**CASE AUTH/3236/8/19**

# HEALTH PROFESSIONAL v MERCK SHARP & DOHME

## Information on Disclosure UK

**A health professional complained about information on the Disclosure UK database. The complainant had raised matters previously regarding data for 2017 posted by Merck Sharp & Dohme Limited and these were considered in Case AUTH/3141/12/18. That case had been appealed. Following notification of the outcome of the Panel's ruling in that case, the complainant noted that there was a further incorrect entry on Disclosure UK.**

**The complainant stated that he/she was disappointed that, despite the efforts of both the Panel and the organisations concerned, the 2018 Disclosure database included a further incorrect entry indicating that he/she received financial support from Merck Sharp & Dohme. This further underlined his/her concern of a systemic failure of data verification.**

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

**The Panel considered that disclosure of a transfer of value against an individual who had not received such a transfer meant that Merck Sharp & Dohme had not complied with the Code. Breaches of the Code were ruled including that the published information was inaccurate and misleading.**

**The Panel identified that incorrect material was on Disclosure UK on 23 July 2019 and Merck Sharp & Dohme was notified on 26 July of its rulings in Case AUTH/3141/12/18. It was concerning that Merck Sharp & Dohme had not carried out additional checks prior to publication of the data given the complaint in Case AUTH/3141/12/18 which was sent to the company in January 2019. The failure to conduct comprehensive checks and cross checks meant that high standards had not been maintained and a breach was ruled.**

**The Panel was very concerned that when the undertakings were signed in Case AUTH/3141/12/18, Merck Sharp & Dohme knew that incorrect information regarding the same complainant was still present on Disclosure UK. It had been so informed by the Panel on 26 July when it had advised the company of its rulings in Case AUTH/3141/12/18.**

**The Panel considered that as the undertaking had not been given until 13 August, the second publication of incorrect information on Disclosure UK in June did not amount to a breach of that undertaking and therefore ruled no breach of the Code including Clause 2.**

**The Panel considered that, on balance, to inaccurately disclose information about a named individual who had not received any transfer of value from the company for a second time reduced confidence and brought discredit upon the industry, particularly as Merck Sharp & Dohme had time and opportunity to double check the position. Further, to sign the undertaking required for the previous case on 13 August, stating that the**

**incorrect data had last appeared on Disclosure UK in January, with no acknowledgement that the company knew on 26 July that further incorrect data about the same health professional had been published was extremely concerning. The Panel ruled a breach of Clause 2.**

A health professional complained about information on the Disclosure UK database. The complainant had raised matters previously regarding data for 2017 posted by Merck Sharp & Dohme Limited and these were considered in Case AUTH/3141/12/18. That case had been appealed by Merck Sharp & Dohme. Following notification of the outcome of the Panel's ruling in that case, the complainant noted that there was a further incorrect entry on Disclosure UK (6 August 2019).

**COMPLAINT**

The complainant stated that he/she was disappointed that, despite the efforts of both the Panel and the organisations concerned, the 2018 Disclosure database included a further incorrect entry indicating that he/she received funding from Merck Sharp & Dohme. This further underlined his/her concern of a systemic failure of data verification either at the PMCPA or its member organisations.

[Note: In relation to this last point the complainant was advised that the PMCPA had no involvement in the transfers of value data that was disclosed on the ABPI's Disclosure UK database.]

When writing to Merck Sharp & Dohme, the Authority asked the company to consider the requirements of Clauses 2, 7.2, 9.1, 24.1 and 29 of the Code and Clause 2 in relation to the provision of the undertaking given in Case AUTH/3141/12/18.

**RESPONSE**

Merck Sharp & Dohme submitted that it was very disappointed to receive such a complaint given the history of this matter and the recent ruling in Case AUTH/3141/12/18.

Merck Sharp & Dohme stated it was fully committed to transparency of pharmaceutical company interactions with health professionals and healthcare organisations (HCOs), which it firmly believed to be in the public interest. It was committed to collecting and disclosing accurate information about any transfers of value and had worked hard to establish systems designed to ensure that this happened.

Ensuring transparency of transfers of value on an individualised basis was an exacting task; a significant amount of information had to be gathered and processed from a wide array of different sources. Merck Sharp & Dohme stated it was at the forefront of developing robust systems, but noted that ensuring accuracy of information required full engagement by, and contributions from, all stakeholders involved in the process. That included not only the relevant pharmaceutical company and the ABPI, but also the individual health professionals and healthcare organisations involved. Merck Sharp & Dohme stated that it and the ABPI went to significant lengths to check information with the relevant health professionals and HCOs prior to pre-disclosure. However, health professionals and HCOs were often subject to many conflicting demands, which meant that they might not respond to industry pre-disclosure requests and so inaccuracies might occur.

Merck Sharp & Dohme deeply regretted any inaccuracies that might have occurred, but it believed that its system was as robust as it could reasonably be. Mindful of the possibility that the PMCPA might rule a breach of the Code and request appropriate undertakings, Merck Sharp & Dohme very much hoped that it would not be forced to move away from individual reporting in favour of aggregate reporting, simply because of the fear that further errors might result in breaches of undertaking.

**Summary of Investigation Findings**

Merck Sharp & Dohme submitted that the complaint was not the result of a systemic issue or failure in its transparency systems and procedures. Rather, it was the result of a highly regrettable and unfortunate, yet isolated, sequence of events and timings. Some of these were within Merck Sharp & Dohme's control and it had taken steps to further enhance systems to ensure that users were subjected to additional oversight and control. However, the issues were compounded by failures of third-party service providers to both Merck Sharp & Dohme and the ABPI. Merck Sharp & Dohme sought to exert more robust controls over third parties. It hoped that the ABPI similarly recognised the issues with its systems and processes and that it also took appropriate corrective action.

**Merck Sharp & Dohme's Transparency Procedures**

Merck Sharp & Dohme's transparency procedures were included in its response to Case AUTH/3141/12/18. A flowchart setting out the way in which the transfer of value transparency processes worked was provided. The key elements were:

- Any proposal that Merck Sharp & Dohme transferred anything of value to either a health professional or HCO was handled in accordance with the company's internal anti-bribery and corruption system (ABC System). As part of this process a Merck Sharp & Dohme employee must select an appropriate unique identifier for the recipient health professional or HCO, which was carried forward into the other internal systems that processed and eventually submitted transparency data to the ABPI pre-disclosure system.

- A key component of that system was operated by a third-party vendor. For funding of attendance at meetings, the third party system, (i) recorded Merck Sharp & Dohme transfers of value for meetings and congress attendance, and (ii) co-ordinated the compliance and logistics of congress attendance for both Merck Sharp & Dohme employees and sponsored health professionals (each health professional was identified by a unique identifier which Merck Sharp & Dohme employees had to input manually).

- After the data capture, the third party system submitted its data to Merck Sharp & Dohme's internal AGS system (MSD Portal) automatically. Under the terms of Merck Sharp & Dohme's contractual arrangement the third party must transfer entries into Merck Sharp & Dohme's AGS system within 90 days after the activity had occurred.

- Once the third party had transmitted the information to the AGS system, Merck Sharp & Dohme reviewed the data in its AGS system vs that in its ABC system – checking all relevant data had been uploaded and that the reasons and values were correct.

- Once this had been done, the data was uploaded to the Merck Sharp & Dohme Portal and one of the most important safety net measures was seen ie the system generated a letter or email to each health professional and HCO identified as having received a transfer of value from Merck Sharp & Dohme. Those letters required health professionals and HCOs to verify the information and notify the company if there were any errors or inaccuracies before Merck Sharp & Dohme transmitted the data to the ABPI Portal.

- Where health professionals or HCOs raised a query, it was investigated immediately and responded to in a timely manner. In most cases Merck Sharp & Dohme did not receive any objection and uploaded the information to the ABPI Portal.

- The ABPI then made a second attempt to verify the accuracy of information with individual health professionals and HCOs and it was only if there was no objection at that stage that the transparency data were published.

- Merck Sharp & Dohme believed that this system was as robust as it could reasonably be, consistent with the company's current desire to publish individualised data. As discussed below, however, it was clear that the system did not function as it should in this instance, which was particularly regrettable given that the complainant had already been disappointed previously.

**Investigation Findings**

Merck Sharp & Dohme provided a detailed summary of the sequence of events that led to the current complaint.

Merck Sharp & Dohme noted that the error in Case AUTH/3141/12/18 related to an incorrect disclosure of transfer of value associated with attendance at the American Society of Clinical Oncology (ASCO) congress during 2017. The error arose because a Merck Sharp & Dohme employee selected the complainant from the ABC System, instead of the name of the person who was the intended subject of the single transfer of value. (The two health professionals shared almost the same name-only their middle names differed).

Unfortunately, the unique identifier relating to this health professional was carried forward into the other internal systems that processed and eventually submitted to the ABPI pre-disclosure system. Merck Sharp & Dohme noted that the error only occurred once but was unfortunately carried through to give rise to the issues in the current complaint.

In 2018, before the receipt of the complaint in Case AUTH/3141/12/18, Merck Sharp & Dohme had also agreed to fund attendance at the European Society for Medical Oncology (ESMO) conference. Unfortunately, as the request was processed through the ABC System, the identification error was 'carried through' so that the transfer of value relating to ESMO was linked to the wrong health professional.

On receipt of the initial complaint, Merck Sharp & Dohme immediately deleted the inaccurate information relating to attendance at ASCO and contacted the correct health professional, so that the transfer of value could be disclosed against his/her name instead. Merck Sharp & Dohme corrected the initial error in disclosure on 11 January 2019. This was delayed

somewhat by the migration of the ABPI disclosure system from one software platform to another.

A senior management team (the Compliance Committee) met in January to discuss the issue. The Compliance Committee was responsible for ensuring that appropriate management structure, processes, resources, training and personnel were in place to ensure ongoing compliance with legal and regulatory requirements in all human health business areas and alignment with Merck Sharp & Dohme's parent company's Corporate Compliance Program. All matters of divisional compliance were included within the scope of the Compliance Committee. The issue was also discussed by a company-wide team of reviewers (Signatory Meeting) across all aspects of the business. Key outputs were to underline the critical importance of accuracy and data input across the systems. A company-wide retraining on Standard Operating Procedure 12 – 'Engaging an Expert' – started in March 2019.

On 29 January 2019, the company checked whether data relating to the ESMO funding was linked to the complainant on the AGS system and found that there was no information relating to the ESMO conference against his/her name. As this check was carried out more than 90 days after the ESMO conference, it was considered reasonable to assume that the third party system would already have transferred any relevant data into the AGS system. In the normal course, this would have been the end of the matter. Unfortunately, and unknown to Merck Sharp & Dohme, the third party had not submitted data from its system within the 90-day limit. If it had done so in accordance with its contractual obligations, Merck Sharp & Dohme would have identified the error and would have been able to correct the information.

However, Merck Sharp & Dohme's safety net remained. Merck Sharp & Dohme had provided full and complete pre-disclosure information to the complainant in March 2019. Merck Sharp & Dohme anticipated that a health professional receiving such a pre-disclosure notification would have responded, to allow the company to correct any inaccuracies of the disclosure prior to submission to the ABPI Disclosure UK. The company would then have hoped that the communication it subsequently sent as part of the pre-verification would have identified any inaccuracy (especially given that he/she was aware of a previous error). Unfortunately, no reply was received.

Merck Sharp & Dohme noted that the ABPI would also have sent the complainant a further pre-disclosure notice, as an additional safety net presumably designed to detect and rectify errors, and the company assumed that the complainant either did not receive it or did not respond to this further check to the process.

**Subsequent Events**

On 30 June the ABPI public disclosure list for 2018 Transfers of Value went live, including the information relating to the complainant.

On receipt of the Panel's ruling on Case AUTH/3141/12/18 on 26 July 2019, Merck Sharp & Dohme identified the error with dismay. Merck Sharp & Dohme notified the ABPI disclosure system C&C immediately on 26 July, uploading a corrected file to remove this incorrect data at 14:44. C&C validated this relevant deletion and returned this data for approval on 29 July; Merck Sharp & Dohme approved the data on the same day.

In line with the associated procedures, Merck Sharp & Dohme had understood that the online information should have been corrected immediately, or at the very latest by the beginning of

the following working day. The entity operating the ABPI disclosure UK system, which was not a Merck Sharp & Dohme contracted third party, indicated that it did not comply with this standard process:

> 'any information removed from the submission will either be instantly removed or removed by the beginning of the next working day. I apologise that in this instance it does appear that the data was not removed in line with that timeframe, but was actually online for a further 10 days.'

Merck Sharp & Dohme noted that it took 10 business days and therefore remained visible until 13 August when the correction was finally implemented.

As requested, Merck Sharp & Dohme attempted to obtain the screenshot of the data available for viewing on the day the complainant wrote his/her complaint. However, as this was a live database, and Merck Sharp & Dohme did not receive the complaint until 15 August, ABPI's supplier had informed Merck Sharp & Dohme that it was not possible to provide this. Merck Sharp & Dohme did not have any control over the disclosure platform other than the data submitted to it. However, it could be inferred from the correspondence, that on 6 August the incorrect data remained in the public disclosure.

Merck Sharp & Dohme accepted that these facts and the corrective actions taken on 26 July did not absolve the company from its obligations under the Code. However, it strongly believed it showed that Merck Sharp & Dohme had not acted in a wilful or deliberate manner to record information against the complainant. It operated what it considered was a robust system diligently and in good faith. A sequence of unfortunate events and timings meant that an employee's error in 2017 was carried through to the following year's data. That was not to downplay the seriousness of this issue and Merck Sharp & Dohme apologised for it. It had also carefully considered what corrective and preventive actions the company might introduce to enhance its systems.

**Corrective and Preventive Actions (CAPAs)**

In addition to the measures implemented in response to Case AUTH/3141/12/18 outlined above, Merck Sharp & Dohme listed the following further CAPAs:

1 It had conducted a retrospective check of all submissions made by the relevant employee through internal transfer of value data systems for 2017/2018.

2 The employee would receive additional competency-based retraining. In addition, data submissions into this system would mandate that a manager checked any inputted data.

3 Merck Sharp & Dohme had checked its 2018 public disclosures for duplicate name errors against the full database of health professionals, and had not detected any additional errors beyond this case.

Merck Sharp & Dohme had also identified a number of CAPAs relating to the internal processes, procedures and training:

1 As an interim measure until item 3 below was complete, it added a two person check at the health professional identification stage of the process, when a search

result during engaging an expert pulled up more than one entry for the same name. This would be mandated for all Merck Sharp & Dohme employees engaging with these systems effective as of 16 September 2019.

2 Updated and combined Transfer of Value and Consent to Transfer of Value guidelines for clarity and to reduce complexity to be completed by 30 September 2019.

3 Company-wide retraining on the new guideline during Q4 2019. Until this was complete, all employees were reminded to update their knowledge on the current guideline, with explicit mention of the importance of selecting the correct health professional at the outset of any activity.

4 As a priority, review processes through an independent external expert experienced in these complex processes and systems including the third party system. It would then be in a position to implement potential recommendations. The processes would be mapped and potential areas of weakness and improvement identified and, where appropriate, re-engineer the process.

5 In October, internal auditors would review the transfer of value process and current practice to identify areas for quality improvement.

6 Merck Sharp & Dohme would engage with the ABPI Disclosure UK team to determine if there were any improvements which could be made around the pre-disclosure and transfer of value processes.

7 Remind all Merck Sharp & Dohme employees in the UK of the importance of correct identification of a health professional at the outset.

8 This case and the CAPAs would be discussed at the September 'Human Health Managers' call. This was normally chaired by the managing director, to ensure the transfer of value process with associated CAPAs was discussed, understood and enforced across the business with managers having responsibility for implementation and compliance.

9 Relevant information about the transfer of value process would be presented at the next company-wide Town Hall as a further channel to reinforce the transfer of value process, as well as notifying all employees of their responsibilities relating to CAPA 1 above.

Merck Sharp & Dohme responded with respect to the specific alleged clauses:

**Clause 7.2**

Merck Sharp & Dohme denied a breach of Clause 7.2.

Merck Sharp & Dohme referred to its appeal submission in Case AUTH/3141/12/18 which remained pending. To summarise, Merck Sharp & Dohme understood that Clause 7 as a whole, including 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 own opinion of the therapeutic value of the medicine' which pointed to information on product. The supplementary information of Clause 7 further stated that: 'this clause is not limited to information or claims of a medicinal or scientific nature. [It included], inter alia, information or claims relating to pricing and market share'. There was no reference to transfers of value in this information, and Merck Sharp & Dohme believed this was out of scope of Clause 7.2.

**Clause 24.1**

Merck Sharp & Dohme accepted that given the background to the recent Panel decision for Case AUTH/3141/12/18, there was a breach of Clause 24.1.

**Clause 9.1**

As Merck Sharp & Dohme held itself to the highest standards, it accepted a breach of Clause 9.1. The company apologised for the error and was taking significant action to prevent an occurrence such as this in future as detailed under response to Clauses 29 and 2 below. As referred to in the response in Case AUTH/3141/12/18 and in this case, it acknowledged that the employee error made in 2017 relating to the ASCO 2017 conference, and subsequently carried over to transfers of value related to ESMO 2018, the latter which had yet to be disclosed.

As the Panel noted in its ruling in Case AUTH/3141/12/18, 'it appeared that [Merck Sharp & Dohme] did have a process in place that had the potential to identify errors before the information was published on Disclosure UK' and that it had, therefore, not breached Clause 9.1. That remained the case. Merck Sharp & Dohme stood behind its transfer of value processes and system, but obviously regretted any inaccuracy that might have occurred. This was not deliberate. The company strove to maintain high standards and considered that this complaint was the result of an unfortunate sequence of events and timings within both Merck Sharp & Dohme and the ABPI. Merck Sharp & Dohme submitted that it had exercised due diligence to rectify this issue, which unfortunately now appeared not to have been so.

Merck Sharp & Dohme noted that its transparency processes and those of the ABPI included the safety net of asking health professionals to verify their information. While not wishing to diminish the company's responsibility for the issues, the ability of companies and the ABPI to maintain high standards relied, to some extent, on health professionals checking their figures.

**Clause 2**

Merck Sharp & Dohme denied a breach of Clause 2. It apologised unreservedly to the complainant for the upset caused but did not believe this sequence of events led to industry discredit, patient safety concerns, or indeed merited the particular censure of Clause 2.

As noted by the Panel in its ruling in Case AUTH/3141/12/18, 'this error was in relation to one individual and there was no evidence that there was a systemic issue in this regard' and that there was no breach of Clause 2. Rather, this case was unfortunate and unintended. While Merck Sharp & Dohme admitted the initial error, which was caused by incorrect identification of a health professional within the ABC system well before October 2018 and Case AUTH/3141/12/18, this would normally have been detected by the pre-disclosure processes. Merck Sharp & Dohme went beyond the industry standard, by undertaking an additional pre-disclosure check prior to submitting information to the ABPI pre-disclosure system. For unknown reasons, there was no response to these pre-disclosure checks.

Merck Sharp & Dohme detected the public disclosure error internally on 26 July 2019 via the ABPI public database, before the Panel searched the Disclosure UK database on 31 July, and before the complainant raised the complaint with the PMCPA on 6 August. As soon as the error was detected, the company submitted a data correction to the ABPI to authorise the removal of incorrect disclosure data and the ABPI's third party informed Merck Sharp & Dohme that its normal process would be to remove this data within one working day.

Unfortunately, in this case, the ABPI Disclosure UK system allowed this data to be visible for 10 working days beyond Merck Sharp & Dohme's initial notification. It was during this time that the PMCPA and the complainant viewed data that according to the ABPI, should have been removed by 29 July. Merck Sharp & Dohme had no jurisdiction or control over the ABPI disclosure process after data submission and was not accountable for delays in this system.

Merck Sharp & Dohme submitted that it had appropriate processes and systems in place for transfers of value. In 2018 it disclosed 479 transfers of value to individual health professionals. Of these, only three were flagged as potential errors; two were detected by the pre-disclosure process designed as a safety-net for these potential errors, and therefore were intercepted and prevented from public disclosure, and the remaining one related to this case. As a result of the error in both of these cases, Merck Sharp & Dohme checked its 2018 public disclosures for duplicate name errors against the full database of health professionals and had not detected any additional errors beyond this case.

Merck Sharp & Dohme was aware that in future, isolated cases such as these might be mitigated against by addressing the manual employee entry into the relevant databases, as in this case, an initial error in health professional identification had repercussions for data input across the inter-communicating systems and led to incorrect disclosure. Merck Sharp & Dohme recognised that through this process, a data integrity issue could be caused by a human error. As outlined above, it had undertaken a number of CAPA steps since this complaint.

In particular, it placed immediate sanctions on the Merck Sharp & Dohme employee (details were provided). The company was undertaking a retrospective check of all historic transfer of value submissions submitted by the employee in these cases for 2017 and 2018.

Regarding the systems and processes, Merck Sharp & Dohme had invited its internal auditors to inspect its transfer of value processes and data in October 2019 and had sought an external independent expert to scrutinise its transfer of value systems and processes with a view to acting on and implementing recommendations.

**Responses to Clauses 29, 9.1 and 2 following undertakings provided on 31 July and 13 August 2019**

**Clause 29**

Merck Sharp & Dohme denied a breach of Clause 29.

The current complaint was the result of an error in 2017 that regrettably carried over. Moreover, the initial undertaking was signed and submitted on 31 July 2019, with a subsequent undertaking made on 13 August, following the acceptance of breach of Clause 24.1 and appeal of Clause 7.2. The disclosure error occurred much earlier, and Merck Sharp & Dohme had detected it on 26 July internally, before the complaint from both the Panel and the PMCPA on

31 July and the 15 August letter of complaint. It had already completed the rectification procedure with ABPI Disclosure UK by 29 July, when the ABPI Disclosure database should have, by its standards, removed this data completely.

Therefore, Merck Sharp & Dohme respectfully denied a breach of undertaking, as the repeat error was addressed by company processes by 29 July, with assurance from the ABPI provider of the removal of the incorrect data on 29 July. In accordance with ABPI standards, Merck Sharp & Dohme expected the rectification process to complete on 29 July before the first submission of the undertaking on 31 July, followed by the PMCPA panel screenshots of incorrect disclosure on 31 July, and then the complainant's viewing of the incorrect public data on 6 August.

Following Case AUTH/3141/12/18, Merck Sharp & Dohme submitted that the corrective and preventative actions taken were proportionate and adequate, relating to employee retraining, company-wide retraining on the source of this error - Engaging an Expert, as well as following the compliance processes by discussing the issue at the Compliance Committee Meeting and the Signatory Meeting.

**Clause 9.1**

Merck Sharp & Dohme denied a breach of Clause 9.1 with respect to a breach of undertaking.

The disclosure error occurred much earlier than the initial undertaking on 31 July and the final undertaking on 13 August, and had also been corrected by 29 July, when Merck Sharp & Dohme fulfilled its responsibility to correct the data with the ABPI disclosure platform. Merck Sharp & Dohme was not responsible for the delays by the ABPI and its third party, which failed to remove this data from public disclosure beyond their standard timelines. Merck Sharp & Dohme employed corrective and preventative actions in place with respect to the employee, and the systems involved in this case.

**Clause 2**

Merck Sharp & Dohme denied a breach of Clause 2.

The company apologised to the complainant for the upset caused but did not believe these sequence of events involving Merck Sharp & Dohme and the ABPI disclosure UK system merited the particular censure of Clause 2. It had tried to engage with the complainant regarding the initial complaint, and the safety net double pre-disclosure system by Merck Sharp & Dohme and the ABPI relied, to some extent, on the health professional engaging with these notifications.

Merck Sharp & Dohme was aware of a potential error in 2018 data for the complainant, and had checked its data file submissions to find no evidence of incorrect data. Merck Sharp & Dohme went on to notice the error in July, before both the complainants' letter, and the PMCPA Panel's screenshots of 31 July. At that time, it was assured by the ABPI's own system that the incorrect data was removed as per ABPI standards, on 29 July. Merck Sharp & Dohme submitted the first undertaking to the Authority on 31 July, ie after it had corrected the disclosure error. The commitment to rectify the error in data on the ABPI database on 29 July was the responsibility of C&C and, unfortunately, the data was subsequently visible for a further ten working days.

Merck Sharp & Dohme submitted it had implemented what it believed were proportional and appropriate preventative measures between the initial notification of Case AUTH/3141/12/18 and the Panel review and the submission of undertakings on 31 July and therefore it did not consider that it had failed to implement remedial preventative actions. The original error which led to both cases was made by the employee before October 2018, and therefore significantly before all the actions the company had now put in place. Merck Sharp & Dohme accepted that there was a need for an extensive system and process review and it had highlighted this as a priority – detailed in the CAPAs already discussed.

**Summary**

At the time the PMCPA recorded screenshots, and the current complaint on 31 July and 6 August respectively, Merck Sharp & Dohme submitted its corrective actions were complete, and it believed as per the standards of the ABPI disclosure system, that this error was rectified in respect of the undertakings signed 31 July 2019. Merck Sharp & Dohme accepted that it made an error, systems intervened and corrected it, but the company was also let down by the failures of the ABPI disclosure system, as it was assured that incorrect data was removed on 29 July 2019. In reality, this incorrect data was visible significantly beyond the timelines committed to by the disclosure system itself.

Given the regrettable sequence of events and unfortunate timings outlined above, Merck Sharp & Dohme hoped that the PMCPA would understand that the unfortunate events reflected an isolated issue and set of circumstances, rather than a fundamental, systemic flaw in the company's systems. There were a series of issues with its third party and also with the ABPI's systems and vendor. Merck Sharp & Dohme nevertheless accepted responsibility for its employee's error and had acted to ensure the risks of recurrence were further minimized.

This case, was the result of the same employee mistake being carried forward, was the first time Merck Sharp & Dohme had made an error in the public disclosure of a transfer of value to a health professional, and it processed many hundreds of transfers of value annually. It did not believe that this case should merit the particular censure of Clause 2.

Merck Sharp & Dohme hoped the Panel would see how seriously it had taken this repeat occurrence both to rectify the error and to put in a multi-faceted approach to prevent a future occurrence. In both these related cases, Merck Sharp & Dohme submitted it actioned the corrective procedures promptly and its preventative actions commenced on 22 January, several months before the Panel's outcome in July, and were ongoing and rigorous, involving all arms of the business, external independent review, and its employees.

**PANEL RULING**

The Panel noted that the case had arisen following consideration of Case AUTH/3141/12/18. That case had been appealed as set out below.

**Case AUTH/3141/12/18 Appeal by Merck Sharp & Dohme – Clause 7.2**

Merck Sharp & Dohme's understanding was 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 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 transfer of value in this information and this was out of scope of Clause 7.2.

Merck Sharp & Dohme submitted that if Clause 7.2 applied to non-product related transfer 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, clarity for the industry would be helpful.

Merck Sharp & Dohme submitted that a breach of Clause 7.2 in this instance was not appropriate and was unwarranted and the clarity that the Appeal Board could bring to this would be welcomed.

**Case AUTH/3141/12/18 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.

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 this 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.

**Case AUTH/3236/8/19**

In relation to the matter now before it, the Panel concluded that another incorrect disclosure had been published by Merck Sharp & Dohme.

The Panel noted Merck Sharp & Dohme's comments about the safety net in place for the engagement of health professionals in the disclosure process. However, it was perhaps not surprising that the complainant had not responded to the pre-disclosure correspondence from Merck Sharp & Dohme given that he/she was not expecting it.

The Panel considered that disclosure of a transfer of value against an individual who had not received such a transfer meant that Merck Sharp & Dohme had not complied with the Code. A

breach of Clause 24.1 was ruled. The Panel also ruled a breach of Clause 7.2 as the published information was inaccurate and misleading.

The Panel identified that incorrect material was on Disclosure UK on 23 July 2019 and Merck Sharp & Dohme was notified on 26 July of its rulings in Case AUTH/3141/12/18. It was concerning that Merck Sharp & Dohme had not carried out additional checks prior to publication of the data given the complaint in Case AUTH/3141/12/18 which was sent to the company in January 2019.

Once Merck Sharp & Dohme received notification from the PMCPA regarding the Panel's ruling in Case AUTH/3141/12/18 it identified the error with dismay. The Panel noted that the root problem in the previous case was that two health professionals with the same first name and surname had been mixed up and a transfer of value had been attributed to the wrong one. Knowing that it had a problem, the Panel noted that on 29 January Merck Sharp & Dohme checked whether data relating to the ESMO funding was linked, wrongly, and found that it was not. As this was more than 90 days after the ESMO conference, and so past the time when data should have been transferred to the system by the third-party, the company assumed that the transfer of value had not been attributed to the wrong health professional It appeared, however, that the company had not simultaneously checked to see that the data had been correctly attributed. In the Panel's view, this second check should have shown that the relevant third party had not submitted data from its system within the contractual 90 day limit and that further checks would be required and thus the error would have been picked up prior to submission of the Disclosure report for 2018. Once notified of the error following publication in June the relevant third party took 10 business days to remove the incorrect information from the disclosure database rather than its standard process of removing data within one business day. The Panel accepted that third parties had not kept to agreed timelines, however Merck Sharp & Dohme could have carried out a further check on this health professional including prior to submitting the data to the ABPI at the end of March. The failure to conduct comprehensive checks and cross checks meant that high standards had not been maintained and a breach of Clause 9.1 was ruled.

The Panel then considered whether or not there had been a breach of undertaking. The Panel did not consider that potential issues with undertakings in relation to the disclosure of transfer of value data meant that companies should move from individual disclosure to aggregate disclosure as submitted by Merck Sharp & Dohme. If a breach of undertaking was alleged, it would be considered on its own merits as with every case considered under the Code. The Panel noted that Merck Sharp & Dohme provided an undertaking on 31 July 2019 stating that the date on which incorrect information last appeared on Disclosure UK was 11 January 2019. The company then decided to appeal the ruling of a breach of Clause 7.2 so an amended undertaking was provided on 13 August.

The Panel was very concerned that when the undertakings were signed, Merck Sharp & Dohme knew that incorrect information regarding the same complainant was still present on Disclosure UK. It had been so informed by the Panel on 26 July when it had advised the company of its rulings in Case AUTH/3141/12/18.

The Panel considered that as the undertaking had not been given until 13 August, the second publication of incorrect information on Disclosure UK in June did not amount to a breach of that undertaking. The Panel therefore ruled no breach of Clauses 29, 9.1 and 2.

Noting its decisions above, the Panel then turned to consider Clause 2 in relation to the publication of the inaccurate information. The Panel noted that a ruling of a breach of Clause 2 was used as a sign of particular censure. It considered that, on balance, to inaccurately disclose information about a named individual who had not received any transfer of value from the company for a second time reduced confidence and brought discredit upon the industry, particularly as Merck Sharp & Dohme had time and opportunity to double check the position. Further, to sign the undertaking required for the previous case on 13 August, stating that the incorrect data had last appeared on Disclosure UK in January, with no acknowledgement that the company knew on 26 July that further incorrect data about the complainant had been published was extremely concerning. The Panel ruled a breach of Clause 2.

**Complaint received** **15 August 2019**

**Case completed** **20 January 2020**