

CASE AUTH/3285/12/19

EX-EMPLOYEE v DAIICHI-SANKYO

Disclosure of payments on Disclosure UK

An ex-employee complained about the gross underreporting of transfers of value by Daiichi-Sankyo.

The complainant stated that the Disclosure UK website showed that the company declared in 2018 that its healthcare professional registration fees were £7,937.60 for named individuals and zero for aggregated disclosures.

The complainant stated that in August 2018 the company sponsored 100 healthcare professionals to attend the European Society of Cardiology (ESC) congress in Germany and paid for travel, accommodation, food and registration fees. The complainant referred to a staff briefing that showed the names of the healthcare professionals. From searching Disclosure UK many of these healthcare professionals had no activities with Daiichi Sankyo listed. If all these people had decided to remain anonymous, the aggregated data had not been reported.

The complainant estimated that it must have cost at least 69,000 Euros in registration fees to take 100 healthcare professionals. Daiichi-Sankyo only declared under £8,000. The complainant stated that looking at the disclosure of travel and accommodation costs, there was £47,724.20 detailed disclosures and £10,067.10 disclosed in aggregate. This was obviously too low to account for flying 100 people from UK to Munich return and accommodation costs for a 5-day congress.

The complainant alleged that Daiichi-Sankyo had not declared other congress fees in 2018 and probably, in 2017 and 2016. This was likely to be a pattern of behaviour.

Disclosure was very important, and the complainant alleged that to have such a huge discrepancy was a failure that brought the industry into disrepute. The fact that Daiichi-Sankyo had declared some fees seemed to say that the company had some kind of process in place but had maybe chosen to hide how many people they sponsored to go to ESC as 100 was a huge number to take. Daiichi-Sankyo should have declared 2018 payments by the end of June 2019 but had not.

The detailed response from Daiichi-Sankyo is given below.

The Panel noted that the presentation provided by the complainant indicated that there were 760 participants at ESC 2018 with 120 from the UK. A list of Daiichi-Sankyo's attendees was included. The Panel noted Daiichi-Sankyo submission that it funded flights, accommodation and congress registration to ESC in 2018 for 98 health professionals. In relation to ESC 2016 and 2017 Daiichi-Sankyo paid travel, accommodation and registration fees for 15 and 28 health professionals respectively.

The Panel noted that these transfers of values had not been disclosed on an individual or aggregate basis. The Panel was extremely concerned to note that when asked to quantify the total transfers of value that had not been disclosed for 2018, 2017 and 2016, a total of around £471,000 was described as being identified as unreported by Daiichi-Sankyo and that the company stated it did not have complete visibility of the total transfers of value that had not been reported.

The Panel noted Daiichi-Sankyo's submission that the error related to issues in respect of indirect transfers of value where the administration and logistics support for events was contracted to a third party. The Panel noted Daiichi-Sankyo's submission that in these cases the third party should have included details of transfers of value for each health professional along with the invoice and either the third party had not provided the information or Daiichi-Sankyo had not requested it. The review of the report from the financial system assumed that the data shown was complete and this was not so; the report did not contain health professional itemised transfers of value data for the activities. Further, the review did not include sign off by departmental heads with budget responsibility. It appeared to the Panel that the errors were not helped by the lack of training and a standard operating procedure (SOP). The local SOP was prepared after the complaint was received.

The Panel considered that the information published on Disclosure UK at the time of the complaint was not comprehensive in relation to support to health professionals to attend conferences in 2018, 2017 and 2016. The Panel ruled a breach of the Code in relation to the omitted 2018, 2017 and 2016 data as acknowledged by Daiichi-Sankyo. Consequently, as the data had not been disclosed Daiichi-Sankyo had not met the requirement to disclose by 30 June of the relevant year and the Panel ruled breaches of the Code as acknowledged by Daiichi-Sankyo. The data had not been disclosed either as a transfer of value to an individual health professional or in aggregate and therefore the Panel ruled breaches of the Code as acknowledged by Daiichi-Sankyo.

With regard to the requirement to document all disclosures and retain records for 5 years the Panel noted that Daiichi-Sankyo denied a breach in this regard. However, in response to a request for further information, the Panel noted Daiichi-Sankyo's submission that it did not have complete visibility of the total transfers of value that were unreported and it listed the payments it had managed to identify. The Panel noted the apparent inconsistencies and that Daiichi-Sankyo had not been able to produce all of the relevant data. The Panel therefore ruled a breach of the Code.

The Panel noted that Daiichi-Sankyo had published a methodological note so had met the requirements of the Code. The company had not followed its methodological note but this was covered by the rulings of breaches of the Code above. The Panel therefore ruled no breach of the Code, which was upheld on appeal by the complainant.

The Panel noted that there had been a requirement in the Code since 2012 to disclose financial details of sponsorship of UK health professionals etc in relation to attendance at meetings. This included registration fees, costs of accommodation and travel. At that time the information was to be disclosed in aggregate. Changes were made to the Code since then including the need to disclose transfers of value on an individual basis.

The Panel noted that in 2018 Daiichi-Sankyo had under reported the transfers of value by at least £398,000. The figure published on Disclosure UK (checked in January 2020) was just under £280,000. The Panel queried why the issue had not come to light sooner given the numbers of UK health professionals which attended the ESC and the costs of that support. The Panel considered that the magnitude of under reporting was of serious concern. There was also under reporting in 2017 and 2016.

The Panel was also concerned that the company's processes were inadequate. The new SOP was designed to assist with the new process but the Panel queried whether it was sufficiently robust, particularly with regard to checking the data. It did not appear that the company had corrected the data on Disclosure UK and this must be prioritised. It would in any event need to be updated as part of the requisite undertaking.

The disclosure of transfers of value was an important part of self-regulation and it was of serious concern that Daiichi-Sankyo had not been transparent about the transfers of value for so many years.

High standards had not been maintained and therefore the Panel ruled a breach of the Code as acknowledged by Daiichi-Sankyo.

The Panel noted that a ruling of a breach of Clause 2 was used as a sign of particular censure. It considered that to fail to disclose the required information on Disclosure UK was extremely concerning as was the scale of the under reporting. Daiichi-Sankyo's process was inadequate. The Panel ruled a breach of Clause 2.

The Panel decided that as Daiichi-Sankyo's conduct raised concerns about the company's procedures it warranted consideration by the Appeal Board. The Panel decided to report Daiichi-Sankyo to the Appeal Board under Paragraph 8.2 of the Constitution and Procedure.

The Appeal Board noted the Panel's comments and rulings of breaches of the Code including Clause 2 and its decision to report Daiichi-Sankyo to the Appeal Board. The Appeal Board noted that Daiichi-Sankyo had submitted that it was in the process of addressing the issues and it had apologised.

The Appeal Board did not understand why Daiichi-Sankyo had been unable to realise that it needed to disclose transfers of value in relation to funded flights, accommodation and congress registration through a third-party agency. The representatives from Daiichi-Sankyo acknowledged and recognised that the company had not fully understood and implemented its responsibility to correctly disclose transfers of value over a three-year period. The representatives from Daiichi-Sankyo acknowledged that its methodology which focused on direct transfers of value was not adequate and there was no SOP to cover transfers of value in place during this time.

The Appeal Board considered that this case demonstrated that Daiichi-Sankyo had grossly under reported the true position of its transfers of value over a sustained period. It noted from the company representatives that the third-party had supplied data to Daiichi-Sankyo but that the company could not locate the data. The Appeal Board noted the explanation of the company representatives that a certain employee who had/ought to have received the data had left the company. The Appeal Board considered that the

issue was broader than one individual's failing. There was a fundamental and systemic failure of the company's processes and a complete misunderstanding of the requirements and application of the Code. The Appeal Board queried whether the company's submissions truly reflected the urgency of the situation.

The Appeal Board decided that in accordance with Paragraph 11.3 of the Constitution and Procedure, Daiichi-Sankyo should be publicly reprimanded for its fundamental systemic failure to have adequate processes in place to correctly disclose transfers of value over a three-year period. The Appeal Board also decided to require an audit of Daiichi-Sankyo's procedures in relation to the Code. The audit should take place as soon as possible. On receipt of the report of the audit the Appeal Board would consider whether further sanctions were necessary.

On receipt of the report for the September 2020 audit, the Appeal Board considered that the report indicated that Daiichi-Sankyo had a systemic lack of governance in the UK. Greater compliance resource was needed urgently to address gaps. Key senior staff needed to provide consistent leadership on compliance and continue to improve their personal knowledge and accountability. The medical and marketing departments needed a better working relationship. All staff needed to understand the importance of compliance and the role of self-regulation and to be clear about the differences between promotional and non-promotional activity.

In addition, the Appeal Board noted that the audit report highlighted many concerns that needed to be addressed and that significant commitment was required to address these matters.

The Appeal Board decided that Daiichi-Sankyo should be re-audited in March 2021 at which point it expected it to be able to demonstrate significant progress. On receipt of the report for the re-audit the Appeal Board would decide whether further sanctions were necessary.

The Appeal Board subsequently agreed to a request from Daiichi-Sankyo to defer the re-audit to May 2021 in order to give the company time to update and embed its standard operating procedures and training regarding the 2021 Code which would come into operation on 1 July 2021. The Appeal Board requested Daiichi Sankyo to provide a comprehensive progress report by the end of March.

At its meeting in April 2021 the Appeal Board received the progress report from Daiichi-Sankyo which it considered was helpful.

On receipt of the May 2021 re-audit report the Appeal Board considered that since the report of the September 2020 audit there had been some meaningful progress and it appeared that matters were beginning to head in the right direction. The Appeal Board noted that a more formal compliance framework had now been established and that there was now a compliance director in role. It was important that senior staff continued to improve their leadership and role modelling on compliance matters. All staff had to understand their responsibility for compliance.

The Appeal Board noted that further improvement was required and the report of the May 2021 re-audit highlighted areas of concern to focus on.

The Appeal Board decided that Daiichi-Sankyo should be re-audited in March 2022 at which point it expected the company to demonstrate significant and embedded progress. On receipt of the report for that re-audit the Appeal Board would decide whether further sanctions were necessary.

On receipt of the March 2022 re-audit, the Appeal Board considered that since the report of the May 2021 re-audit there had been good progress and it appeared that matters were continuing to head in the right direction. The Appeal Board noted that the compliance framework appeared to be well established. It was important that senior staff continued to improve their leadership and role modelling on compliance matters.

Whilst acknowledging an improvement in certain areas the Appeal Board noted that the report of the March 2022 re-audit highlighted a number of concerns regarding Daiichi-Sankyo materials.

The Appeal Board decided that Daiichi-Sankyo should be re-audited. The re-audit should assess the company broadly whilst paying particular attention to the company's materials and activities. The Appeal Board decided that the re-audit should take place in October/November 2022 at which point it expected the company to demonstrate progress in relation to the recommendations of the March 2022 re-audit. On receipt of the report for that re-audit the Appeal Board would decide whether further sanctions were necessary.

On receipt of the November 2022 re-audit report the Appeal Board understood that recommendations from the March 2022 re-audit had either been completed or were ongoing with good progress made. The Appeal Board considered that Daiichi-Sankyo demonstrated sustained progress with a compliance framework which was now established, embedded and functional, and there was clear company support for compliance. The Appeal Board considered that in terms of compliance culture the company had made significant progress since the first audit. The Appeal Board noted that the company had moved to more regular third-party audit of its material and that it had reduced its active materials and it now had greater overall control in this regard. The Appeal Board considered that Daiichi-Sankyo must ensure that all the comments and recommendations in the November 2022 re-audit were addressed. The Appeal Board was unclear why Daiichi Sankyo had not accepted certain recommendations from its external third party auditor and queried whether the compliance culture was sufficiently embedded. The Appeal Board was particularly concerned about Daiichi-Sankyo's understanding of its undertaking given in Case AUTH/3504/4/21.

The Appeal Board understood from the re-audit report that there were a number of cases concerning Daiichi-Sankyo still to be considered by the Panel. As rulings had not been made in these cases, it was agreed this would not form part of the decision making and cases would be reviewed by the Appeal Board either at appeal (if a case went to appeal) or at case completion.

On the basis that Daiichi-Sankyo continued to make improvements, in particular with regards to its materials where the Appeal Board expected to see learnings from cases applied broadly, and that the progress shown to date was continued and commitment to

compliance was maintained, the Appeal Board decided that no further action was required.

An ex-employee of Daiichi-Sankyo submitted a complaint about the disclosure of transfers of value by Daiichi-Sankyo.

COMPLAINT

The complainant stated that the Disclosure UK website showed that the company declared in 2018 that its healthcare professional registration fees were £7,937.60 for named healthcare professionals and zero for aggregated disclosures. The complainant alleged this was a gross underreporting.

The complainant stated that in August 2018 the company sponsored 100 healthcare professionals to attend the European Society of Cardiology (ESC) congress in Munich, Germany. The company paid for the travel, accommodation, food and registration fees. The complainant referred to a staff briefing that showed the names of the healthcare professionals. From searching Disclosure UK many of these healthcare professionals had no activities with Daiichi Sankyo listed. Perhaps all these people chose to be anonymous, but the aggregated data had not been reported.

Registration fee information on the 2019 ESC website indicated even the cheapest early fee for a standard registration was 690 Euros. The complainant was certain that in 2018 the prices were similar. Therefore, it must have cost about 69,000 Euros at least in registration fees, just for that one conference alone to take 100 healthcare professionals. Daiichi-Sankyo only declared under £8,000. Even if all the healthcare professionals asked to be anonymous, this should at least have been declared in aggregate, but there was a zero declaration.

The complainant stated that looking at the disclosure of the travel and accommodation costs, there was £47,724.20 detailed disclosures and £10,067.10 disclosed in aggregate. This was obviously too low to account for flying 100 people from UK to Munich return and putting them in hotels for a 5 day congress.

The complainant alleged that Daiichi-Sankyo had not declared other congress fees as well in 2018 as healthcare professionals were taken to other conferences. Looking back to 2017 and 2016 would probably show that many healthcare professional payments for congresses had not been declared. This was likely to be a pattern of behaviour.

Disclosure was very important, and the complainant alleged that to have such a huge discrepancy was a failure that brought the industry into disrepute. The fact that Daiichi-Sankyo had declared some fees seemed to say that the company had some kind of process in place but had maybe chosen to hide how many people they sponsored to go to ESC as 100 was a huge number to take. Daiichi-Sankyo should have declared 2018 payments by the end of June 2019 but had not.

The complainant alleged breaches of Clauses 2, 9.1, 22.5, 24.1, 24.4, 24.6, 24.7, 24.9 and 24.10.

RESPONSE

Daiichi-Sankyo submitted that it had always been committed to complying with the letter and spirit of the Code. It understood that companies were required to document and publicly disclose certain transfers of value made directly or indirectly to health professionals and healthcare organisations located in Europe. In the UK this was via the ABPI central platform, Disclosure UK. Falling short of the standards required by the Code was a particular disappointment to Daiichi-Sankyo.

Daiichi-Sankyo UK took 98 healthcare professionals to the ESC 2018 Congress. In respect of each relevant delegate the level of sponsorship was travel and accommodation and registration fees. The levels of sponsorship were not reported on Disclosure UK. Daiichi-Sankyo had failed to submit transfers of values made to UK health professionals sponsored to attend the 2018 ESC Congress and acknowledged breaches of Clauses 22.5, 24.1 and 24.4.

There had been no public disclosure of the 2018 transfers of values made to UK health professionals sponsored to attend the 2018 ESC Congress in relation to the requirements of Clause 24 of the Code. Daiichi-Sankyo acknowledged that this failure was also in breach of Clauses 24.7 and 24.9.

Daiichi-Sankyo denied a breach of Clause 24.6. Daiichi-Sankyo submitted that it documented all disclosures and retained the records for at least five years after the end of the calendar year to which they related. The issue raised by the complainant was in respect to omissions.

Daiichi-Sankyo submitted that the transfer of value disclosures were accompanied by methodological notes as required by Clause 24.10 and the company thus denied a breach of Clause 24.10.

Daiichi-Sankyo regretted its failures in respect of Clauses 22.5, 24.1, 24.4, 24.7 and 24.9 and acknowledged that high standards were not maintained with regard to the full reporting of transfers of value. Daiichi-Sankyo acknowledged a breach of Clause 9.1.

Daiichi-Sankyo agreed that transparency in relation to transfers of value to health professionals and healthcare organisations was important to the reputation of the pharmaceutical industry. Daiichi-Sankyo submitted that the omission related to incomplete submissions of transfers of value data. It was for the PMCPA to decide whether the circumstances warranted a breach of Clause 2.

Daiichi-Sankyo set out the root causes as follows:

- Department heads with budget responsibility for congress activities failed to conduct appropriate conversations with the marketing events co-ordinators or monitor their activities to ensure the collection of transfers of value tracking sheets relating to health professionals sponsored to attend the events were duly collated for incorporation into the transfer of value report. The consequence being that indirect transfers of value relating to congresses were not properly identified, and therefore under-reported.
- The review process for transfers of value reporting was not robust enough to identify these issues.

- A local standard operating procedure (SOP) had been prepared to address the issue and a copy was provided.

Daiichi-Sankyo stated that in relation to ESC Congress transfers of value for 2016 and 2017, Daiichi-Sankyo paid travel, accommodation and registration fees for 15, and 28 healthcare professionals respectively. The issues identified and outlined above also impacted the transfer of value for these years.

Daiichi-Sankyo noted that the complainant speculated as to whether a deliberate attempt was made to not disclose the number of healthcare professionals sponsored at the 2018 ESC Congress. This was not so as outlined by the root cause explanations.

In response to a request from the case preparation manager for further information, Daiichi-Sankyo stated that the process followed in relation to the identification of transfers of value incurred in 2018, 2017, and 2016 focused on accessing the information for reporting from its financial system. Daiichi-Sankyo UK **local** transfers of value consisted of direct and indirect transfers where the activities for both categories of transfers was initiated and contracted by the company. The financial results for both activities was reported in the financial system. The difference being that direct transfers of value relating to speaker meetings, consultancy and advisory services were automatically captured in the system by healthcare professional as they were linked to individual healthcare professional contracts.

In respect to indirect transfers of value where the administration and logistics support for events was contracted to a third party, two things should happen on completion of the engagement, the presentation of the invoice along with a supporting file that showed the transfers of value for each healthcare professional that had received a transfer of value. The supporting file was either not provided by the third party or not formally requested by Daiichi-Sankyo UK at the time. In this case, the financials reflected the invoice payment but no individual healthcare professional itemisation for transfer of value purposes. As a result and in the absence of the information on individual healthcare professional itemisation, the wrong assumption was made regarding the completeness of the transfers of value information within the financial reports. Therefore, the reports did not contain healthcare professional itemized transfers of value data for these activities.

The review process for the data was based on the identification of transfers of value reports from the financial system. However, as noted above, the assumption that the itemised transfers of value from the system showing activity for each healthcare professional, represented the total transfers of value that needed to be reviewed was not correct.

The review failed to incorporate sign-offs of the transfers of value by the departmental heads with budget responsibility for engagements that would attract transfers of value, but focused on reasonableness checks around the transfers of value information presented from the financial system, linked back to the meetings data – including attendees – that was stored in Daiichi-Sankyo's system.

No training was given to department heads and marketing events co-coordinators regarding their respective roles re transfers of value outside of a review of the overall consolidated transfer of value numbers for completeness. This was flawed as the review was not based on full information, a number of steps were being put in place to improve the identification, review and reporting of transfers of value.

In response to the complainant's allegations that this was a pattern of behaviour and referred to other congress fees and the inference that this was a systemic issue beyond the 2018 ESC meeting, Daiichi-Sankyo stated that the processes used to identify transfers of value from UK contracted activity was flawed as it only focused on direct transfers of value. This was clearly an oversight that required process improvement.

In light of this, Daiichi-Sankyo would put in place the following improvements:

- a) Local transfers of value policy.
- b) Training for heads of department and all relevant staff.
- c) Enhancements to procurement procedures to identify engagements with transfers of value implications and the intermediary (third party); and to obtain after such activity a report on transfers of value before final payment was made.
- d) Capture of all future transfers of value (direct and indirect) in a single repository
- e) Quarterly monitoring of transfers of value reporting to provide the assurance that the new procedures were operating as intended.
- f) Sign-off from each budget owner as to the completeness of the data, along with final sign-off from the finance director and general manager.

When asked to quantify the total transfers of value that had not been disclosed for 2018, 2017, and 2016 on an aggregate and individual basis, Daiichi-Sankyo stated that it did not have complete visibility of the total transfers of value that had been unreported. The company had however managed to identify the following:

Year	Event	HCPs	ToV £'000s
2018	ESC – European Society of Cardiology	98	325
2018	ESOC – European Stroke Organisation Conference	33	71
2018	ETNA – European Transcultural Nursing Association	1	2
2017	ESC – European Society of Cardiology	28	51
2016	ESC – European Society of Cardiology	15	22

PANEL RULING

The Panel noted that two codes applied to the time period at issue in this case. The 2019 Code and the 2016 Code. However, the clauses cited by the complainant were the same in each Code; the only difference related to the supplementary information to Clause 24.1 Consent to Disclosure. As this change to the supplementary information was not relevant to this case, the Panel decided therefore to consider the case under the 2019 Code.

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 that the presentation provided by the complainant indicated that there were 760 participants at ESC 2018 with 120 from the UK. A list of Daiichi-Sankyo's attendees was included. The Panel noted Daiichi-Sankyo submission that it funded flights, accommodation and congress registration to ESC in 2018 for 98 health professionals. In relation to ESC 2016 and 2017 Daiichi-Sankyo paid travel, accommodation and registration fees for 15 and 28 health professionals respectively. The Panel noted that these transfers of values had not been disclosed on an individual or aggregate basis. The Panel was extremely concerned to note that when asked to quantify the total transfers of value that had not been disclosed for 2018, 2017 and 2016, a total of around £471,000 was described as being identified as unreported by Daiichi-Sankyo and that the company stated it did not have complete visibility of the total transfers of value that had not been reported.

The Panel noted Daiichi-Sankyo's submission that the error related to issues in respect of indirect transfers of value where the administration and logistics support for events was contracted to a third party. The Panel noted Daiichi-Sankyo's submission that in these cases the third party should have included details of transfers of value for each health professional along with the invoice and either the third party had not provided the information or Daiichi-Sankyo had not requested it. The review of the report from the financial system assumed that the data shown was complete and this was not so; the report did not contain health professional itemised transfers of value data for the activities. Further, the review did not include sign off by departmental heads with budget responsibility. It appeared to the Panel that the errors were not helped by the lack of training and a SOP. The local SOP was prepared after the complaint was received.

The Panel considered that the information published on Disclosure UK at the time of the complaint was not comprehensive in relation to support to health professionals to attend conferences in 2018, 2017 and 2016. The Panel ruled a breach of Clause 22.5 of the 2019 Code in relation to the omitted 2018, 2017 and 2016 data as acknowledged by Daiichi-Sankyo. Consequently, as the data had not been disclosed Daiichi-Sankyo had not met the requirement to disclose by 30 June of the relevant year and the Panel ruled breaches of Clauses 24.1 and 24.4 as acknowledged by Daiichi-Sankyo. The data had not been disclosed either as a transfer of value to an individual health professional or in aggregate and therefore the Panel ruled breaches of Clauses 24.7 and 24.9 as acknowledged by Daiichi-Sankyo.

With regard to the requirement to document all disclosures and retain records for 5 years the Panel noted that Daiichi-Sankyo denied a breach in this regard. However, in response to a request for further information, the Panel noted Daiichi-Sankyo's submission that it did not have complete visibility of the total transfers of value that were unreported and it listed the payments it had managed to identify. The Panel noted the apparent inconsistencies and that Daiichi-Sankyo had not been able to produce all of the relevant data. The Panel therefore ruled a breach of Clause 24.6.

The Panel noted that Daiichi-Sankyo had published a methodological note so had met the requirements of Clause 24.10. The company had not followed its methodological note but this was covered by the rulings of breaches of the Code above. The Panel therefore ruled no breach of Clause 24.10. This ruling was appealed.

The Panel noted that there had been a requirement in the Code since 2012 to disclose financial details of sponsorship of UK health professionals etc in relation to attendance at meetings. This included registration fees, costs of accommodation and travel. At that time the information was

to be disclosed in aggregate. Changes were made to the Code since then including the need to disclose transfers of value on an individual basis.

The Panel noted that in 2018 Daiichi-Sankyo had under reported the transfers of value by at least £398,000. The figure published on Disclosure UK (checked in January 2020) was just under £280,000. The Panel queried why the issue had not come to light sooner given the numbers of UK health professionals which attended the ESC and the costs of that support. The Panel considered that the magnitude of under reporting was of serious concern. There was also under reporting in 2017 and 2016.

The Panel was also concerned that the company's processes were inadequate. The new SOP was designed to assist with the new process but the Panel queried whether it was sufficiently robust, particularly with regard to checking the data. It did not appear that the company had corrected the data on Disclosure UK and this must be prioritised. It would in any event need to be updated as part of the requisite undertaking.

The disclosure of transfers of value was an important part of self-regulation and it was of serious concern that Daiichi-Sankyo had not been transparent about the transfers of value for so many years.

High standards had not been maintained and therefore the Panel ruled a breach of Clause 9.1 as acknowledged by Daiichi-Sankyo.

The Panel noted that a ruling of a breach of Clause 2 was used as a sign of particular censure. It considered that to fail to disclose the required information on Disclosure UK was extremely concerning as was the scale of the under reporting. Daiichi-Sankyo's process was inadequate. The Panel ruled a breach of Clause 2.

The Panel decided that as Daiichi-Sankyo's conduct raised concerns about the company's procedures it warranted consideration by the Appeal Board. The Panel decided to report Daiichi-Sankyo to the Appeal Board under Paragraph 8.2 of the Constitution and Procedure.

APPEAL FROM THE COMPLAINANT

The complainant appealed the ruling of no breach of Clause 24.10.

The complainant alleged that whilst the company might well have published a methodological note, it was certainly not the methodology 'used' by the company in its transfers of value disclosure. Furthermore, the recognition methodology described was not 'applied' in this disclosure. In fact, the company 'used' and 'applied' a completely different (and non-compliant) methodology than the one it published, as acknowledged. It was not sufficient just to publish a note, Daiichi-Sankyo must also use and apply that note in order to be compliant. Otherwise any company could just publish any incorrect note, and not bother to check it described the procedure it was actually following. There was therefore a breach of Clause 24.10.

RESPONSE FROM DAIICHI-SANKYO

Daiichi Sankyo submitted that it maintained its position that having published methodological notes the requirements of Clause 24.10 were met. The Panel had ruled no breach of Clause 24.10.

FINAL COMMENTS FROM THE COMPLAINANT

The complainant had no final comments.

APPEAL BOARD RULING

The Appeal Board noted that neither the complainant nor Daiichi-Sankyo had provided a copy of the methodological note in question. There appeared to be agreement from both parties that a methodological note existed and Daiichi-Sankyo submitted that it was used. The Appeal Board noted the submission of the company representatives at the appeal that the note was not to the standard required to cover all transfers of value. In the absence of a copy of the methodological note the Appeal Board noted that there was no evidence of whether the methodological note referred to indirect transfers of value and was not followed or made no reference to indirect transfers of value. The Appeal Board noted that the complainant had the burden of proof and had not provided evidence to establish that Daiichi-Sankyo's methodological note was in breach of the requirements of Clause 24.10. Consequently, the Appeal Board upheld the Panel's ruling of no breach of Clause 24.10. The appeal on this point was unsuccessful.

COMMENTS FROM DAIICHI-SANKYO ON THE REPORT

Daiichi-Sankyo accepted the Panel's rulings of breaches of the Code.

Daiichi-Sankyo submitted that despite its greatest efforts, it did not yet have complete visibility of the total transfers of value that had been historically unreported, beyond certain payments that were already identified as previously notified to the PMCPA in January 2020. Daiichi-Sankyo was committed to providing as complete an update as possible, as well as improving its transfers of value procedures and controls. This process had commenced with a thorough review of the 2019 transfers of value and applying the learnings from the 2019 review to help further identify transfers of value relating to the prior years.

Daiichi-Sankyo submitted that a critical part of the control process involved contacting third party event organizers that had helped it in the planning and logistics for congresses that it now depended on to provide the relevant transfers of value information per health professional. Even though the company had pushed for timely replies, this part of the process took time.

Daiichi-Sankyo gave details of how it would update the information for previous years.

Daiichi-Sankyo submitted that in order to continually improve its systems and processes, it would bring in an independent consulting company, very experienced in audit services, to review its procedures and processes in line with the requirements of the Code. The engagement would commence in March 2020 and would cover the following as a minimum: 14 areas of the Code that align to activities of Daiichi-Sankyo; and a Compliance Management Program which would include written standards (policy updates and review, and accessibility of policies) training (staff and contractors), communications (policies, code updates, case reviews), and compliance culture/monitoring procedures.

Daiichi-Sankyo submitted that such in-depth assessment would take seven weeks, would involve most of its company staff and a final report and action plan would be delivered at the end of April 2020. A copy would be sent to the PMCPA. Daiichi-Sankyo submitted that it was

pleased to have the consulting company on board, subject to contract; it had a strong track record of delivering audit services.

At the consideration of the report the representatives from Daiichi-Sankyo submitted that the company fully accepted, with regret, that it had fallen short of the standards required by the Code.

Daiichi-Sankyo submitted that it had significant regret in not complying with the requirements for transfers of value. This was not due to willful or deliberate practice, but due to a lack of experience in the business at that time in ensuring the company complied fully with this area of the Code.

Daiichi-Sankyo submitted that its review had found the following root causes:

- Relevant staff did not have sufficient conversations to ensure transfers of value were monitored.
- The review process for transfers of value was not sufficiently robust to find these issues. As set out this related to indirect transfers of value spend as opposed to direct payments to health professional/healthcare organisations.
- At the time an SOP was not in place to document the procedure required, and Daiichi-Sankyo relied instead on its methodology document.

As set out in the various correspondences Daiichi-Sankyo submitted that it had taken the following steps to ensure that its transfers of value reporting fully met the standards expected.

- Daiichi-Sankyo submitted that it identified that it needed to do a very thorough review in order to ensure it fully understood the breadth and depth of the transfers of value issue.
- As such its approach was to use 2019 as an appropriate 'stress-test' of its new processes to ensure that this would then give full learnings to apply to the prior years (2016-18).
- This led Daiichi-Sankyo to put forward its undertaking to submit all data to Disclosure UK by 31 March 2020.

Daiichi-Sankyo submitted that it had brought in external support in terms of policy and process creation, and transfers of value operational management, as well as bringing in its European transfers of value subject matter expert.

The company had created an SOP to cover the full end-to-end transfers of value process.

Daiichi-Sankyo submitted that it had contacted suppliers on any transactions that might have a transfers of value element and was in the process of compiling the overall submission for 2019, and resubmissions for 2016-18. The company had reflected on its disappointment in its failure in regard to this matter and had taken the clear decision to bring in an external agency to do a thorough review of key areas of compliance covering: Process and governance framework; Materials review; Meetings review; Disclosure and financial review; NHS/3rd Party collaborations; External communications.

APPEAL BOARD CONSIDERATION OF THE REPORT FROM THE PANEL

The Appeal Board noted the Panel's comments and rulings of breaches of Clauses 2, 9.1, 22.5, 24.1, 24.4, 24.6, 24.7 and 24.9 of the Code, including its decision to report Daiichi-Sankyo to the Appeal Board. The Appeal Board noted that Daiichi-Sankyo had submitted that it was in the process of addressing the issues and it had apologised.

The Appeal Board did not understand why Daiichi-Sankyo had been unable to realise that it needed to disclose transfers of value in relation to funded flights, accommodation and congress registration through a third-party agency. The representatives from Daiichi-Sankyo acknowledged and recognised that the company had not fully understood and implemented its responsibility to correctly disclose transfers of value over a three-year period. The representatives from Daiichi-Sankyo acknowledged that its methodology which focused on direct transfers of value was not adequate and there was no SOP to cover transfers of value in place during this time.

The Appeal Board considered that this case demonstrated that Daiichi-Sankyo had grossly under reported the true position of its transfers of value over a sustained period. It noted from the company representatives that the third-party had supplied data to Daiichi-Sankyo but that the company could not locate the data. The Appeal Board noted the explanation of the company representatives that a certain employee who had/ought to have received the data had left the company. The Appeal Board considered that the issue was broader than one individual's failing. There was a fundamental and systemic failure of the company's processes and a complete misunderstanding of the requirements and application of the Code. The Appeal Board queried whether the company's submissions truly reflected the urgency of the situation.

The Appeal Board decided that in accordance with Paragraph 11.3 of the Constitution and Procedure, Daiichi-Sankyo should be publicly reprimanded for its fundamental systemic failure to have adequate processes in place to correctly disclose transfers of value over a three-year period. The Appeal Board also decided to require an audit of Daiichi-Sankyo's procedures in relation to the Code. The audit should take place as soon as possible. On receipt of the report of the audit the Appeal Board would consider whether further sanctions were necessary.

FURTHER CONSIDERATION BY THE APPEAL BOARD

On receipt of the report for the September 2020 audit, the Appeal Board considered that the report indicated that Daiichi-Sankyo had a systemic lack of governance in the UK. Greater compliance resource was needed urgently to address gaps. Key senior staff needed to provide consistent leadership on compliance and continue to improve their personal knowledge and accountability. The medical and marketing departments needed a better working relationship. All staff needed to understand the importance of compliance and the role of self-regulation and to be clear about the differences between promotional and non-promotional activity.

In addition, the Appeal Board noted that the audit report highlighted many concerns that needed to be addressed and that significant commitment was required to address these matters.

The Appeal Board decided that Daiichi-Sankyo should be re-audited in March 2021 at which point it expected it to be able to demonstrate significant progress. On receipt of the report for the re-audit the Appeal Board would decide whether further sanctions were necessary.

The Appeal Board subsequently agreed to a request from Daiichi-Sankyo to defer the re-audit to May 2021 in order to give the company time to update and embed its standard operating procedures and training regarding the 2021 Code which would come into operation on 1 July 2021. The Appeal Board requested Daiichi Sankyo to provide a comprehensive progress report by the end of March.

FURTHER CONSIDERATION BY THE APPEAL BOARD

At its meeting in April 2021 the Appeal Board received the progress report from Daiichi-Sankyo which it considered was helpful.

On receipt of the May 2021 re-audit report the Appeal Board considered that since the report of the September 2020 audit there had been some meaningful progress and it appeared that matters were beginning to head in the right direction. The Appeal Board noted that a more formal compliance framework had now been established and that there was now a compliance director in role. It was important that senior staff continued to improve their leadership and role modelling on compliance matters. All staff had to understand their responsibility for compliance.

The Appeal Board noted that further improvement was required and the report of the May 2021 re-audit highlighted areas of concern to focus on.

The Appeal Board decided that Daiichi-Sankyo should be re-audited in March 2022 at which point it expected the company to demonstrate significant and embedded progress. On receipt of the report for that re-audit the Appeal Board would decide whether further sanctions were necessary.

FURTHER CONSIDERATION BY THE APPEAL BOARD

On receipt of the March 2022 re-audit, the Appeal Board considered that since the report of the May 2021 re-audit there had been good progress and it appeared that matters were continuing to head in the right direction. The Appeal Board noted that the compliance framework appeared to be well established. It was important that senior staff continued to improve their leadership and role modelling on compliance matters.

Whilst acknowledging an improvement in certain areas the Appeal Board noted that the report of the March 2022 re-audit highlighted a number of concerns regarding Daiichi-Sankyo materials.

The Appeal Board decided that Daiichi-Sankyo should be re-audited. The re-audit should assess the company broadly whilst paying particular attention to the company's materials and activities. The Appeal Board decided that the re-audit should take place in October/November 2022 at which point it expected the company to demonstrate progress in relation to the recommendations of the March 2022 re-audit. On receipt of the report for that re-audit the Appeal Board would decide whether further sanctions were necessary.

FURTHER CONSIDERATION BY THE APPEAL BOARD

On receipt of the November 2022 re-audit report the Appeal Board understood that recommendations from the March 2022 re-audit had either been completed or were ongoing with good progress made. The Appeal Board considered that Daiichi-Sankyo demonstrated

sustained progress with a compliance framework which was now established, embedded and functional, and there was clear company support for compliance. The Appeal Board considered that in terms of compliance culture the company had made significant progress since the first audit. The Appeal Board noted that the company had moved to more regular third-party audit of its material and that it had reduced its active materials and it now had greater overall control in this regard. The Appeal Board considered that Daiichi-Sankyo must ensure that all the comments and recommendations in the November 2022 re-audit were addressed. The Appeal Board was unclear why Daiichi Sankyo had not accepted certain recommendations from its external third party auditor and queried whether the compliance culture was sufficiently embedded. The Appeal Board was particularly concerned about Daiichi-Sankyo's understanding of its undertaking given in Case AUTH/3504/4/21.

The Appeal Board understood from the re-audit report that there were a number of cases concerning Daiichi-Sankyo still to be considered by the Panel. As rulings had not been made in these cases, it was agreed this would not form part of the decision making and cases would be reviewed by the Appeal Board either at appeal (if a case went to appeal) or at case completion.

On the basis that Daiichi-Sankyo continued to make improvements, in particular with regards to its materials where the Appeal Board expected to see learnings from cases applied broadly, and that the progress shown to date was continued and commitment to compliance was maintained, the Appeal Board decided that no further action was required.

Complaint received	30 November 2019
Undertaking received	13 February 2020
Appeal Board consideration	11 March, 10 December 2020, 21 January 2021, 22 April 2021, 16 September 2021, 28 April 2022, 23 February 2023
Interim case report first published	1 September 2020
Case completed	23 February 2023