CASE AUTH/3141/12/18

HEALTH PROFESSIONAL V MERCK SHARP & DOHME

Information on Disclosure UK

A health professional complained that the Disclosure UK website indicated that he/she had received financial support from Merck Sharp & Dohme which was not so. The complainant stated that he/she had never received any support from the company and had no contact with it in any capacity. The complainant submitted that the incorrect data had resulted in personal reputational damage and a potential fraud investigation.

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

The Panel noted that Merck Sharp & Dohme had sponsored an individual, with the same name as the complainant, to attend an international congress. The Panel further noted that although the individuals had identical first and last names, each had a unique ID number. A Merck Sharp & Dohme employee's lack of attention to detail resulted in the transfer of value being declared against the wrong individual. The Panel considered that disclosing transfers of value against an individual who had not received such transfers of value meant that Merck Sharp & Dohme had not complied with the requirements of the Code. A breach of the Code was ruled. The Panel further considered that the information published on Disclosure UK was inaccurate and misleading. A further breach of the Code was ruled. This ruling was appealed by Merck Sharp & Dohme.

The Panel noted the distress that the error had caused the complainant. However, the Panel also noted that, according to Merck Sharp & Dohme, the company had sent a letter to the complainant's workplace outlining its intention to publish the data but received no response. A response would have prompted the company to check the data before public disclosure. That Merck Sharp & Dohme had a process that had the potential to identify errors, and taking everything into consideration, on balance, the Panel did not consider that the company had failed to maintain high standards. No breach of the Code was ruled.

The Panel did not consider that the circumstances of this case warranted a ruling of a breach of Clause 2 and no breach of that clause was ruled.

Merck Sharp & Dohme appealed the Panel's ruling with regard to the information published on Disclosure UK being inaccurate and misleading on the basis that the clause of the Code cited only related to medicines and was not applicable to information about transfers of value. To rule a breach of that clause in relation to transfers of value would set a precedent and clarity on this point, from the Appeal Board, would be helpful.

The Appeal Board considered that all information provided by pharmaceutical companies should be accurate and it did not agree with Merck Sharp & Dohme's submission that the clause in question only related to information about medicines. The Appeal Board noted

that the information published on Disclosure UK had been inaccurate and misleading and it upheld the Panel's ruling of a breach of the Code.

A contactable health professional complained that information about him/her published by Merck Sharp & Dohme on the Disclosure UK database was inaccurate.

COMPLAINT

The complainant noted that the Disclosure UK database indicated that he/she had received financial support from Merck Sharp & Dohme which was not so; he/she had never had support of any kind from Merck Sharp & Dohme and had had no contact with the company in any capacity.

The complainant submitted that the incorrect data had resulted in personal reputational damage within his/her employing organisation and a potential investigation by NHS Fraud.

The complainant asked that the error be immediately corrected and the incorrect data removed from the public domain, an explanation be provided as to why the error had occurred, and reassurance be given that processes were in place to ensure that the error would not be repeated.

When writing to Merck Sharp & Dohme, the Authority asked it to bear in mind the requirements of Clauses 2, 7.2, 9.1, 24.1, 24.2 and 24.7 of the 2016 Code.

RESPONSE

Merck Sharp & Dohme acknowledged that the transfer of value attributed to the complainant and published by Disclosure UK was incorrect and should have been attributed to another physician with a similar name (the two health professionals had the same first and surnames but different middle names), job location and role. The company had already apologised directly to the complainant and the data had now been removed from the Disclosure UK platform.

Although an error was made in identifying the correct health professional, Merck Sharp & Dohme denied any breach of the Code.

Merck Sharp & Dohme explained that in 2017, it engaged a consultant with a view to funding flights and congress registration to the American Society of Clinical Oncology (ASCO) that year. Standard procedures were followed and the health professional concerned completed a due diligence questionnaire (DDQ), agreeing to a declaration of transfer of value and this was completed by him/her with first name, surname and place of work. A Merck Sharp & Dohme employee then submitted information about the flight and congress registration to ASCO to the company's in-house anti-bribery and corruption (ABC) online system which recorded activities associated with transfers of value to health professionals. The employee searched for the health professional in the system by name so as to upload and assign the completed DDQ to the relevant record. Other than first name and surname, the ABC online system relied on other identifiers, namely place of employment and job role to identify the correct health professional. In this case the correct health professional was identified, and the correct DDQ attached to his/her ABC record.

Subsequently a Master ABC Workflow was created for this activity. The Master ABC workflow was a record of an activity to which health professionals were assigned, in this case, for the purpose of ASCO attendance in 2017. A further search for the health professional was initiated by searching again on the same ABC system using first and last names. This search brought up 11 results, all with the same name, with no middle names listed for any entries. In error, the employee selected the complainant (same first name and surname) who also worked in the same geographical area with a similar specialist role. The transfer of value for the ASCO congress was then uploaded and applied to the wrong health professional. This was the crucial error.

Once recorded in the ABC Workflow, health professionals were identified by their unique numerical identifier for the purpose of transfer of value processing and notification.

Merck Sharp & Dohme stated that at the 2017 year-end, it collated the transfer of value from all sources, reconciled several database sources and prepared for submission of the annual transfer of value to the ABPI. This transfer of value was one of 899 transfers of value declared that year.

In addition to the pre-disclosure process operated by Disclosure UK, although this was not practice across the industry, Merck Sharp & Dohme carried out its own separate process of pre-disclosure notification by sending letters outlining its intention to disclose transfers of value to the relevant health professionals. A letter was sent to the complainant's workplace in February 2018. No response was received within the 28-day period, or thereafter, which would have acted as a trigger for the company to check and correct relevant details. As a result, the error was not identified, and Merck Sharp & Dohme's internal disclosure process did not require any further checks to be carried out.

Subsequently, in accordance with its own procedures, the ABPI Disclosure Team notified the complainant of the intended disclosure; he/she raised no query in connection with that communication and, in the normal course of events, the transfers of value were made public on 30 June 2018. No concerns were raised by the complainant until December 2018.

Merck Sharp & Dohme noted that on 21 December, just after its offices had closed for the Christmas break, it received an email from the Disclosure Team at the ABPI with the query from the complainant regarding the transfer of value. Merck Sharp & Dohme emailed the complainant on 3 January 2019 to ask for further details to clarify and resolve the issue although he/she had not responded.

Merck Sharp & Dohme submitted that corrective actions were immediately carried out on receipt of the complainant's query sent via the ABPI Disclosure Team. The complainant was removed from the public list on 11 January 2019 and a letter of apology sent the next day. This removal was delayed as the ABPI disclosure system was in the process of being moved from one service provider to another. The new service provider assured the company that the complainant's name was removed at the earliest opportunity.

Merck Sharp & Dohme stated that it had also notified the 'correct' health professional that there was an error with his disclosure of transfer of value which included ASCO in 2017 and ESMO in 2018. The latter ESMO (European Society for Medical Oncology) congress would be disclosed in 2019. On 11 January, Merck Sharp & Dohme submitted a corrected disclosure file to the ABPI.

Merck Sharp & Dohme submitted that the employee who selected the wrong health professional in error would be re-trained on use of the ABC online system and the associated standard operating procedure. Other users of the ABC online system would also be appropriately trained.

With regard to specific clauses, Merck Sharp & Dohme submitted the following:

> Clause 24.1: Merck Sharp & Dohme made a declaration of transfer and followed its established processes which included notifying the complainant of its intention to declare the transfer of value. The correct financial amount was declared although due to human error it was applied to the complainant who had a similar name, worked in the same city and had a similar job title to the intended clinician. This error was at the point of data entry and not a breach of the systems and processes which were in place. The company denied a breach of Clause 24.1.
>
> Clauses 24.2: Merck Sharp & Dohme stated that its processes were designed to fulfil the requirements of Clauses 24.2 and 22.5. As stated above, a human error meant that this declaration was applied to another clinician. In the light of this, the company denied a breach of Clauses 24.2 or of 22.5.
>
> Clause 7.2: This clause related to misleading information, claims and comparisons and was primarily intended to address information relating to products and promotional material. As a result, Merck Sharp & Dohme considered that Clause 7.2 was not applicable and so it denied a breach of that clause.
>
> Clause 9.1: The necessary robust and effective systems and processes were in place within the company and included additional safeguards beyond the ABPI Disclosure UK system. The similarities in name, work location and job role resulted in an error. This was an isolated incident and did not reflect a systemic failure or inadequacies within company processes. There were systems built in to the process to address potential errors or queries, but these relied on intervention by the health professional concerned, which were not triggered in this case. Merck Sharp & Dohme stated that as soon as it knew about the error it took steps to rectify the issue and, on that basis, it denied a breach of Clause 9.1.
>
> Clause 2: Given its comments above regarding Clause 9.1, Merck Sharp & Dohme did not consider that the error brought discredit upon, or reduced confidence in, the pharmaceutical industry or in the disclosure process; it denied a breach of Clause 2.

In summary, Merck Sharp & Dohme submitted that its current systems and processes were robust and effective. In this case, appropriate disclosure procedures were followed, and disclosure occurred, although a simple human data entry error by an employee led to disclosure against the wrong health professional. The clinicians involved had identical first and last names, both worked in the same city and had similar job titles. Merck Sharp & Dohme stated that it had checked its systems and did not consider they needed to be changed. The issue had been addressed with the employee concerned and appropriate training would be provided to other users of the ABC online system. Furthermore, the company had apologised to the complainant for the error and had ensured that his/her name was removed from the public record.

On balance, Merck Sharp & Dohme did not consider that it should be found in breach of the Code.

PANEL RULING

The Panel noted that Clause 24.2 described the transfers of value covered by Clause 24.1 and included, *inter alia*, sponsorship of health professionals by way of registration fees, accommodation and travel. Failure to document and publicly disclose transfers of value as described in Clause 24.2 would be a breach of Clause 24.1.

The Panel noted Merck Sharp & Dohme's submission that it funded flights and congress registration to ASCO in 2017 for an individual with the same first and last names as the complainant. It appeared to the Panel that this was incorrectly disclosed against the complainant due to an error by a Merck Sharp & Dohme employee.

The Panel noted Merck Sharp & Dohme's submission that the employee searched for the health professional in the company's internal system by name which brought up eleven results with the same first and last names. The Panel noted, from the screen shots provided by Merck Sharp & Dohme, that the complainant appeared to be first on the list and the correct individual was number eleven on that list. The Panel noted that although the individuals had identical first and last names, each was associated with a unique local ID number. The employee's error demonstrated a lack of attention to detail given Merck Sharp & Dohme's submission that the employee had previously searched for, selected and uploaded the completed Due Diligence Questionnaire to the correct health professional record and therefore, in the Panel's view, the previously assigned unique local ID number should have been cross-checked.

The Panel considered that disclosing transfers of value against an individual who had not received such transfers of value meant that Merck Sharp & Dohme had not complied with the requirements of the Code and a breach of Clause 24.1 was ruled.

The Panel considered that the information published on Disclosure UK at the time of the complaint was inaccurate and misleading and a breach of Clause 7.2 was ruled.

The Panel noted the distress that the error had caused the complainant. However, the Panel noted Merck Sharp & Dohme's submission that a letter was sent to the complainant's workplace in February 2018 outlining the company's intention to disclose transfers of value and no response was received from the complainant; such a response would have acted as a trigger for the company to check and correct relevant details before public disclosure. The Panel noted that Merck Sharp & Dohme appeared to have a process in place that had the potential to identify errors before the information was published on Disclosure UK. Taking everything into consideration and on balance, the Panel did not consider that Merck Sharp & Dohme had failed to maintain high standards in this regard and no breach of Clause 9.1 was ruled.

The Panel noted that Clause 24.7 was raised by the case preparation manager. Clause 24.7 stated that different categories of transfers of value to individual health professionals could be aggregated on a category by category basis, provided that itemised disclosure would be made available upon request to the relevant recipient or the relevant authorities. The Panel did not consider that the complainant had made an allegation with regard to Clause 24.7 and therefore made no ruling.

The Panel noted that Clause 2 was a sign of particular censure and reserved for such use. It appeared to the Panel, on the information before it, that this error was in relation to one individual and there was no evidence that there was a systemic issue with the company's processes in this regard. The Panel, therefore, did not consider that the particular circumstances of this case warranted a ruling of a breach of Clause 2 and ruled no breach accordingly.

APPEAL BY MERCK SHARP & DOHME

Merck Sharp & Dohme appealed the Panel's ruling of a breach of Clause 7.2 stating that a breach of that clause in this instance was not appropriate and was unwarranted. Merck Sharp & Dohme understood that Clause 7.2 and its supplementary information, related specifically to information, claims and comparisons for medicines and did not have broader application across other areas. The clause specifically mentioned an evaluation of all evidence and the completeness of information to allow the recipient to form 'their opinion of the therapeutic value of the medicine' which pointed to information on a product. The supplementary information to Clause 7 further stated that 'this clause is not limited to information or claims of a medicinal or scientific nature. It includes, *inter alia*, information or claims relating to pricing and market share'. There was no reference to transfers of value in this information and this was out of scope of Clause 7.2. Conversely in Merck Sharp & Dohme's view if Clause 7.2 did apply to non-product related transfers of value information, this was not clear within the clause itself and potentially blurred the boundaries of this clause. This was the first case of this kind and potentially set a precedent for future decisions which would be unfortunate. Therefore, the clarity that the Appeal Board could bring to this would be welcomed.

RESPONSE FROM THE COMPLAINANT

The complainant noted that Merck Sharp & Dohme had stated that 'a letter was sent to the complainant's workplace in February 2018'. The complainant stated that he/she had worked in a named specialty at a named NHS trust until June 2016. In February 2016 he/she was appointed to a role at a named clinical commissioning group (CCG). The other health professional with the same name was employed in a different specialty. Neither had worked in the same institution or in the same specialty. The complainant stated that he/she had never been employed as a consultant at either of the two hospitals trusts where the other health professional with the same name worked. Nor, prior to January 2019, had he/she received any correspondence from Merck Sharp & Dohme concerning entry in the database. It was not apparent to what address this letter was sent. For the purposes of clarity, the complainant noted that in October 2017, two local trusts merged to form one NHS foundation trust.

The complainant alleged that these factual inaccuracies served to underline the lack of clarity in the process by which individuals were identified on the database.

The complainant stated that his/her chief concern was the personal reputational damage which could have been inflicted if his/her current employers considered that he/she had received funding from commercial organisations and had failed to disclose it to them. This potential conflict of interest was of particular concern to those working in a commissioning environment. In this respect, the findings of this review, and the earlier correspondence the complainant had received from Merck Sharp & Dohme, was reassuring.

The complainant was also concerned that there was a systematic failing within Merck Sharp & Dohme which allowed these errors to occur. There might be a structural or a process problem within the reporting system.

APPEAL BOARD RULING

The Appeal Board noted that Merck Sharp & Dohme had acknowledged that the transfer of value information attributed to the complainant and published on Disclosure UK was incorrect. The company had accepted the Panel's ruling of a breach of Clause 24.1. Clause 24.1 required that companies must document and publicly disclose certain transfers of value to health professionals and healthcare organisations but did not specifically require that such disclosures were accurate.

The Appeal Board considered that it was important that all information provided by pharmaceutical companies, including transfers of value, was accurate. In that regard, the Appeal Board noted that Clause 7.2 stated, *inter alia*, that 'Information, claims and comparisons must be accurate, balanced, fair, objective and unambiguous and must be based on an up-to-date evaluation of all the evidence and reflect that evidence clearly. They must not mislead either directly or by implication, by distortion, exaggeration or undue emphasis.' The Appeal Board noted that the supplementary information to Clause 7, General, stated that the application of the clause was not limited to information or claims of a medical or scientific nature. The Appeal Board did not agree with Merck Sharp & Dohme's submission that Clause 7.2 related only to information claims and comparisons for medicines. The Appeal Board noted that Clause 7.2 also applied to information to the public as set out in the supplementary information to Clause 26.2, Information to the public.

The Appeal Board considered that the information published on Disclosure UK, regarding the complainant, at the time of the complaint was inaccurate and misleading and this was covered by Clause 7.2, it therefore upheld the Panel's ruling of a breach of Clause 7.2. The appeal was unsuccessful.

Complaint received **21 December 2018**

Case completed **15 November 2019**