

CASE AUTH/3680/8/22

VOLUNTARY ADMISSION BY ASTELLAS

Undeclared transfers of value

CASE SUMMARY

This case was in relation to undeclared transfers of value to two healthcare organisations and five patient organisations between 2019 and 2021.

The Panel ruled a breach of the following Clauses of the 2019 Code in relation to two payments made to the European Renal Association (ERA), one in 2019 and one in 2020, which had not been disclosed as part of its Annual Disclosure for these years and should have been published by 30 June 2020 and 30 June 2021, respectively:

Breach of Clause 24.1	Failure to publicly disclose certain transfers of value made directly to healthcare organisations located in Europe
Breach of Clause 24.4	Failure to disclose transfers of value annually within the first six months after the end of the calendar year in which the transfers of value were made

The Panel ruled a breach of the following Clauses of the 2021 Code in relation to two payments made in 2021, one to the ERA and one to the International Continence Society (ICS), which had not been disclosed as part of Astellas' Annual 2021 Disclosure via the ABPI Disclosure Portal and should have been published by 30 June 2022:

Breach of Clause 28.1	Failure to publicly disclose certain transfers of value made directly to healthcare organisations located in Europe
Breach of Clause 31.1	Failure to disclose transfers of value annually within the first six months after the end of the calendar year in which the transfers of value were made

The Panel ruled a breach of the following Clause of the 2019 Code in relation to one payment made to Kidney Research UK in 2020 which had not been included in its 2020 patient organisation disclosure on the Astellas website by the end of June 2021:

Breach of Clause 27.7	Failure to disclose transfers of value to a patient organisation that must be done within the first six months after the end of the calendar year in which the transfers of value were made
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The Panel ruled a breach of the following Clauses of the 2021 Code in relation to five payments to patient organisations made in 2021; two to Leukaemia Care, one to Kidney

Care UK, one to Prostate Care UK and one to Duchenne UK, had not been disclosed as part of Astellas' Annual 2021 Disclosure via the Astellas website by the end of June 2022:

Breach of Clause 29.1	Failure to publicly disclose transfers of value to a patient organisation
Breach of Clause 31.1	Failure to disclose transfers of value to patient organisations annually within the first six months after the end of the calendar year in which the transfers of value were made

Overall, the Panel ruled a breach of the following Clause of the 2021 Code as the disclosure of transfers of value was an important part of self-regulation and it considered that high standards had not been maintained:

Breach of Clause 5.1	Failing to maintain high standards
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The Panel ruled no breach of the following Clause of the 2021 Code as it considered, on balance, that in the particular circumstances of this case, its ruling of a breach of Clause 5.1 was sufficient in relation to the failure to publicly disclose the healthcare organisation and patient organisation payments and an additional breach of Clause 2 was not warranted:

No Breach of Clause 2	Requirement that activities or material must not bring discredit upon, or reduce confidence in, the pharmaceutical industry
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**This summary is not intended to be read in isolation.
For full details, please see the full case report below.**

FULL CASE REPORT

Astellas Pharma Ltd made a voluntary admission about undeclared transfers of value (ToVs) to healthcare organisations (HCOs) in 2019, 2020 and 2021 and patient organisations in 2020 and 2021.

As Paragraph 5.6 of the Constitution and Procedure required the Director to treat a voluntary admission as a complaint, the matter was taken up with Astellas.

COMPLAINT

Astellas explained that it had always been committed to complying with both the letter and spirit of the ABPI Code of Practice; it fully understood its obligation to publicly disclose certain ToVs made directly or indirectly to health professionals, healthcare organisations and patient organisations located in the UK, whether made by Astellas or other members of the Astellas Group.

Astellas informed the PMCPA that during routine monitoring of Astellas group non-Astellas Pharma Ltd interactions, an error was identified in reporting a 2022 interaction with a medical

conference organisation. Upon further investigation, it was discovered this error had also occurred in Astellas' submitted ToV disclosures for 2019, 2020 and 2021 for the same organisation. During this full and thorough investigation, Astellas also identified (i) an error with reporting sponsorship related to a second healthcare organisation; (ii) five patient organisation payments which had not been included in Astellas' recent 2021 patient organisation disclosure, and (iii) one patient organisation payment which had not been included in Astellas' 2020 disclosure. Astellas acknowledged this fell short of the required standards for disclosure which was particularly disappointing for Astellas.

Astellas completed a root cause analysis on the medical conference organisation, sponsorship and the patient organisation payments as outlined below:

- Medical conference organisation:
 - The European Renal Association (ERA) was an organisation which promoted health and care in nephrology and, among other things, organised medical congresses which were attended by delegates from all over the world; its operative headquarters was in Italy and its registered office in the UK. The organisation had been set up in Astellas' accounting system as a third-party vendor.
 - Astellas used a single supplier system, where it was important to ensure the correct Vendor Identifier Code was selected and assigned to the supplier. When the Purchase Order was raised, this triggered a set of General Ledger (GL) Codes that were used for correct reporting. Once a vendor was set up within the supplier system there was no requirement to make routine annual amendments unless circumstances changed, eg, payment details. Therefore, the account was not checked when setting up subsequent engagements.
 - Through the investigation it was discovered that the organisation had been sponsored by Astellas annually between 2019 and 2022.
 - Astellas' disclosure methodological note stated: ***'Where services are provided by a 3rd party provider on behalf of several HCPs/HCOs (e.g., to provide national/regional educational meetings) and the recipient HCPs/HCOs cannot be individually identified, Astellas will disclose against the 3rd party provider'***.
 - Given the Astellas methodology for disclosure of ToVs to 3rd parties providing national/regional educational meetings, the organisation should have been set up as a healthcare organisation instead of a third-party. The assigned GL Code did not support the payment pulling through to the UK ToV disclosure for HCOs in 2019, 2020 and 2021. The amounts identified equated to:

2019 = £39,440 (9% of Astellas' HCO disclosure for that year)
 2020 = £84,899 (11% of Astellas' HCO disclosure for that year)
 2021 = £53,859 (6% of Astellas' HCO disclosure for that year)
 Total = £178,198 across the 3 years.

- Sponsorship:
 - The International Continence Society (ICS) was a registered charity with a global health focus which strove to improve the quality of life for people affected by urinary, bowel and pelvic floor disorders by advancing pure, applied and clinical science through education, research and advocacy.
 - Although it was a UK-registered charity, Astellas noted it had over 3,000 members. It was a thriving society of urologists, uro-gynaecologists, physiotherapists, nurses and research scientists with a focus on research and education in continence and pelvic floor disorders. Therefore, Astellas had identified it as a healthcare organisation and previously reported payments against the organisation, as a healthcare organisation, in 2020.
 - The sponsorship for £58,523 (7% of Astellas' HCO disclosure for that year), in support of a conference run by the society in 2021, was set up with, and paid to, the third-party congress organiser based in Switzerland, however, the named society was the recipient of the funding and therefore disclosure should have taken place in the UK.
 - The assigned GL Code did not support the payment pulling through to the UK HCO ToV disclosure for this HCO.

Astellas had identified no additional issues with other 3rd Party suppliers which should have been classified as an HCO during its investigation.

Following the investigation, Astellas believed the healthcare organisation errors with the payments to the two healthcare organisations were isolated incidents related to human error in selecting Vendor Identifier and GL Code selection.

- Patient Organisations:
 - As indicated above, during the in-depth review of all payment activities, related to interactions created by above country teams, Astellas also identified six patient organisation payments which had not been included in its 2020 and 2021 patient organisation disclosure on the Astellas website.
 - It was understood that the Astellas team raising these patient organisation interactions were mistaken on the GL Codes to be used for these types of interactions to ensure they pulled through for ToV disclosure in the UK. Upon identification of these errors, an update had been made to the UK PO disclosure templates for 2020 and 2021 on the Astellas website.

Astellas believed the patient organisation errors were a result of incorrect GL Codes being used when setting up payments to patient organisations and their representatives therefore, they did not pull through to the UK disclosure.

Conclusion

In summary, Astellas submitted it had identified an error with one healthcare organisation recipient where payments had not been disclosed in 2019, 2020 and 2021 and one healthcare

organisation where the payment had not been disclosed in 2021. These errors related to GL Code selection which impacted healthcare organisation reporting for these two healthcare organisations and had been rectified. Astellas also submitted that during the investigation of the healthcare organisation, reporting it identified an additional matter related to six patient organisation payments which had been isolated to a single root cause. Astellas had a strong culture of compliance and always strove to identify errors and improve processes. Astellas accepted this was its error and it had a duty to rectify and self-report in line with the letter and spirit of the ABPI Code of Practice. Astellas had developed a full corrective and preventive action (CAPA) plan to ensure these errors were corrected, templates were resubmitted and errors were not repeated in future disclosures.

Astellas believed the PMCPA should consider Clause 24.1 of the 2019 ABPI Code of Practice for the 2019 and 2020 disclosure errors and Clause 28.1 of the 2021 ABPI Code of Practice for the 2021 errors. In relation to the patient organisation disclosure errors, Astellas believed the PMCPA should consider Clause 27.7 of the 2019 ABPI Code of Practice for the payment in 2020 to Kidney Research UK, and Clause 29.1 of the 2021 ABPI Code of Practice for the payments made in the 2021 to Leukaemia Care, Kidney Care UK, Prostate Cancer UK and Duchenne UK.

When writing to Astellas, the Authority asked it to consider the requirements of Clauses 24.1, 24.4 and 27.7 of the 2019 Code and Clauses 28.1, 31.1 and 29.1 of the 2021 Code which included those clauses cited by Astellas. Astellas was also asked to bear in mind Clauses 9.1 and 2 of the 2019 Code and Clauses 5.1 and 2 of the 2021 Code in relation to the undisclosed transfers in 2021.

RESPONSE

By way of a short summary, Astellas provided a recap on the matter at hand. On 4 August 2022, Astellas informed the PMCPA that, as a consequence of a finding during routine monitoring and review, it had identified a total of 4 healthcare organisation and 6 patient organisation payments which had not been disclosed on either the ABPI Disclosure Portal (HCOs) or Astellas' website (patient organisations) between 2019 and 2021. On discovering these omissions, Astellas conducted a thorough root cause analysis and had developed a full CAPA Plan to ensure these errors were corrected, templates were resubmitted, and errors were not repeated in future disclosures. The CAPA Plan contained 3 key corrective actions, which had all been completed, and 4 key preventive actions, of which 3 had already been completed and one, relating to an additional Global Governance Programme, would be completed by the end of March 2023.

As requested, Astellas provided further details below on this matter in relation to the requirements of Clauses 24.1, 24.4, 27.7, 9.1 and 2 of the 2019 Code and Clauses 28.1, 29.1, 31.1, 5.1 and 2 of the 2021 Code.

Transfers of Value to Healthcare Organisations – 2019 and 2020

Regarding the undisclosed transfers of value made for the Sponsorship of the healthcare organisations, Astellas reported 4 transfers of value had not been disclosed via the ABPI Disclosure Portal in 2019, 2020 and 2021.

Further details requested on these were as follows:

- **ERA – 2019:**
 - The transfer of value made was for the Sponsorship of the ERA Congress.
 - The ERA Congress took place on 13 – 16 June 2019 in Budapest.
 - The ToV was made over 2 payments on 24 April 2019 for £29,198 and 9 May 2019 for £10,242. Total payment of £39,440 (9% of Astellas' HCO disclosure for that year).
 - These 2 payments covered the Sponsorship cost and included an Industry Symposium and Exhibition Booth.

- **ERA – 2020:**
 - The transfer of value made was for the Sponsorship of the ERA Congress.
 - The ERA Congress 2020 took place on 6 – 9 June 2020 and was attended virtually.
 - The ToV was made over 4 payments on 25 June 2020 for £17,968, 9 July 2020 for £13,476, 23rd July 2020 for £44,471 and 20 August 2020 for £8,984. Total payment of £84,899 (11% of Astellas' HCO disclosure for that year).
 - These 4 payments covered the Sponsorship cost and included Medical Symposium, Exhibition Booth, Commercial Congress Sponsorship and Medical Congress Sponsorship.

This equated to a total amount of £124,339 across 2 years to ERA.

With reference to the requirements of Clauses 24.1, 24.4, 9.1 and 2 of the 2019 ABPI Code of Practice:

Clause 24.1 - 'Companies must document and publicly disclose certain transfers of value made directly or indirectly to health professionals and healthcare organisations located in Europe':

Astellas accepted a breach of Clause 24.1 as it did not publicly disclose the ToVs made to ERA as part of its Annual 2019 and 2020 Disclosure via the ABPI Disclosure Portal.

Clause 24.4 – 'Disclosures must be made annually in respect of each calendar year. Disclosure must be in the first six months after the end of the calendar year in which the transfers of value were made':

Astellas refuted a breach of Clause 24.4 as the Annual Company Disclosure was submitted within the required timelines for health professional and healthcare organisation disclosures for both 2019 and 2020. The Astellas Disclosure data for 2019 transfers of value were loaded onto the ABPI Disclosure Platform on 12 March 2020 and published in line with ABPI Portal process for that year; and Astellas' Disclosure data for 2020 transfers of value were loaded onto the ABPI Disclosure Platform on 23 March 2021 and published in line with the ABPI Portal process for

that year. Astellas also believed this matter had already been addressed in Clause 24.1 in relation to the individual identified payments.

Clause 9.1 – ‘High standards must be maintained at all times’:

Astellas refuted a breach of Clause 9.1. As evidenced within the enclosed standard operating procedures (SOPs), Astellas had clear and detailed processes in place which outlined the process of Disclosure. Astellas’ Quality Documents were trained out to Astellas staff via its Learning Management System (LMS) and training was refreshed annually. Astellas also had a Global Transparency Team, who worked closely with the local affiliates, responsible for the oversight of payments made to health professionals/HCOs and POs and annual reporting for each affiliate in line with their respective reporting timelines. Astellas believed its processes, systems and training supported high standards within the organisation along with its strong Compliance Culture and openness to speak up when an issue had been identified. The issues identified above were as a result of human error when setting up the Vendor ID, which was compounded when disclosure was made against the same vendor in subsequent years. Astellas firmly believed it continually maintained high standards for recording and reporting ToVs, and where errors were identified taking appropriate actions.

Clause 2 – ‘Activities or materials associated with promotion must never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry’:

Astellas refuted a breach of Clause 2 and submitted that the findings contained in the voluntary admission, in the context of the disclosures made by Astellas and the industry as a whole, would not discredit the industry. Astellas’ investigation supported the conclusion that this was not a systemic issue. Astellas believed the actions taken, including the decision to submit a voluntary admission, demonstrated the maturity of its Compliance Culture and provided evidence of its high standards of self-regulation including the ability to act and correct quickly.

Transfers of Value to Healthcare Organisations – 2021

- **ERA – 2021:**

- The transfer of value made was for the Sponsorship of the ERA Congress.
- ERA Congress took place on 5 – 8 June 2021 in Berlin, however, Astellas had a virtual attendance.
- Date transfer of value made: This was made on 3 June 2022 for £53,859 (6% of Astellas’ HCO disclosure for that year).
- This payment covered the Sponsorship cost and included a Premium Exhibition Package and an Industry Symposium.

- **ICS – 2021:**

- The transfer of value was made for the Sponsorship of the ICS Conference
- The ICS Conference took place on 14 – 17 October 2021, Astellas had a virtual attendance.
- Date ToV made: This was made on 25 August 2021 for £58,523 (7% of Astellas’ disclosure payment for that year).

- This payment included the Sponsorship cost.

This equated to a single payment of £53,859 to ERA and a single payment of £58,523 to ICS.

With reference to the requirements of Clauses 28.1, 31.1, 5.1 and 2 of the 2021 ABPI Code of Practice:

Clause 28.1 – ‘Companies must document and publicly disclose annually certain transfers of value made directly or indirectly to health professionals, other relevant decision makers and healthcare organisations located in Europe. This includes any employee of a pharmaceutical company whose primary occupation is that of a practising health professional’:

Astellas accepted a breach of Clause 28.1 as it did not publicly disclose the transfers of value made to The ERA and The ICS as part of its Annual 2021 Disclosure via the ABPI Disclosure Portal.

31.1 – ‘Disclosures must be made annually in respect of each calendar year. Disclosure must be in the first six months after the end of the calendar year in which the transfers of value were made’:

Astellas refuted a breach of Clause 31.1 as the Annual company disclosure was submitted within the required timelines for health professional and healthcare organisation disclosures for 2021. Astellas’ Disclosure data for 2021 transfers of value were loaded onto the ABPI Disclosure Platform on 28 March 2022 and published in line with ABPI Portal process for that year. Astellas also believed this matter has already been addressed in Clause 28.1 in relation to the individual identified payments.

Clause 5.1 – ‘High standards must be maintained at all times’:

Astellas refuted a breach of Clause 5.1. As evidenced within the SOPs provided, Astellas had clear and detailed processes in place which outlined the process of Disclosure. All Astellas Quality Documents were trained out to Astellas staff via its learning management system and training was refreshed annually; Astellas also had a Global Transparency Team, who worked closely with the local affiliates, responsible for the oversight of payments made to health professionals/healthcare organisations and patient organisations and annual reporting for each affiliate in line with their respective reporting timelines. Astellas believed its processes, systems and training supported high standards within the organisation along with its strong Compliance Culture and openness to speak up when an issue had been identified. The issues identified were as a result of human error, when selecting the GL Codes. Astellas firmly believed it continually maintained high standards for recording and reporting transfers of value, and where errors were identified took appropriate actions.

Clause 2 – ‘Activities or materials associated with promotion must never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry’:

Astellas refuted a breach of Clause 2 and submitted that the findings contained in the voluntary admission, in the context of the disclosures made by Astellas and the

industry as a whole, would not discredit the industry. Astellas' investigation supported the conclusion that this was not a systemic issue. Astellas believed the actions taken, including the decision to submit a voluntary admission, demonstrated the maturity of its Compliance Culture and provided evidence of its high standards of self-regulation including the ability to act and correct quickly.

Transfers of value to Patient Organisations 2020

In relation to the undisclosed transfers of value made to the patient organisations: Kidney Research UK, Leukaemia Care, Kidney Care UK, Prostate Cancer UK and Duchenne UK; Astellas reported there were 6 ToVs, made to 5 patient organisations, that had not been disclosed within the 2020 and 2021 Patient Organisation Disclosures on the Astellas website. The details of each patient organisation were captured in Attachment 1 (Voluntary Admission Letter dated 4 August 2022). Below is our response to the further information requested:

- **Kidney Research UK – 2020:**
 - The transfer of value was made for a Speaker Service at an internal Disease Awareness educational event conducted for World Kidney Day in 2020.
 - The Speaker Service took place on 12 March 2020 at the Astellas Office in Woking.
 - The transfer of value was made on 14 April 2020 for £350.

With reference to the requirements of Clauses 27.7, 9.1 and 2 of the 2019 ABPI Code of Practice:

Clause 27.7 – ‘Each company must make publicly available, at a national or European level, a list of patient organisations to which it provides financial support and/or significant indirect/non-financial support, which must include a description of the nature of the support that is sufficiently complete to enable the average reader to form an understanding of the significance of the support. The list of organisations being given support must be disclosed annually in respect of each calendar year. Disclosure must be in the first six months after the end of the calendar year in which the transfers of value were made’:

Astellas accepted a breach of Clause 27.7 as it did not publicly disclose the transfer of value made to Kidney Research UK as part of its Annual 2020 Disclosure via the Astellas website. The Astellas Disclosure data for 2020 transfers of value was loaded onto, and available for viewing via, the Astellas website on 30 June 2021.

Clause 9.1 – ‘High standards must be maintained at all times’:

Astellas refuted a breach of Clause 9.1. As evidenced within the SOPs provided, Astellas had clear and detailed processes in place which outlined the process of Disclosure, all Astellas Quality Documents were trained out to Astellas staff via its learning management system and training was refreshed annually. Astellas also had a Global Transparency Team, who worked closely with the local affiliates, responsible for the oversight of payments made to health professionals/healthcare organisations and patient organisations and annual reporting for each affiliate in line with their respective reporting timelines. Astellas believed its processes, systems

and training supported high standards within the organisation along with its strong Compliance Culture and openness to speak up when an issue had been identified. The issues identified were as a result of human error, when selecting the GL Codes. Astellas firmly believed it continually maintained high standards for recording and reporting transfers of value, and where errors were identified, took appropriate actions.

Clause 2 – ‘Activities or materials associated with promotion must never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry’:

Astellas refuted a breach of Clause 2 and submitted that the findings contained in the voluntary admission, in the context of the disclosures made by Astellas and the industry as a whole, would not discredit the industry. Astellas’ investigation supported the conclusion that this was not a systemic issue. Astellas believed the actions taken, including the decision to submit a voluntary admission, demonstrated the maturity of its Compliance Culture and provided evidence of its high standards of self-regulation including the ability to act and correct quickly.

Transfers of Value to Patient Organisations 2021

- **Leukaemia Care – 2021:**
 - The transfer of value was made for a Speaker Service to create a video series titled ‘AML at home’.
 - The Speaker Service was conducted over a series of dates during 2021.
 - The transfer of value was made on 18 August 2021 for £725. This incorporated two services provided through the patient organisation and the contracted amount for each service was £350 and £375.
- **Kidney Care UK – 2021:**
 - The transfer of value was made for a Speaker Service to provide a Patient Perspective at an Astellas Internal Global Brand Team Meeting.
 - The Speaker Service was conducted virtually on 16 March 2021.
 - The transfer of value was made on 11 August 2021 for £67.
- **Prostate Cancer UK – 2021:**
 - The transfer of value was made for a Speaker Service to discuss Prostate Cancer at an Astellas Internal Medical Meeting.
 - The Speaker Service was conducted virtually on 24 November 2021.
 - The transfer of value was made on 16 February 2021 for £75.
- **Duchenne UK – 2021:**
 - The transfer of value made was for a Sponsorship to support the production of educational material titled ‘Essential guide to adolescence and beyond’.
 - The transfer of value was made on 18 August 2021 for £15,000.
 - This payment supported Sponsorship costs including the development and production of materials by Duchenne UK.

With reference to the requirements of Clauses 29.1, 31.1, 5.1 and 2 of the 2021 ABPI Code of Practice:

Clause 29.1 – ‘Companies must make publicly available annually, a list of patient organisations to which it provides donations, grants or sponsorship (including in relation to events/meetings) or with whom it has engaged to provide contracted services over the reporting period. This information must be disclosed on the company website either on a national or European level. Each reporting period shall cover a full calendar year’:

Astellas accepted a breach of Clause 29.1 as it did not publicly disclose the transfer of value made to the above-mentioned patient organisations as part of its Annual 2021 Disclosure via the Astellas website.

Clause 31.1 – ‘Disclosures must be made annually in respect of each calendar year and must be in the first six months after the end of the calendar year in which the transfers of value/ payments were made’:

Astellas refuted a breach of Clause 31.1 as the Annual company disclosure was submitted within the required timelines for 2021 Patient Organisation Disclosures to the Astellas website. The Astellas Patient Organisation Disclosure data for 2021 was loaded onto, and available for viewing on 30 June 2022. Astellas also believed this matter had already been addressed in Clause 29.1 in relation to the individual identified payments.

Clause 5.1– ‘High standards must be maintained at all times’:

Astellas refuted a breach of Clause 5.1. As evidenced within the SOPs provided, Astellas had clear and detailed processes in place which outlined the process of disclosure, all Astellas Quality Documents were trained out to Astellas staff via its learning management system and training was refreshed annually. Astellas also had a Global Transparency Team, who worked closely with the local affiliates, responsible for the oversight of payments made to health professionals/healthcare organisations and patient organisations, and annual reporting for each affiliate in line with their respective reporting timelines. Astellas believed its processes, systems and training supported high standards within the organisation along with its strong Compliance Culture and openness to speak up when an issue had been identified. The issues identified were as a result of human error when selecting the GL Codes. Astellas firmly believed it continually maintained high standards for recording and reporting transfers of value, and where errors were identified, took appropriate actions.

Clause 2 – ‘Activities or materials associated with promotion must never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry’:

Astellas refuted a breach of Clause 2 and submitted that the findings contained in the voluntary admission, in the context of the disclosures made by Astellas and the industry as a whole, would not discredit the industry. Astellas’ investigation supported the conclusion that this was not a systemic issue. Astellas believed the actions taken, including the decision to submit a voluntary admission, demonstrated

the maturity of its Compliance Culture and provided evidence of its high standards of self-regulation including the ability to act and correct quickly.

PANEL RULING

The Panel noted Astellas' explanation that as a consequence of a finding during routine monitoring and review, it had identified a total of 4 healthcare organisation and 6 patient organisation payments which had not been disclosed on either the ABPI Disclosure Portal (HCOs) or Astellas' website (patient organisations) between 2019 and 2021.

HCO Disclosures

The Panel noted that Clause 24.1 of the 2019 Code stated that companies must document and publicly disclose certain transfers of value made directly or indirectly to health professionals and healthcare organisations located in Europe. Clause 24.4 of the 2019 Code required that such disclosures must be made annually in respect of each calendar year and must be in the first six months after the end of the calendar year in which the transfers of value were made.

The Panel noted Astellas' submission that two payments made to the ERA, one in 2019 and one in 2020, had not been disclosed as part of its Annual Disclosure for these years, which should have been published by 30 June 2020 and 30 June 2021, respectively, via the ABPI Disclosure Portal and the Panel therefore ruled a **breach of Clause 24.1 of the 2019 Code** in relation to each of the two undisclosed payments as acknowledged by Astellas. Consequently, as the data had not been disclosed, Astellas had not met the requirement to disclose in the first six months of each of the relevant years to which these payments related (by 30 June 2020 and 30 June 2021 respectively) and the Panel ruled a **breach of Clause 24.4 of the 2019 Code** in relation to each of the two undisclosed payments.

Clause 28.1 of the 2021 Code stated that companies must document and publicly disclose annually certain transfers of value made directly or indirectly to health professionals, other relevant decision makers and healthcare organisations located in Europe. Clause 31.1 of the 2021 Code stated that Disclosures must be made annually in respect of each calendar year. Disclosure must be in the first six months after the end of the calendar year in which the transfers of value/payments were made.

The Panel noted that two payments made in 2021, one to the ERA and one to the ICS, had not been disclosed as part of Astellas' Annual 2021 Disclosure via the ABPI Disclosure Portal which should have been published by 30 June 2022 and the Panel therefore ruled a **breach of Clause 28.1 of the 2021 Code** in relation to the two undisclosed payments as acknowledged by Astellas. Consequently, as the data had not been disclosed, Astellas had not met the requirement to disclose by 30 June 2022 and the Panel therefore ruled a **breach of Clause 31.1 of the 2021 Code**.

Patient Organisation Disclosures

The Panel noted that Clause 27.7 of the 2019 Code stated, amongst other things, that each company must make publicly available, at a national or European level, a list of patient organisations to which it provides financial support and/or significant indirect/non-financial support, which must include a description of the nature of the support that is sufficiently complete to enable the average reader to form an understanding of the significance of the

support. The list of organisations being given support must be disclosed annually in respect of each calendar year. Disclosure must be in the first six months after the end of the calendar year in which the transfers of value were made.

The Panel noted Astellas' submission that one payment made to Kidney Research UK in 2020 had not been included in its 2020 patient organisation disclosure on the Astellas website by the end of June 2021 and the Panel therefore ruled a **breach of Clause 27.7 of the 2019 Code** as acknowledged by Astellas.

Clause 29.1 of the 2021 Code stated, amongst other things, that companies must make publicly available, annually, a list of patient organisations to which it provides donations, grants or sponsorship (including in relation to events/meetings) or with whom it has engaged to provide contracted services over the reporting period. This information must be disclosed on the company website either on a national or European level. Each reporting period shall cover a full calendar year. Clause 31.1 of the 2021 Code which applied to transfers of value to patient organisations as set out in Clause 29 stated that disclosures must be made annually in respect of each calendar year. Disclosure must be in the first six months after the end of the calendar year in which the transfers of value/payments were made.

The Panel noted that five payments to patient organisations made in 2021; two to Leukaemia Care, one to Kidney Care UK, one to Prostate Care UK and one to Duchenne UK, had not been disclosed as part of Astellas' Annual 2021 Disclosure via the Astellas website by the end of June 2022 and the Panel therefore ruled a **breach of Clause 29.1 of the 2021 Code** in relation to each of the five undisclosed payments as acknowledged by Astellas. Consequently, as these payments had not been disclosed, Astellas had not met the requirement to disclose by 30 June 2022 and the Panel therefore ruled a **breach of Clause 31.1 of the 2021 Code**.

The Panel noted that Astellas was asked to bear in mind Clauses 9.1 and 2 of the 2019 Code in relation to the undisclosed transfers in 2019 and 2020 and Clauses 5.1 and 2 of the 2021 Code in relation to the undisclosed transfers in 2021. The Panel, however, considered that the requirements with regard to disclosure of transfers of value in relation to healthcare organisations and patient organisations and Clauses 9.1 (2019 Code) and 5.1 (2021 Code) and Clause 2 were closely similar in both versions of the Code. The Panel, therefore, decided to make an overall Clause 5.1 and 2 ruling under the 2021 Code in this regard as this was the Code that was in operation at the time the complaint was submitted.

The Panel noted that the disclosure of transfers of value was an important part of self-regulation and considered that high standards had not been maintained and, overall, a **breach of Clause 5.1 of the 2021 Code** was ruled.

In the Panel's view, transparency in relation to transfers of value was an important means of building and maintaining confidence in the pharmaceutical industry. Whilst the Panel was concerned that the requirements of the Code had not been met in relation to disclosure of payments made to healthcare organisations and patient organisations over multiple years, as required by the Code, and payments made in 2019, 2020 and 2021 had only been identified in 2022, it noted that the errors were identified during the company's own routine monitoring and review. The Panel further noted Astellas' submission that following its investigation, Astellas believed the HCO errors were isolated incidents related to human error in selecting Vendor Identifier and GL Codes and the patient organisation errors were a result of incorrect GL Codes being used when setting up payments to patient organisations and their representatives so that

they did not pull through to the UK disclosure; Astellas' had developed a full CAPA plan to ensure these errors were corrected, templates were resubmitted and errors were not repeated in future disclosures.

The Panel noted its comments and rulings above and considered, on balance, that in the particular circumstances of this case, its ruling of a breach of Clause 5.1 was sufficient in relation to the failure to publicly disclose the HCO and patient organisation payments and an additional breach of Clause 2 was not warranted. The Panel therefore, on balance, ruled **no breach of Clause 2**.

Complaint received **4 August 2022**

Case completed **18 July 2023**