

VOLUNTARY ADMISSION BY LEO

Undisclosed transfers of value to patient organisations in 2019

Leo Pharma UK made a voluntary admission about undisclosed transfers of value to patient organisations in 2019.

Leo stated that in the process of compiling the list of patient organisation disclosures for 2020 (due to be published by the end of June 2021), it had come to light that there were three [sic] transfers of value made to UK-based patient organisations, from the Leo Pharma global organisation in 2019. Leo Pharma UK were not aware or informed of these interactions and transfers of value between the global organisation and the patient organisations. Therefore, in the patient organisation disclosures list published belatedly in December 2020 then updated in January 2021, these transfers of value were undeclared, and the associated contracts between the global Leo Pharma organisation and the UK headquartered patient organisations were not certified.

The detailed response from Leo is given below.

The Panel noted that in the process of compiling the list of patient organisation disclosures for 2020 (due to be published by the end of June 2021), Leo had discovered that there were four transfers of value made to three UK based patient organisations in 2019, from the Leo Pharma global organisation, which had not been disclosed.

The Panel noted Leo's subsequent submission that one of these four payments, the payment to the International Alliance of Patients' Organisations (IAPO) for sponsorship of a congress in 2019, was made in April 2020. The Panel noted that this payment to IAPO did not therefore need to be disclosed until the end of June 2021. The Panel noted Leo's submission that disclosure of this transfer of value was made by the end of June 2021. The Panel therefore ruled no breach of the Code in relation to the payment to IAPO.

In relation to the two payments made to the Gorlin Syndrome Group (June and October 2019) for two separate activities, and the payment made to Lupus Europe in March 2019, the Panel noted that these three payments had not been disclosed by the end of June 2020, as required by the Code, and thus the Panel ruled a breach of the Code as acknowledged by Leo.

The Panel noted Leo's submission that the contracts between Leo Pharma A/S (global) and the three UK based patient organisations for the four activities in question were not certified. The Panel further noted Leo's subsequent submission that two of the four activities (Gorlin Syndrome Group consultancy expenses and Lupus Europe advisory sessions) were contracted services provided by the patient organisations and therefore

the written agreements for those services did not need to be certified. The Panel therefore ruled no breach of the Code in relation to those two contracts.

The Panel noted Leo's submission that the contracts for the other two activities in question (Gorlin Syndrome Group R&D collaboration agreement and sponsorship at IAPO Asia Pacific Congress) were not contracted services provided by the patient organisations and the written agreements had not been certified as required by the Code; the Panel therefore ruled a breach of the Code in relation to each contract.

The Panel noted from Leo's submission that until the end of 2020, it did not have an electronic approval system in place for cross-border activities, including interactions with patient organisations, which would automatically flag cross-border interactions and associated transfers of value to the UK affiliate. It was unclear to the Panel what processes Leo had in place prior to this and at the time of the activities in question; Leo made no submission in that regard. Nonetheless, the requirements of the Code had not been met in relation to disclosure of payments made to patient organisations and certification of written agreements as required by the Code. The Panel ruled a breach of the Code as high standards had not been maintained.

Clause 2 was a sign of particular censure and was reserved for such use. The Panel considered that it was most regrettable that Leo was a year late in disclosing payments made to patient organisations in 2019. Furthermore, this was the third time that Leo had not met the requirements of the Code in relation to payments made in 2019 to patient organisations.

The Panel was concerned that these omissions were only discovered during the process of compiling the list of payments made in 2020 to patient organisations; the Panel was concerned that cross-border payments to UK patient organisations were not checked as part of Leo's investigation into the first two complaints about failure to disclose payments made to patient organisations in 2019 (Cases AUTH/3418/11/20 and AUTH/3498/3/21). Taking all of the circumstances into consideration, the Panel considered, on balance, that Leo's numerous failures in relation to disclosure of payments made to patient organisations in 2019 and its lack of oversight of overseas affiliate's interactions with UK based patient organisations had brought discredit upon and reduced confidence in the pharmaceutical industry, and a breach of Clause 2 was ruled.

Leo Pharma UK made a voluntary admission about undisclosed transfers of value to patient organisations in 2019.

VOLUNTARY ADMISSION

Background

In Case AUTH/3418/11/20, Leo Pharma UK admitted a breach of Clause 27.7 of the Code due to the failure to disclose transfers of value to patient organisations for the year 2019 within the first six months of 2020. Leo Pharma UK subsequently published this list on the Leo Pharma UK/IE website in December 2020, with a further update in January 2021. This January update was part of the subject of a further complaint, Case AUTH/3498/3/21.

Summary of events

Leo stated that in the process of compiling the list of patient organisation disclosures for 2020 (due to be published by the end of June 2021), it had come to light that there were three [sic] transfers of value made to UK-based patient organisations, from the Leo Pharma global organisation in 2019. Leo Pharma UK was not aware or informed of these interactions and transfers of value between the global organisation and the patient organisations. Therefore, in the patient organisation disclosures list published belatedly in December 2020 then updated in January 2021, these transfers of value were undeclared, and the associated contracts between the global Leo Pharma organisation and the UK headquartered patient organisations were not certified.

The patient organisations in question were, the International Alliance of Patients' Organisations, the Gorlin Syndrome Group and Lupus Europe.

Corrective and preventative actions

Leo Pharma UK sincerely regretted this omission. In terms of corrective actions, the 2019 list of transfers of value to patient organisations had now been updated to include these three payments with details of the amounts and activities being supported. Furthermore, since the end of 2020, Leo Pharma had in place an electronic approval system for any cross-border activities, including interactions with patient organisations, which captured any transfers of value occurring cross-borders and automatically flagged these interactions, as well as the associated transfers of value, to the UK affiliate. Therefore, this system also ensured local approval, and certification of agreements between global and UK-based patient organisations.

Voluntary admission

Leo Pharma acknowledged responsibility for this omission, and therefore regrettably voluntarily admitted breaches of Clauses 14.3, 27.3 and 27.7.

When writing to Leo, the Authority asked it to consider the requirements of Clauses 14.3, 27.3 and 27.7 as cited by Leo and, in addition, Clauses 9.1 and 2 of the 2019 Code.

RESPONSE

Leo Pharma confirmed that the details of the transfers of value to the three patient organisations which were undeclared were as follows:

1) Gorlin Syndrome Group

R&D Collaboration Agreement - training seminar and production of an educational film.

Date of payment: October 2019.

Monetary Value: £12,469.

2) Gorlin Syndrome Group

Consultancy - expenses incurred in training Leo Pharma staff.

Date of payment: June 2019.

Monetary Value: £41.35.

3) Lupus Europe

Corporate Partnership – 3 in-person advisory sessions in Denmark and 2 online advisory sessions.

Date of payment: March 2019.

Monetary Value: 100,000 DKK.

4) International Alliance of Patients' Organisations (IAPO)

Sponsorship at IAPO Asia Pacific Congress, 13-14 November 2019.

Date of Payment: April 2020.

Monetary Value: €10,000.

Leo Pharma submitted that with regard to the entry for IAPO, although the activity took place in late 2019, the payment actually took place in 2020, and had therefore been disclosed as a 2020 transfer of value.

Following a request for further information, Leo provided copies of four contracts with the three patient organisations for each activity described above and submitted that activities 2 (Gorlin Syndrome Group consultancy expenses) and 3 (Lupus Europe advisory sessions) were contracted services provided by the patient organisations and therefore certification of the contracts was not a requirement as outlined in the supplementary information to Clause 27.8 of the 2019 Code. Leo confirmed that with regards to activity 4 (sponsorship at IAPO Asia Pacific congress), which took place in late 2019 and payment made in 2020, disclosure of this transfer of value was made by the end of June 2021 (the list of UK/IE patient organisations to which Leo provided support in 2020 was provided).

PANEL RULING

Clause 27.7 of the 2019 Code stated that each company must make publicly available, at a national or European level, a list of patient organisations to which it provided 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 published information must include the monetary value of financial support and of invoiced costs.

The Panel noted Leo's submission that in the process of compiling the list of patient organisation disclosures for 2020 (due to be published by the end of June 2021), it had discovered that there were four transfers of value made to three UK based patient organisations in 2019, from the Leo Pharma global organisation, which had not been disclosed.

The Panel noted Leo's subsequent submission that one of these four payments, the payment of €10,000 to the International Alliance of Patients' Organisations (IAPO) for sponsorship at IAPO Asia Pacific Congress in November 2019, was made in April 2020. The Panel noted that this payment to IAPO did not therefore need to be disclosed until the end of June 2021. The Panel noted Leo's submission that disclosure of this transfer of value was made by the end of June 2021. The Panel therefore ruled no breach of Clause 27.7 in relation to the payment to IAPO.

In relation to the two payments made to the Gorlin Syndrome Group (June and October 2019) for two separate activities, and the payment made to Lupus Europe in March 2019, the Panel

noted that these three payments had not been disclosed by the end of June 2020, as required by the Code and thus the Panel ruled a breach of Clause 27.7 as acknowledged by Leo.

The Panel noted that Leo had also voluntarily admitted a breach of Clause 27.3 in relation to the contracts between Leo Pharma A/S (global) and the UK headquartered patient organisations for each of the four activities in question. The Panel noted that Clause 27.3 stated that companies working with patient organisations must have in place a written agreement setting out exactly what has been agreed, including funding, in relation to every significant activity or ongoing relationship. The supplementary information to Clause 27.3 stated that the written agreement must be certified as set out in Clause 14.3. Clause 14.3 stated that material relating to working with patient organisations as described in Clause 27 and its supplementary information must be certified in advance in a manner similar to that provided for by Clause 14.1. In the Panel's view, Leo's voluntary admission in relation to the contracts was solely in relation to their lack of certification and no admission had been made in relation to their content. The Panel considered that certification of the contracts would be ruled upon under Clause 14.3 and therefore the Panel made no ruling in relation to Clause 27.3.

The Panel noted Leo's submission that the contracts between Leo Pharma A/S (global) and the three UK based patient organisations for the four activities in question were not certified. The Panel further noted Leo's subsequent submission that two of the four activities in question (Gorlin Syndrome Group consultancy expenses and Lupus Europe advisory sessions) were contracted services provided by the patient organisations and therefore the written agreements for those services did not need to be certified. The Panel noted that the supplementary information to Clause 27.8 stated that when companies engage patient organisations to provide services under Clause 27.8, the contracts for those services do not need to be certified. The Panel therefore ruled no breach of Clause 14.3 in relation to the contracts for the Gorlin Syndrome Group consultancy expenses and the Lupus Europe advisory sessions.

The Panel noted Leo's submission that the contracts for the other two activities in question (Gorlin Syndrome Group R&D collaboration agreement and sponsorship at IAPO Asia Pacific Congress) were not contracted services provided by the patient organisations and the written agreements had not been certified as required by the Code; the Panel therefore ruled a breach of Clause 14.3 in relation to each contract.

The Panel noted from Leo's submission that until the end of 2020, it did not have an electronic approval system in place for cross-border activities, including interactions with patient organisations, which would automatically flag cross-border interactions and associated transfers of value to the UK affiliate. It was unclear to the Panel what systems and processes Leo had in place prior to this and at the time of the activities in question; Leo made no submission in that regard. Nonetheless, the requirements of the Code had not been met in relation to disclosure of payments made to patient organisations and certification of written agreements as required by the Code. The Panel considered that high standards had not been maintained in this regard and a breach of Clause 9.1 was ruled.

Clause 2 was a sign of particular censure and was reserved for such use. The Panel considered that it was most regrettable that Leo was a year late in disclosing payments made to patient organisations in 2019. Furthermore, this was the third time that Leo had not met the requirements of the Code in relation to payments made in 2019 to patient organisations.

The Panel noted that Leo first published its list of patient organisations to which it had made payments to in 2019 in December 2020, which was more than 5 months later than required by the Code and only following the receipt of a complaint (Case AUTH/3418/11/20). This list needed to be updated in January 2021 as it was discovered that it was again incomplete which resulted in a further complaint (Case AUTH/3498/3/21).

Turning to the present case (Case AUTH/3527/6/21), the Panel was concerned that the omissions relating to payments made to patient organisations in 2019 by Leo global were only discovered during the process of compiling the list of payments made in 2020 to patient organisations; the Panel was concerned that cross-border payments to UK patient organisations were not checked as part of Leo's investigation into the first two complaints about failure to disclose payments made to patient organisations in 2019 (Cases AUTH/3418/11/20 and AUTH/3498/3/21). Taking all of the circumstances into consideration, the Panel considered, on balance, that Leo's numerous failures in relation to disclosure of payments made to patient organisations in 2019 and its lack of oversight of overseas affiliate's interactions with UK based patient organisations had brought discredit upon and reduced confidence in the pharmaceutical industry, and a breach of Clause 2 was ruled.

Complaint received 25 June 2021

Case completed 17 December 2021