

CASE AUTH/3847/11/23

VOLUNTARY ADMISSION BY NOVO NORDISK

Undisclosed transfers of value

CASE SUMMARY

This case was a voluntary admission by Novo Nordisk concerning undisclosed transfers of value of approximately £7.8 million over a three-year period selected by Novo Nordisk as part of its internal investigation (2020-2022). The failures to disclose related to approximately 500 transfers of value to over 150 different vendors and represented between 10-14% of each year's total transfers of value.

The outcome under the 2019 Code was:

Breach of Clause 2	Bringing discredit upon, and reducing confidence in, the pharmaceutical industry
Breach of Clause 9.1	Failing to maintain high standards
Breach of Clause 23.2	Failing to publicly disclose details of the fees paid to consultants in the UK for certain services rendered by them
Breach of Clause 24.1	Failing to document and publicly disclose annually certain transfers of value made directly or indirectly to health professionals, other relevant decision makers and healthcare organisations
Breach of Clause 24.4	Failing to make disclosures annually in respect of each calendar year in the first six months after the end of the calendar year in which the transfers of value were made
Breach of Clause 27.7	Failing to make publicly available a list of patient organisations which it supports
Breach of Clause 27.8	Failing to meet the disclosure requirements when engaging patient organisations
No Breach of Clause 23.4	Requirement that fees, expenses and the like due to consultants must be disclosed.

The outcome under the 2021 Code:

Breach of Clause 2	Bringing discredit upon, and reducing confidence in, the pharmaceutical industry
Breach of Clause 5.1	Failing to maintain high standards
Breach of Clause 24.4 (x2)	Failing to disclose annually details of the fees and expenses paid to UK individuals, organisations etc for contracted services
Breach of Clause 24.6 (x2)	Failing to meet the disclosure requirements for fees and expenses for contracted services
Breach of Clause 28.1	Failing to document and publicly disclose annually certain transfers of value made directly or indirectly to health

	professionals, other relevant decision makers and healthcare organisations
Breach of Clause 29.1	Failing to make publicly available annually, a list of patient organisations to which it provides donations, grants or sponsorship or with whom it has engaged to provide contracted services over the reporting period
Breach of Clause 29.2	Failing to meet the disclosure requirements for the provision of donations, grants or sponsorship to a patient organisation
Breach of Clause 30.1	Failing to make publicly available annually details of the fees for certain contracted services paid to members of the UK public, including patients and journalists
Breach of Clause 31.1	Failing to make disclosures annually in respect of each calendar year in the first six months after the end of the calendar year in which the transfers of value were made

The outcome under the 2021 Code, in relation to associated expenses for contracted services in 2022, was:

No Breach of Clause 24.4	Requirement to disclose annually details of the fees and expenses paid to UK individuals, organisations etc for contracted services
No Breach of Clause 24.6	Requirement to meet the disclosure requirements for fees and expenses for contracted services

The Panel decided to report the company to the Appeal Board under Paragraph 8.2 of the Constitution and Procedure for it to decide whether further sanctions were appropriate.

The Code of Practice Appeal Board required Novo Nordisk to be publicly reprimanded.

**This summary is not intended to be read in isolation.
For full details, please see the full case report below.**

FULL CASE REPORT

A voluntary admission was received from Novo Nordisk Limited in relation to undisclosed transfers of value.

VOLUNTARY ADMISSION

Novo Nordisk stated it was committed to complying with both the letter and spirit of the Code; Novo Nordisk fully understood its obligation to publicly disclose certain transfer of values (ToVs) made directly or indirectly to Healthcare Professionals (HCPs), Healthcare Organisations (HCOs), Patient Organisations (POs), Other Relevant Decision Makers (ORDMs) and Members of the Public (MoPs), including Patients and Journalists located in the UK, whether made by Novo Nordisk or above country members of Novo Nordisk.

Novo Nordisk informed the PMCPA that it had discovered that ‘tagging’ of UK vendors as HCPs HCOs, POs, ORDMs and MOPs (including Patients and Journalists) had been inconsistent and as a result several omissions in reporting had been identified for the 2020, 2021 and 2022 ToV disclosure reporting years. As a result, a full and thorough investigation had been conducted and Novo Nordisk had identified approximately 155 vendors with disclosable ToVs from 2020 to 2022 were untagged. This approximated to:

- Total Undisclosed ToVs in 2020: 1.6 million
- Total Undisclosed ToVs in 2021: 2.5 million
- Total Undisclosed ToVs in 2022: 2.3 million.

Novo Nordisk acknowledged that these were significant omissions, and the situation fell far short of the required standards for disclosure which was particularly disappointing for Novo Nordisk.

Novo Nordisk completed a root cause analysis as part of the investigation, the key points of which were set out below:

- Novo Nordisk used a single supplier system (SAP), where it was the responsibility of the individual setting up the supplier to ensure the correct vendor tag was selected and assigned. When the individual raised a Purchase Order or coded the invoice, this triggered a set of General Ledger (GL) accounts 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 change eg, payment details. Therefore, the vendors were not checked when setting up subsequent engagements.
- All UK vendors who had not been tagged within the SAP finance system were reviewed.
- Any queries identified were reviewed and the final list of vendors who were identified as untagged were then correctly tagged by Novo Nordisk’s Global Master Vendor team.
- Payment data was collated for these vendors for the period of 2020 – 2022 and reviewed on an activity level basis. This data was then categorised to identify all disclosable ToVs.

In summary, Novo Nordisk had identified omissions in the ToV reporting of untagged vendors and as a result payments to these vendors had not been disclosed in 2020, 2021 and 2022. Novo Nordisk had a strong culture of continuous improvement and consistently strove to identify errors and enhance processes. Novo Nordisk accepted this was the company’s error and had a duty to rectify and self-report in line with the letter and spirit of the Code.

Novo Nordisk had developed a full Corrective Action and Preventative Action (CAPA) Plan to ensure these omissions were corrected, templates were resubmitted, and omissions were not repeated in future disclosures. The corrective and preventative actions include:

- Correcting all identified undisclosed ToVs and either resubmitting to the ABPI Disclosure Portal or updating novonordisk.co.uk (dependent on ToV recipient type).
- Implementing a newly created Standard Operating Procedure (SOP) that detailed the process for the tracking and disclosure of ToVs. The SOP would be trained out to Novo Nordisk and above country individuals. Novo Nordisk training sessions were scheduled for 13th/17th/20th November 2023 and the above country training would take

place on 16 November 2023. This would include dedicated training for all those responsible for the setup of new vendors and coding of payments.

- Ensuring the approval of any new vendors or changes to existing vendors were completed by the UK Compliance team. Novo Nordisk stated this approval step would be introduced by the end of year 2023. In the interim, manual checks would be performed on all new vendors by the Compliance team.
- Engagement of significant external support to understand the full extent of the issue. Novo Nordisk would inform the PMCPA once it was aware of any additional omissions and the timelines for addressing them. Additionally, Novo Nordisk would use this support as extra resource to support with tracking and reporting of ToV disclosures.
- Recruiting one full time employee from the Global Novo Nordisk HCP Payment Office dedicated to UK ToV to ensure tight controls throughout the planning, tracking, and reporting stages of the ToV process.
- Training to be carried out by the Global Business Ethics Compliance Office for teams who made cross border ToVs. This would include the principles and process behind Planning, Tracking and Reporting ToVs.

Novo Nordisk believed the PMCPA should consider Clauses 23.2, 23.4, 24.1, 24.2, 24.4, 27.7, 27.8, 9.1 and 2 of the 2019 Code and Clauses 24.4, 28.1, 28.2, 29.1, 29.2, 31.1, 5.1 and 2 of the 2021 Code. The Case Preparation Manager also asked Novo Nordisk to consider Clauses 24.6 and 30.1 of the 2021 Code.

RESPONSE

Novo Nordisk stated that it had no further comments in relation to the requirements of Clauses 23.2, 23.4, 24.1, 24.2, 24.4, 27.7, 27.8, 9.1 and 2 of the 2019 Code and Clauses 24.4, 28.1, 28.2, 29.1, 29.2, 31.1, 5.1 and 2 of the 2021 Code. In addition, Novo Nordisk agreed that the requirements of Clauses 24.6 and 30.1 of the 2021 Code were relevant to this case as raised by the Case Preparation Manager.

Novo Nordisk stated that the issues in this case became apparent following receipt of the complaint in Case AUTH/3752/3/23. As part of the document collation exercise conducted for the investigation into that case, it was noted that there were some discrepancies between amounts paid and amounts specified on agreements. This led to initiating a thorough review and root cause analysis of discrepancies. For context, a few measures were in effect at the time:

1. A broad range of activities with disclosable Transfer of Value were already on hold as a result of the recommendations from the December 2022 PMCPA audit to address the process gaps and enhance the required oversight.
 - Sponsorships originating from the UK: 27-Oct-2022
 - Novo Nordisk speaker meetings which utilised materials from Speaker Slide Library: 2-Feb-2023
 - Cross border engagements with UK HCOs / HCPs (exemption only for R&D based activities): 27-Mar-2023 (official communication from Business Ethics and Compliance Office)
2. Strengthening of the ToV disclosure process was also highlighted during the audit and hence an SOP was in development.

Actions taken upon identification of the discrepancies were:

Review of all payments made over the period of the past 3 years (2020-2022) with UK HCOs/HCPs. This process was very manual and time-consuming but an important part of the retrospective root-cause analysis. In parallel Novo Nordisk started tagging all relevant organisations that were historically missed and assessed all activities that required disclosures.

The analysis demonstrated the issues listed below:

- The major contributing factor was identified to be error in tagging the organisations within the SAP system (0.7% of UK HCOs/HCPs with disclosable values were not tagged). Importantly three of the HCOs that were not tagged, contributed to over £3 million pounds of undisclosed amounts over the three years.
- In some cases, tagging had been missed, whilst for others disclosure had not been captured correctly, for example donations had been disclosed against the recipient organisation but not disclosed against the HCO providing the donation
- Multiple records existed for the same vendor with some of the instances not being tagged.
- It was the responsibility of the individual setting up the supplier to ensure the correct Vendor tag was selected and assigned. When the individual raised a Purchase Order or coded the invoice, this triggered a set of General Ledger (GL) accounts that were used for correct reporting. In some cases, this was not being completed correctly.
- 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 vendors were not checked when setting up subsequent engagements.

Novo Nordisk provided a spreadsheet that detailed the undisclosed ToVs, a full breakdown by year, recipient type (health professional (HCP), other relevant decision maker (ORDM), healthcare organisation (HCO), patient organisation (PO) and public (including patients and journalists)) and category of ToV (eg, fees for service, sponsorships, grants, donations etc.). This spreadsheet also indicated whether any of the undisclosed ToVs related to research and development (R&D) and/or cross-border activities.

In addition, Novo Nordisk had provided a summary page which captured:

- An overview of the above including the proportion of ToVs undisclosed versus disclosed per year including recipient type.
- The total number of vendors in our SAP Master Vendor Database and number of unique untagged vendors with disclosable values between 2020-2022.

The Voluntary admission was filed, and further investigation and analysis would be needed by [named consultancy]. Please note, at this stage this was a best estimate until Novo Nordisk's investigation was completed (including any findings highlighted by [named agency] who Novo Nordisk had engaged to support us in addressing these matters). Should Novo Nordisk discover any further information the company would notify the PMCPA promptly.

The following CAPAs had been put in place:

- Correcting all identified undisclosed ToVs and either resubmitting to the ABPI Disclosure Portal or updating novonordisk.co.uk (dependent on ToV recipient type).
- Implementing a newly created SOP that detailed the process for the tracking and disclosure of ToVs. The SOP had been trained out to Novo Nordisk and above

country individuals. Novo Nordisk's training sessions took place on 13/17/20 November 2023 and the above country training took place on 16 November 2023. This included dedicated training for all those responsible for the setup of new vendors and coding of payments.

- Ensuring the approval of any new vendors or changes to existing vendors were completed by the UK Compliance team. This approval step would be introduced by the end of year 2023. In the interim, manual checks would be performed on all new vendors by the Compliance team.
- Engagement of significant external support (named consultancy) to understand the full extent of the issue. Additionally, Novo Nordisk would use this support as extra resource to support with tracking and reporting of ToV disclosures.
- Recruiting one full time employee from the Global Novo Nordisk HCP Payment Office dedicated to UK ToV to ensure tight controls throughout the planning, tracking, and reporting stages of the ToV process.
- Training would be carried out throughout December by the Global Business Ethics Compliance Office for teams who made cross border ToVs. This would include the principles and process behind Planning, Tracking and Reporting ToVs.

Novo Nordisk provided copies of relevant policies and procedures.

Novo Nordisk stated policies and procedures relating to ToV were identified as a gap in the early stages of its compliance improvement activities following receipt of the report for the December 2022 PMCPA audit, an SOP was developed and became effective on 24 October 2023. The findings of the CAPA mentioned above were incorporated into the compliance improvement plan.

Novo Nordisk stated that it was acutely aware of the scale of this issue, and sincerely apologised. It reassured the PMCPA that it was working to address this as its number one priority with all the resources required, and activities would remain on pause until it was confident robust processes were in place, staff training had been completed and the named consultancy onboarded.

PANEL RULING

The Panel noted Novo Nordisk's submission that the issues in this voluntary admission became apparent following receipt of a previous case, Case AUTH/3752/3/23, where during its investigation into that case, discrepancies between amounts paid and amounts specified on agreements were noted. Actions taken upon identification of these discrepancies included a review of all payments made over the past 3 years (2020-2022) with UK HCOs/HCPs. In parallel, Novo Nordisk started tagging all relevant organisations that were historically missed and assessed all activities that required disclosures.

The Panel noted Novo Nordisk's submission that its analysis demonstrated the major contributing factor was an error in tagging the organisations within the SAP system (0.7% of UK HCOs/HCPs with disclosable values were not tagged); three of the HCOs that were not tagged, contributed to over £3 million pounds of undisclosed amounts over the three years. Novo Nordisk stated that in some cases, tagging had been missed, whilst for others disclosure had not been captured correctly. According to Novo Nordisk, health professionals, healthcare organisations, patient organisation, other relevant decision makers and members of the public (including Patients and Journalists) with disclosable transfers of value, were 'untagged'. The

Panel noted Novo Nordisk's submission that further investigation and analysis would be needed by its consultants and that the figures were a best estimate at the time of its response in November 2023.

The Panel noted Novo Nordisk's original response included a spreadsheet which showed that the proportion of ToVs undisclosed were 11.6%, 16.4% and 12.2% in 2020, 2021 and 2022 respectively. Whilst not apparent on the face of the spreadsheet, the aforementioned percentages appeared to show the undisclosed ToVs as a percentage of the disclosed ToVs; in the Panel's view, the more relevant figure was the undisclosed ToVs as a proportion of the total amount that ought to have been disclosed.

From the data provided, which the Panel noted according to Novo Nordisk was a best estimate, the proportions of undisclosed ToVs as a proportion of the total amount that ought to have been disclosed appeared to be 10.4%, 14.1% and 10.9% for 2020, 2021 and 2022 respectively as per the Panel's calculations.

The Panel was concerned that there appeared to be differences between Novo Nordisk's spreadsheet and its admission. In its admission, Novo Nordisk stated that the undisclosed ToVs totalled £1.6 million, £2.5 million, and £2.3 million for 2020, 2021 and 2022 respectively, totalling £6.4 million. However, the relevant totals on the Novo Nordisk spreadsheet summed to over £7.8 million, consisting of £1,722,112.12, £3,224,335.75 and £2,857,858.52 for 2020, 2021 and 2022 respectively. The reason for the differences in the annual and overall figures was unclear.

The Panel noted the undisclosed transfers of value submitted by Novo Nordisk in the spreadsheet were for the following:

- For each of the years 2020, 2021 and 2022 data was provided for patient organisations, donations and grants, sponsorship, contracted services fees and R&D aggregate.
- The 2020 data also included Travel and Accommodation; no undisclosed transfers of value for contracted services expenses or joint working were documented
- The 2021 data also included contracted services expenses; no undisclosed transfers of value for travel and accommodation or joint working were documented.

The 2022 data also included transfers of value for collaborative working, previously joint working, and patients and journalists (each provided separately); travel and accommodation was also included. The requirement for the disclosure of transfers of value for patients and journalists only came into effect for transfers of value made in 2022. No undisclosed transfers of value for contracted services expenses were documented.

The Panel noted that the 2019 and 2021 Codes were applicable to the 2020-2022 disclosure periods at issue in this case. The Panel noted the Code required disclosures to be made annually in respect of each calendar year within the first six months after the end of the calendar year in which the transfers of value were made.

The Panel noted the undisclosed transfers of value pertaining to the years 2021-2022 should have been disclosed in the first six months of 2022 and 2023 respectively and therefore **ruled a breach of Clause 31.1 of the 2021 Code** with respect to each annual disclosure cycle. Noting the 2021 Code came into effect on 1 July 2021, and that the undisclosed 2020 transfers of value should have been disclosed in the first six months of 2021, the Panel **ruled a breach of Clause**

24.4 of the 2019 Code in relation to the failure to disclose the 2020 transfers of value by 30 June 2021.

The Panel noted Clause 23.2 of the 2019 Code stated that pharmaceutical companies must publicly disclose annually details of the fees paid to UK health professionals, or their employers on their behalf for services provided as consultants. Clause 23.4 qualifies that fees and expenses should be disclosed and the relevant supplementary information to Clause 23.2 stated that fees and agreed expenses should be separately disclosed. The requirements of Clause 24.4 of the 2021 Code were closely similar but of broader application, applying to fees and expenses paid to both UK individuals and organisations including healthcare organisations as contracted services. Clause 24.6 of the 2021 Code similarly stated that fees and expenses due to contracted individuals/organisations must be disclosed and that companies should disclose fees and expenses separately. The Panel noted that it considered transfers of values to the public, journalists and patient organisations under Clauses 30 and 29 respectively.

The Panel noted that Novo Nordisk's spreadsheet of undisclosed transfers of values included the subcategory 'contracted services fees' for each of the three years at issue which according to the Panel's calculations totalled approximately £3,376,000 across 63 vendors; the category for associated contracted service expenses was included for only 2021 and totalled £10,296.00 across 4 vendors. The Panel considered these expenses ought to have been disclosed by 30 June 2022. The Panel noted the omission of data for expenses associated with contracted services and consultancy for those undisclosed transfers of value in 2020 and 2022. The Panel noted Novo Nordisk's submission that its data was a best estimate; it was unclear whether any associated expenses for these years had been disclosed.

The Panel found 16 undisclosed transfers of value in 2020 to health professionals or their employers on their behalf categorised as contracted services and **ruled a breach of Clause 23.2 of the 2019 Code**. Noting there were no associated expenses reported for 2020, the Panel ruled **no breach of Clause 23.4 of the 2019 Code** as there was no evidence before the Panel that such transfers of value had occurred in 2020 and were undisclosed.

In relation to the 19 and 28 undisclosed transfers of value in 2021 and 2022 respectively for contracted services, the Panel ruled **breaches of Clauses 24.4 and 24.6 of the 2021 Code** for each of the two annual disclosure cycles.

The Panel additionally **ruled breaches of Clauses 24.4 and 24.6 of the 2021 Code** with regard to the failure to disclose transfers of value for associated expenses which occurred in 2021. In relation to associated expenses for contracted services in 2022, noting there was no evidence that such transfers of value had occurred and were undisclosed, **the Panel ruled no breach of Clauses 24.4 and 24.6 of the 2021 Code**.

Clause 28.1 of the 2021 Code required companies to 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. The Panel noted that Clause 28.2 described those transfers of value covered by Clause 28.1. Failure to document and publicly disclose transfers of value as described in Clause 28.2 would be a breach of Clause 28.1. The Panel noted that Clauses 24.1 and 24.2 of the 2019 Code were broadly similar in scope and application.

Noting the nature of the undisclosed transfers of value, as set out above, the **Panel ruled a breach of Clause 24.1 of the 2019 Code** in relation to the undisclosed transfers of value in 2020 and **breaches of Clause 28.1 of the 2021 Code** for the undisclosed transfers of value in each of the 2021 and 2022 years. The Panel made no rulings in relation to Clauses 24.2 and 28.2 of the 2019 and 2021 Codes respectively.

The Panel noted Clause 30.1 was introduced in the 2021 Code in relation to the annual disclosure of contracted services provided by the public, including patients and journalists. The supplementary information to Clause 31 stated that the information required by Clause 30 should be publicly disclosed annually in respect of transfers of value made in 2022 and each calendar year thereafter. The Panel noted Novo Nordisk had therefore submitted transfers of value in relation to 2022 disclosures which ought to have been disclosed by 30 June 2023. Noting Novo Nordisk's figures showed approximately £14,300 had been paid to members of the public in 2022, of which 73.8% were undisclosed, the Panel **ruled a breach of Clause 30.1 of the 2021 Code**.

In relation to transfers of value to patient organisations, the Panel noted that there were differences between the relevant requirements in the 2019 and 2021 Codes. Clauses 27.7 and 27.8 of the 2019 Code referred to patient organisations which receive financial support and /or significant indirect/non-financial support, and which provide services. Clauses 29.1 and 29.2 of the 2021 Code referred to contracted services, donations, grants and sponsorship, there was no monetary limitation in relation to indirect financial support (donations). With regard to transfers of value to patient organisations, the Panel noted 19.8%, 18.3% and 19.0% of transfers across 2020, 2021 and 2022 were undisclosed. The Panel **therefore ruled breaches of Clauses 27.7 and 27.8 of the 2019 Code** for transfers of value related to 2020 and **breaches of Clauses 29.1 and 29.2 of the 2021 Code** with respect to transfers of value in each of the years 2021 and 2022.

The Panel noted with particular concern the significant values of several of the undisclosed transfers of value; one HCO for contracted services fees, and one HCO received sponsorships and donations/grants which amounted to approximately £920,000, £927,244 and £1,227,000 across the three years, accounting for approximately 40% of the total value of the undisclosed transfers of value.

The Panel were further concerned that despite undisclosed transfers of value of almost £3.4 million for contracted services across the three years, no undisclosed expenses were associated with these contracted services for 2020 and 2022 and only 4 declarations were included for 2021. The Panel queried the accuracy of the data which had been submitted.

Taking its rulings above into account and noting the content of Novo Nordisk's voluntary admission along with its response, the Panel considered that high standards had not been maintained. **A breach of Clauses 9.1 and 5.1 of the 2019 and 2021 Codes was ruled.**

The Panel found that over 500 transfers of value were reportedly undisclosed between the years 2020 to 2022, consisting of approximately 155 vendors according to Novo Nordisk, to the value of over £7.8 million, as calculated by the Panel.

The Panel noted that a ruling of a breach of Clause 2 was used as a sign of particular censure. In the Panel's view, Novo Nordisk's failure to disclose the required information was extremely concerning as was the scale of the under reporting in terms of both the number of vendors and the value of undisclosed transfers. It was apparent that Novo Nordisk had a lack of oversight

and its processes were wholly inadequate. The Panel was concerned that the subject matter of the voluntary admission only came to light as a result of Novo Nordisk's investigation into another complaint rather than as a result of the company's culture, policies and procedures.

The Panel considered that there appeared to be a systemic failure in relation to compliance with transfers of value. Novo Nordisk did not appear to have adequate oversight and processes in place to correctly disclose transfers of value over, at the very least, a three-year period such that Novo Nordisk had brought discredit upon and reduced confidence in, the pharmaceutical industry. **The Panel ruled a breach of Clause 2 of the 2019 and 2021 Codes.**

The Panel was extremely concerned about its rulings and comments above including the breadth and depth of the apparent difficulties at Novo Nordisk. The Panel noted the importance of transparency and thus the importance of disclosing transfers of value; in the Panel's view such disclosure contributed to public confidence in the arrangements between pharmaceutical companies, health professionals and healthcare organisations.

The Panel noted with concern the differences between Novo Nordisk's response and the figures on the Novo Nordisk spreadsheet and further concerns about some of the calculations on the spreadsheet.

The Panel decided that the breadth and depth of the issues were such that they raised concerns about Novo Nordisk's conduct in relation to the Code and concerns about the company's procedures such that they warranted consideration by the Code of Practice Appeal Board. In reaching this decision, the Panel noted that Novo Nordisk had already been suspended by the ABPI Board and was under audit as a result of Case AUTH/3525/3/23 but considered the subject matter of this case highlighted a specific institutional failure with respect to the disclosure of certain transfers of value. The Panel further noted that the undisclosed vendors for contracted services fees included vendors that were subject of a previous case, Case AUTH/3525/3/23. The Panel, noting Novo Nordisk's governance and processes, decided to **report the company to the Appeal Board** under Paragraph 8.2 of the Constitution and Procedure for it to decide whether further sanctions were appropriate.

NOVO NORDISK COMMENTS ON THE REPORT

Novo Nordisk had accepted the Panel's rulings of breaches of the 2019 and 2021 Code and its comments on the report are reproduced below:

'As previously stated, we are very aware of the seriousness of this matter and understand the reasons behind the Panel reporting Novo Nordisk to the Appeal Board in this case. Once again, we sincerely apologise.

In response to the report, we would like to reassure both the Appeal Board and the PMCPA that the issues that we have faced in terms of transfers of value disclosure are for the most part legacy concerns that we have been addressing through last year and this.

The Appeal Board will be aware that Novo Nordisk was audited by the PMCPA in December 2022 and, on the basis of the report for this audit, the ABPI Board suspended the company from the ABPI in March 2023. Although the Dec '22 audit report stated, "In many areas, Novo Nordisk had a solid compliance framework with automated systems, controls and an established framework of Standard Operating Procedures (SOPs)," there were gaps and

improvements required in a number of areas. In its consideration of the report, the ABPI Board noted that “the necessary compliance structures and processes were only beginning to be put in place following the conclusion of the audit”. The ABPI Board also noted that the process of self-regulation should be “capable of getting companies back to where they need to be in terms of compliance”.

At the time of the December 2022 audit, we had in place processes for the collation and disclosure of transfers of value (ToV), but these were across several local and regional procedures, not consolidated and not robust.

In Q1 2023, on receipt of the report of the December 2022 PMCPA audit (which recommended that Novo Nordisk’s disclosure infrastructure and reporting process was given urgent and significant attention) and a complaint relating to ToV disclosure, we began a more forensic examination of issues in order to develop a comprehensive and effective corrective and preventive action (CAPA) plan and have been working diligently on its execution as part of the process of self-regulation which, as identified by the ABPI Board, should and does aim to get Novo Nordisk to where we need to be in terms of sustainable compliance in that regard.

Resources and focus on ToV have been considerably increased with 8 Novo Nordisk staff, across the UK and Globally, now focused in this area. In addition, we have engaged the services of a consultancy who have approximately 4 individuals working on this). [Named consultancy] have extensive expertise in disclosure requirements, having supported many pharmaceutical companies over many years in this area. [Named consultancy] collated the ToVs made by Novo Nordisk in 2023 in order for us to fulfil our disclosure requirements for this year; the data underwent extensive quality control checking by Novo Nordisk before being submitted to the ABPI Disclosure platform at the end of March 2024. [Named consultancy] will continue to support us in this regard with further ToV submissions.

The details of this ongoing CAPA plan can be found below:

Action	Progress
Correcting all identified undisclosed ToVs	Preliminary analysis has been undertaken as part of voluntary admission submission summary and we have identified the root causes. [Named consultancy] will collate final disclosure updates by end of June 2024. [Named consultancy] will also support with our resubmission of identified undisclosed ToVs to the ABPI Disclosure platform.
Implementing a newly created Standard Operating Procedure (SOP) that details the process for the tracking and disclosure of ToVs.	SOP became effective on 24 October 2023. Training on SOP was provided to all relevant employees.
Ensuring the approval of any new vendors or changes to existing vendors are completed by the UK Compliance team.	Head of compliance notified of any updates to existing vendors as of February 2024. System changes to be implemented for new vendors by end of March 2024.

Engagement of significant external support to understand the full extent of the issue and to assist with CAPAs.	Contract with [named consultancy] signed in January 2024.
Recruiting one full time employee from the Global Novo Nordisk HCP Payment Office dedicated to UK ToV to ensure tight controls throughout the planning, tracking, and reporting stages of the ToV process.	One full time employee from HCP office in position from December 2023.
Training to be carried out by the Global Business Ethics Compliance Office for teams who make cross border ToVs. This will include the principles and process behind Planning, Tracking and Reporting ToVs.	North West Europe region and Swedish affiliate have been trained to date. Global training to be delivered quarterly from April 2024.

We acknowledge and fully appreciate the importance of transparency in relation to any transactional relationship we have with healthcare stakeholders and our past omissions in that regard are significant. However, our reaction to these issues is also worthy of note and is part of the process of Novo Nordisk “getting back to where we need to be in terms of compliance”, self-regulation in practice. We are working to address this as our number 1 priority with all the resources required and having identified the root causes, we are confident that, with the support of our regional colleagues as well as external experts such as [named consultancy], we now have in place a robust and comprehensive ToV process.’

At the consideration of the report, Novo Nordisk presented slides detailing timelines, its ToV process and a vendor analysis, along with its corrective and preventative actions.

APPEAL BOARD CONSIDERATION OF THE REPORT FROM THE PANEL

The Appeal Board took account of the Panel’s finding that Novo Nordisk had failed to disclose transfers of value of approximately £7.8 million over three years, which was the period selected by Novo Nordisk for its internal investigation. The failures to disclose related to over 150 different bodies, largely healthcare organisations, and represented between 10-14% of each year’s total transfers of value.

The Appeal Board considered that the process of internal investigation and voluntary admission which was apparent in this case was to be encouraged. It appeared that this voluntary admission was, in part, prompted by a complaint (Case AUTH/3752/3/23).

The Appeal Board considered the scale of the undisclosed value identified thus far, over a sustained period, was extremely serious. The Appeal Board was concerned that there appeared to be fundamental governance failures. The wide ranging systemic failings apparent to the Appeal Board included inadequate training, processes and monitoring. Accurate disclosure was fundamental to the principle of transparency and maintaining public confidence in the pharmaceutical industry.

Bearing in mind the above, the Appeal Board decided that in accordance with Paragraph 11.3 of the Constitution and Procedure, Novo Nordisk should be publicly reprimanded.

The Appeal Board noted the company was currently under an audit cycle as a result of its suspension by the ABPI Board for Case/AUTH/3525/6/21 and therefore considered that an additional audit sanction by the Appeal Board was not necessary. The Appeal Board expected that the upcoming October 2024 re-audit required by the ABPI Board would, among other things, evaluate the company's current processes in relation to disclosure of transfers of value.

The published public reprimand would state the following:

'Novo Nordisk has been publicly reprimanded by the Code of Practice Appeal Board due to its failure to disclose transfers of value of approximately £7.8 million. The failures occurred over three years, which was the period selected by Novo Nordisk for its internal investigation (Case AUTH/3847/11/23). The failures to disclose related to over 150 different bodies, largely healthcare organisations, and represented between 10-14% of each year's total transfers of value.

The Appeal Board considered the scale of the undisclosed value identified thus far, over a sustained period, was extremely serious. The Appeal Board was concerned that there appeared to be fundamental governance failures. The wide ranging systemic failings apparent to the Appeal Board included inadequate training, processes and monitoring.

Accurate disclosure was fundamental to the principle of transparency and maintaining public confidence in the pharmaceutical industry.

The Appeal Board considered that the process of internal investigation and voluntary admission which was apparent in this case was to be encouraged. It appeared that this voluntary admission was, in part, prompted by a complaint (Case AUTH/3752/3/23).

The Appeal Board noted the company was currently under an audit cycle as a result of its suspension by the ABPI Board (Case AUTH/3525/6/21) and therefore considered that an additional audit sanction by the Appeal Board was not necessary. The Appeal Board expected that the upcoming October 2024 re-audit required by the ABPI Board would, among other things, evaluate the company's current processes in relation to disclosure of transfers of value.'

Voluntary admission 3 November 2023

Case completed 24 April 2024