the publisher. The Panel had no option but to rule a breach of Clause 25 as the publisher's failure to comply with the instructions meant that Merck Sharp & Dohme had breached its undertaking. In the circumstances the Panel did not consider that Merck Sharp & Dohme had failed to maintain high standards or that it had brought discredit upon, or reduced confidence in, the industry. Thus no breach of Clauses 2 and 9.1 were ruled.

Complaint received **4 September 2009**

Case completed **7 October 2009**