

**CASE AUTH/3593/12/21**

## **VOLUNTARY ADMISSION BY LEO**

### **Undeclared transfers of value for 2020**

**Leo Pharma UK made a voluntary admission about undeclared transfers of value (ToVs) in 2020 to health professionals and a healthcare organisation.**

**Leo stated that in March 2021, Leo Pharma UK submitted its data for disclosures of ToVs made to health professionals and healthcare organisations in 2020 to Disclosure UK.**

**In December 2021, the global healthcare compliance team notified Leo Pharma UK that four payments to health professionals and one to a healthcare organisation had been identified as not being included in the UK 2020 disclosure document, and thus had not been disclosed as required. The payments were made by Leo Pharma A/S (the Global organisation).**

**This error happened as an excel report containing all health professional/healthcare organisation payments paid out of Leo Pharma A/S in November 2020, remained in 'pending remediation' status, rather than fully processed, owing to lack of oversight.**

**The detailed response from Leo is given below.**

**The Panel noted Leo's submission that in December 2021, the global healthcare compliance team notified Leo Pharma UK that four payments to UK health professionals and one payment to a UK healthcare organisation was not included in the UK 2020 disclosure document, and thus had not been disclosed by the end of June 2021 as required. The Panel therefore ruled a breach of the Code in relation to the five undisclosed payments, as acknowledged by Leo.**

**Leo Pharma UK made a voluntary admission about undeclared transfers of value (ToVs) in 2020 to health professionals and a healthcare organisation.**

**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 Leo.**

### **VOLUNTARY ADMISSION**

**Leo stated that in March 2021, Leo Pharma UK submitted its data for disclosures of ToVs made to health professionals and healthcare organisations in 2020 to Disclosure UK, the ABPI disclosure platform.**

**Leo explained that in December 2021, the global healthcare compliance team notified Leo Pharma UK that four payments to health professionals and one to a healthcare organisation had been identified as not being included in the UK 2020 disclosure document, thus had not been disclosed as required. The payments were made by Leo Pharma A/S (the Global organisation) and thus were the global company's responsibility.**

Leo stated that an investigation found that a human error, made by the person in the global healthcare compliance team uploading payments made by Leo Pharma A/S, resulted in one month of payments, including, but not limited to, healthcare partners from the UK, not being fully processed into Leo Pharma's transparency system. This error happened as an excel report containing all health professional/healthcare organisation payments paid out of Leo Pharma A/S in November 2020, remained in 'pending remediation' status, rather than fully processed, owing to lack of oversight.

### **Corrective and preventative actions**

Leo Pharma UK sincerely regretted these omissions. In terms of corrective actions, the 2020 transparency report for disclosures of ToVs to UK health professionals and healthcare organisations had been updated to include the five omissions and re-submitted to the ABPI disclosure platform.

Furthermore, a number of actions had been implemented to mitigate the risks of a similar issue happening again:

- An upgrade to the Leo Pharma transparency system was implemented. Within this new version, there was a significantly better overview of data that an individual data submitter was responsible for, including any pending reports not fully processed. This included having a default view seen by a data submitter to be that of any pending upload not having been fully processed, thus prompting the data submitter to take appropriate action.
- Global healthcare compliance conducted a re-training in its transparency reporting team, to ensure the required process and outputs were fully understood.
- A new health professional/healthcare organisation engagement system for cross-border engagements in Leo Pharma was rolled out. In this system, each local affiliate (country of health professional/healthcare organisation) would have an easier and more accessible overview of cross-border engagements with local (ie UK) healthcare partners. This now facilitated a cross-checking of global activities, with the data which had been uploaded by non-UK Leo Pharma entities onto the transparency system, by affiliates.

Leo Pharma acknowledged responsibility for this omission and therefore regrettably voluntarily admitted a breach of Clause 24.1 in this matter.

When writing to Leo, the Authority asked it to consider the requirements of Clause 24.1 of the 2019 Code as cited by Leo.

### **RESPONSE**

Leo provided the details and associated documentation including contracts in relation to the following undeclared ToVs to one healthcare organisation and four health professionals in November 2020 as follows:

- 1 Healthcare organisation: British Association of Dermatology**  
Activity: Congress sponsorship  
Date of payment: 4/11/2020  
Monetary value: £30,000.

- 2 Health professional 1**  
Activity: Advisory board member  
Date of payment: 18/11/2020  
Monetary value: £1,875.
- 3 Health professional 2**  
Activity: Advisory board member  
Date of payment: 18/11/2020  
Monetary value: £930.
- 4 Health professional 3**  
Activity: Advisory board member  
Date of payment: 11/11/2020  
Monetary value: £375.
- 5 Health professional 4**  
Activity: Advisory board member  
Date of payment: 25/11/2020  
Monetary value: £1,350.

Leo noted that these ToVs were identified by Leo's global team on 30 November 2021. Following further internal investigation, they were submitted to Disclosure UK for disclosure on 17 December 2021.

## **PANEL RULING**

Clause 24.1 of the 2019 Code stated that companies must document and publicly disclose certain ToVs made directly or indirectly to health professionals and healthcare organisations located in Europe. The supplementary information stated that disclosure was required even if the payments etc were made by overseas affiliates, head offices in the UK or overseas and UK-based offices and Clause 24.4 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 ToVs were made.

The Panel noted Leo's submission that in December 2021, the global healthcare compliance team notified Leo Pharma UK that four payments to UK health professionals and one payment to a UK healthcare organisation was not included in the UK 2020 disclosure document, and thus had not been disclosed by the end of June 2021 as required. The Panel therefore ruled a breach of Clause 24.1 of the 2019 Code in relation to the five undisclosed payments, as acknowledged by Leo.

**Complaint received**      **17 December 2021**

**Case completed**        **17 October 2022**