

CASE AUTH/3498/3/21

CONTACTABLE COMPLAINANT v LEO

Information on payments to patient organisations

An anonymous, contactable ex-employee of Leo Pharma complained about information on the company's website and on the Disclosure UK website about payments it had made to patient organisations.

The complainant alleged that the document entitled 'List of patient organisations which Leo Pharma UK/IE has provided support in the years 2018 and 2019' (dated January 2021) on the Leo UK website, contained a number of errors and omissions.

The complainant noted that there was no mention on the list that in 2018, the National Eczema Society received funding from Leo Pharma UK but that Leo had disclosed on the Disclosure UK website the amount of £1,000 to the National Eczema Society in 2018.

The complainant noted that on 17 September 2019, a Leo Pharma UK/IE tweet stated:

'We were thrilled to present[name and position]of [@eczemasociety](#) a cheque for £5,217.43 raised by our fantastic [#LEOPharmaTREKFEST](#) team! This amount was matched by Leo Pharma bringing the total donation to an amazing £10,434.86. Thank you to everyone who donated!'

The complainant noted that the amount from Leo UK (£5,317.43) was not disclosed as funding to the National Eczema Society in 2019 in the document on the Leo UK Website.

The complainant stated that he/she could not tell if Leo disclosed funding to patient organisations for 2018 and 2019 in a time frame in accordance with Code requirements. Although he/she could see that the following payments made in 2019 only became available to the public in January 2021 (they were not on the December 2020 version of the list) and therefore this disclosure was outside of the first six months after the end of the 2019:

**'Thrombosis UK
National Thrombosis Week
Date of payment: April 2019
Monetary value: £2,400'**

**'Thrombosis UK
Cancer Comorbidities Initiative
Date of payment: July 2019
Monetary value: £325.60'**

'Thrombosis UK

**Let's Talk Clots Conference
Date of payment: October 2019
Monetary value: £800'**

The complainant alleged that the above were examples where it was not clear to the reader by the description provided what the money was provided for.

The complainant stated that many of the other amounts of funding on the list did not provide a clear description of the significance of the funding or what the money was for, eg 'Donation to match the amount raised in a private capacity by a Leo Pharma employee' was used to describe giving 'Changing Faces' the sum of £1,408.20 in June 2018 - what was that money for?

The detailed response from Leo is given below.

The Panel noted Leo's submission that a transfer of value of £1,000 made in 2018 to the National Eczema Society and published on Disclosure UK, was for the sponsorship of three training events for health professionals in return for which Leo would have a stand at each event. The Panel further noted Leo's submission that for the purposes of that activity, it regarded the National Eczema Society as a healthcare organisation and disclosure was made on Disclosure UK.

The Panel considered that it was possible, depending upon the activity in question, that an organisation could fulfil either the role of a patient organisation or the role of a healthcare organisation. On the evidence before it, the Panel considered that the complainant had not discharged his/her burden of proof that the disclosure of this particular transfer of value to the National Eczema Society on Disclosure UK as opposed to on the list of payments made to patient organisations on the Leo website was inappropriate as alleged and no breach of the 2016 Code was ruled.

The Panel noted Leo's submission that it had matched the amount raised by its employees (£5,217.43) from family and friends for participating in a sponsored walk called 'Trekfest'; a total charitable donation of £10,434.86 was announced on the Leo UK/Ireland Twitter feed in September 2019. The Panel noted, however, that the Code required companies to publish, at a national or European level, a list of patient organisations to which they had provided support; individual announcements of payments on Twitter and the like were not sufficient in that regard. The Panel noted that Leo's payment to the National Eczema Society with regard to 'Trekfest' was not included in the list of payments made to patient organisations in 2019 on the company's website (dated January 2021). The Panel therefore ruled a breach of the 2019 Code in relation to that payment.

The Panel noted that as stated by the complainant the list of patient organisations to which Leo Pharma UK/IE had provided support in the years 2018 and 2019 had two successive versions in recent times on the Leo UK Website, one dated December 2020 and a subsequent document with the same title dated January 2021. The Panel noted Leo's submission that the list was updated between December 2020 and January 2021 because three payments made to Thrombosis UK in 2019 had been missed off the list in December 2020.

In relation to the three payments made to Thrombosis UK in 2019, the Panel noted that these payments had not been disclosed until January 2021 and thus the Panel ruled a breach of the Code in relation to each payment. Leo accepted one breach of the Code and it appealed the remaining two breaches of that clause.

In relation to the description of the three payments made to Thrombosis UK in 2019 on the list dated January 2021, the Panel noted that the record of payments to Thrombosis UK included the name of the organisation, a brief description of the project or initiative for which the support had been given and its monetary value. The Panel considered that it was possible that the payments were for core funding of the projects or initiatives at issue as opposed to specific related activities; the complainant had provided no evidence otherwise and Leo had made no submission in that regard. On the basis of the information before it, the Panel did not consider that the complainant had shown, on the balance of probabilities, that the description of the nature of the support was not sufficiently complete to enable the average reader to form an understanding of its significance as alleged; no breach of the Code was ruled in relation to each of the three payments in that regard.

The Panel was concerned to note that the three payments to Thrombosis UK were missing from the December 2020 list on Leo's website given that in November 2020 Leo was made aware of issues with its disclosure of payments made in 2019 to patient organisations as part of Case AUTH/3418/11/20. The Panel was further concerned that Leo had twice updated its list following that complaint (December 2020 and January 2021) but its donation to the National Eczema Society for Trekfest was still missed. The Panel considered that Leo had failed to maintain high standards in this regard and a breach of the Code was ruled.

Clause 2 was a sign of particular censure and was reserved for such use. The Panel noted that Leo only became aware that it had not disclosed any of its 2019 payments to patient organisations as required by the Code on notification of Case AUTH/3418/11/20 in November 2020 and had subsequently disclosed some but not all of the payments in December 2020, more than 5 months later than the date required by the Code. Furthermore, three payments to Thrombosis UK were not disclosed until January 2021 and Leo only became aware that its donation to the National Eczema Society in relation to Trekfest in 2019 had not been disclosed on its website when it was notified of this complaint (Case AUTH/3498/3/21) in March 2021. In the Panel's view, transparency in relation to transfers of value to patient organisations was an important means of building and maintaining confidence in the pharmaceutical industry. The Panel considered that Leo had reduced confidence in the industry in this regard and ruled a breach of Clause 2 of the Code. This ruling was appealed by Leo.

With regard to the complainant's general observation that many of the other amounts of funding on the January 2021 list did not provide a clear description of the significance of the funding or what the money was for, the Panel considered that it was not for it to make out the complaint and identify the funding at issue. In that regard, however, the complainant had specifically referred to a 'Donation to match the amount raised in a private capacity by a Leo Pharma employee' being used to describe giving 'Changing Faces' £1408.20 in June 2018. The Panel noted that the record of the payment to Changing Faces included the name of the organisation, a statement that the payment was to match an amount raised by an employee in his/her private capacity and its

monetary value. The Panel considered that it was possible that the payment was for core funding as opposed to specific activities; the complainant had provided no evidence otherwise and Leo had made no submission in that regard. The Panel did not consider that the complainant had shown, on the balance of probabilities, that the description of the nature of the support of the payment to Changing Faces was not sufficiently complete to enable the average reader to form an understanding of the significance of the support as alleged and no breach of the 2016 Code was ruled. The Panel noted its comments and rulings here and above at Point 1 and consequently ruled no breaches of the 2016 Code including Clause 2.

The Appeal Board noted that three payments made to Thrombosis UK in 2019 had not been disclosed until January 2021 and thus the Panel had ruled a breach of the 2019 Code in relation to each payment. The Appeal Board considered that the late disclosure of the three payments in question only amounted to one breach of the Code which had been accepted by Leo and ruled accordingly. The appeal on this point was successful.

The Appeal Board considered that it was most regrettable that Leo was more than 6 months late in disclosing payments made to patient organisations in 2019. This was the second time that Leo had not met the requirements of the Code in this regard. The Appeal Board noted that Leo's failures in this regard appeared to be confined to a single year, 2019, and that the reporting period may have been impacted by the Covid-19 pandemic. The Appeal Board considered, on balance, that the Panel's ruling of a breach of the Code above was sufficient in relation to the second failure to publish the patient organisation payments in the requisite time period. Consequently, the Appeal Board ruled no breach of Clause 2. The appeal on this point was successful.

An anonymous, contactable ex-employee of Leo Pharma complained about information on the company's website and on the Disclosure UK website about payments it had made to patient organisations.

COMPLAINT

The complainant alleged that the document entitled 'List of patient organisations which Leo Pharma UK/IE has provided support in the years 2018 and 2019' (ref UK/ IE MAT 42294, dated January 2021) on the Leo UK website, contained a number of errors and omissions.

The complainant noted that there was no mention on the list that in 2018, the National Eczema Society received funding from Leo Pharma UK but that Leo had disclosed on the Disclosure UK website the amount of £1,000 to the National Eczema Society in 2018. However, the National Eczema Society was a patient organisation, not a healthcare organisation and therefore it should have been included on the list of patient organisations receiving Leo funding. That was the first anomaly.

The complainant further noted that on the 17 September 2019, a tweet on the Leo Pharma UK/IE twitter channel stated:

'We were thrilled to present [name and position] of [@eczemasociety](#) a cheque for £5,217.43 raised by our fantastic [#LEOPharmaTREKFEST](#) team! This amount was matched by Leo Pharma bringing the total donation to an amazing £10,434.86. Thank you to everyone who donated!'

The complainant noted that the amount from Leo UK (£5,317.43) was not disclosed as funding to the National Eczema Society in 2019 in the document on the Leo UK Website (ref UK/IE MAT 42294). The only payments on this list for the National Eczema Society in 2019 related to 'Corporate Sponsorship'. This fundraising activity was a different funding stream and had not been disclosed.

The complainant noted that the document entitled 'List of patient organisations which Leo Pharma UK/IE has provided support in the years 2018 and 2019' had had two successive versions in recent times on the Leo UK website, one dated December 2020 (ref UK/IE MAT 41615) and a subsequent version with the same title dated January 2021 (ref UK/IE MAT 42294).

The complainant stated that he/she could not tell if Leo disclosed funding to patient organisations for 2018 and 2019 in a time frame in accordance with Code requirements. Although he/she could see that the following payments made in 2019 only became available to the public in January 2021 (they were not on the December 2020 version of the list) and therefore this disclosure was outside of the first six months after the end of the 2019:

'Thrombosis UK
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Date of payment: July 2019
Monetary value: £325.60'

'Thrombosis UK
Let's Talk Clots Conference
Date of payment: October 2019
Monetary value: £800'

The above were examples where it was not clear to the reader by the description provided what the money was provided for; what activities in National Thrombosis week had support - all activities or one in particular? What aspect of the 'Cancer Comorbidities Initiative' did this money support, the entire initiative or some activities? What did the funding support at the 'Let's Talk Clots Conference' consist of? None of this was clear.

The complainant stated that many of the other amounts of funding on the list did not provide a clear description of the significance of the funding or what the money was for, eg 'Donation to match the amount raised in a private capacity by a Leo Pharma employee' was used to describe giving 'Changing Faces' the sum of £1,408.20 in June 2018 - what was that money for? Leo should be asked about these issues.

When writing to Leo, the Authority asked it to consider the requirements of Clauses 27.7, 9.1 and 2 of the 2016 Code in relation to payments and activities in 2018 and Clauses 27.7, 9.1 and 2 of the 2019 Code in relation to payments and activities in 2019 onwards.

RESPONSE

Leo Pharma stated that it took any concerns raised against its activities extremely seriously and would address the issues raised by the anonymous complainant and the Authority.

Firstly, Leo noted that this topic was addressed as part of a complaint received towards the end of last year, Case AUTH/3418/11/20. Leo assumed that this complaint was from the same complainant and that he/she had clearly monitored the content of the Leo Pharma UK/IE website over many months. Leo further noted that the current list of disclosures on the Leo Pharma UK/IE website to which the complaint referred was updated in light of Case AUTH/3418/11/20. In Leo's response to the previous case it made the admission that disclosures of support to patient organisations for 2019 had not been made within the required 6-month timeframe in 2020.

1 Disclosure UK website disclosure for National Eczema Society in 2018

Leo noted that the complainant had stated that the National Eczema Society was a patient organisation, not a healthcare organisation and therefore the payment of £1,000 should have been included on the list of patient organisations receiving Leo funding. The funding had otherwise been disclosed on the Disclosure UK website.

Leo noted that the requirements of the 2016 Code were applicable in this particular instance. Clause 27.7 in that Code stated:

‘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 updated at least once a year.

Leo explained that the payment of £1,000 was made to the National Eczema Society as event sponsorship, to have a Leo Pharma stand at three health professional training events, taking place in three different locations. Leo contended that that did not construe ‘financial support’ to the National Eczema Society which would have fallen under Clause 27.7, nor did it fall under a contract for provision of a service as per Clause 27.8. Rather it was a transactional agreement and payment which was why, for the purposes of that activity, the National Eczema Society was treated as a healthcare organisation, and a disclosure made on the Disclosure UK website accordingly, as per Clause 24.2:

‘...contributions towards the costs of meetings paid to healthcare organisations or to third parties managing events on their behalf, which may include sponsorship of health professionals by way of registration fees and accommodation and travel’

Leo stated that healthcare organisations were defined in Clause 1.9 of the Code as either a healthcare, medical or scientific association or organisation such as a hospital, clinic, foundation, university or other [sic] address, place of incorporation or primary place of operation was in Europe or an organisation through which one or more health professionals or other relevant decision makers provided services. It was a very broad definition, which, for the purposes of transfer of value disclosures, captured many organisations involved in the delivery of medical services but which would not consider themselves to primarily be healthcare organisations on a day-to-day basis. Whilst there was no equivalent definition of a patient

organisation within the Code, the European Federation of Pharmaceutical Industries and Associations (EFPIA) defined them as not-for-profit organisations (including the umbrella organisations to which they belonged), mainly composed of patients and/or caregivers, that represented and/or supported the needs of patients and/or caregivers.

Leo noted that the National Eczema Society offered a nurse-supported helpline and produced fact-sheets about the different types of eczema, treatments and self-management advice, which reflected the current research evidence and clinical guidelines, and which were reviewed regularly by experienced doctors and nurses. Leo stated that it would therefore argue that while the National Eczema Society clearly fulfilled the role of being a patient organisation, it also fitted into the broader definition of being a healthcare organisation. Leo noted that on the Disclosure UK website, there were several other notable patient organisations which had declarations against them as a healthcare organisation for the purpose of event sponsorship.

Leo submitted that regardless of the specific definition of the transfer of value in question, it was clear that in this instance, Leo had publicly declared the payment, categorised as 'Event sponsorship' on Disclosures UK, and therefore it refuted a breach of Clause 27.7 of the 2016 Code.

2 'Trekfest' charitable donation to National Eczema Society in 2019

Leo explained that in 2019, its employees participated in 'Trekfest', an event where employees walked the distance of a marathon (26.2 miles) along the Thames Path in order to raise money for the National Eczema Society. Leo employees raised £5,217.43 and that amount was matched by Leo, bringing the total charitable donation to £10,434.86. Leo sent out a Tweet on the Leo Pharma UK/IE Twitter feed announcing that .

The donation was a combination of monies raised in a private capacity by company employees through sponsorship by family and friends, as well as a separate donation by Leo at a corporate level. The payment did not represent the typical patient organisation sponsorship or financial support which would normally go through the external affairs department as part of Leo's wider external stakeholder engagement programme for the year. Therefore, the payment was not included in the list of patient organisations supported in 2019. Leo noted that in Case AUTH/3418/11/20 it had admitted to a breach of Clause 27.7 as it had not declared its 2019 patient organisation declarations within the first six months of 2020. The 2019 list on the website was created following that complaint. As Case AUTH/3418/11/20 had not yet been subject to a ruling by the Panel, Leo refuted a further breach of the Code here.

Furthermore, Leo noted that it had made the details of the donation publicly available, by the fact that it had posted details on Twitter. It was therefore clear that there was no effort to hide or conceal the donation, and that Leo had been transparent about the donation, indeed, the complainant would not have been able to make this complaint were that not the case. Leo therefore denied a breach of Clause 27.7 of the 2019 Code.

3 Allegations on timeliness of 2018 and 2019 patient organisation disclosures

Leo noted that it had already addressed this allegation in Case AUTH/3418/11/20 and admitted to a breach of Clause 27.7 in its response. Leo had also in its response in that case commented on the accusation that there was lack of clarity in the descriptions of the funding. The similarity of the allegations between the two complaints, spoke to the high likelihood that

this was the same complainant. As Case AUTH/3418/11/20 had not yet been ruled on, Leo did not feel it appropriate to comment yet again on the same allegations.

On the specific point about the disclosure list being updated between December 2020 and January 2021, the list was updated because three Thrombosis UK 2019 transfers of values had been missed off the list in December due to individuals who knew about those payments being on holiday over the Christmas period. Leo's response to Case AUTH/3418/11/20, stated:

'We would like to assure the Panel that this situation has been rectified as a matter of urgency, and the 2019 patient organisation disclosures are now live on the Leo Pharma UK/IE website. We will also mount an investigation into why our procedures on this topic, which appeared to work adequately in 2019, clearly appeared to have failed this year'.

The list was updated between December and January in the interests of full transparency. Again, as that matter had not yet been ruled on, Leo denied further breaches of the Code, other than that previously stated. Leo noted that it was revising its procedures on this important topic, which had clearly been inadequate in the past. Leo had a standard operating procedure (SOP) on 'Partnering with Patient Organisations', however this did not address the topic of disclosures of support. While Leo could not retrospectively apply a new process or procedure to this matter, the important point would be making sure that for 2020 disclosures which were due by the end of June 2021 and moving forwards, Leo's procedures were robust, and not dependent on changes in personnel or individual knowledge.

The complainant

Leo stated that as a general point, this was now, in all likelihood, the sixth complaint from the same complainant in the space of six months. Leo was unclear as to why the complainant had an unhealthy fixation on the company, nor why he/she appeared to be misusing the self-regulatory system to pursue his/her agenda. Given the peculiar fixation on the company, Leo could only conclude that the complainant must have either previously or currently, some interest or association with the company. Leo noted that the Authority had asked the complainant if he/she had any direct or indirect commercial, financial, or other interest in the matter of the complaint. Was Leo to assume that a negative response was received? If a negative response had been received, Leo asked the Panel to probe on this point, as not only would this be implausible but it would speak to the credibility and integrity of the complainant.

Leo stated that it could not be right, either ethically, or for the aims of self-regulation, for the company to be subjected essentially to an ongoing, anonymous, rolling audit of its online assets. At no point had the complainant contacted Leo with his/her concerns, but had on every occasion, gone directly to the Authority.

Leo stated that it appreciated that the constitution of the PMCPA made it difficult to suggest alternative solutions to this ongoing campaign against the company. One suggestion could be for the PMCPA to request that the complainant try and resolve his/her ongoing issues with Leo directly in the first instance and escalate to the PMCPA only if the matter remained unresolved.

Conclusion

In summary, Leo Pharma UK denied further breaches of the Code relating to the requirements of Clauses 27.7. As a result, there was no warrant for breaches of Clause 9.1 or of Clause 2, a ruling reserved as a sign of particular censure. Leo would also request that the Authority took into consideration that this further complaint appeared to have been made by the same complainant, while the original complaint, Case AUTH/3418/11/20 had yet to be ruled on.

PANEL RULING

The Panel noted Leo's submission that some of the matters raised in this case (Case AUTH/3498/3/21) overlapped with those in Case AUTH/3418/11/20. The Panel further noted that Leo had responded to the allegations in Case AUTH/3418/11/20 more than three months before it was notified of the current case (Case AUTH/3498/3/21) but that it had not received the Panel's ruling for Case AUTH/3418/11/20 when it was notified of Case AUTH/3498/3/21.

The Panel considered that it was unfortunate that Case AUTH/3418/11/20 had not completed before the complaint in Case AUTH/3498/3/21 was submitted. If that had been so then under Paragraph 5.2 of the Constitution and Procedure of the 2019 Code, the Director might, in certain circumstances, have been able to not allow some matters in this case, Case AUTH/3498/3/21, to proceed. Case AUTH/3418/11/20 however had not been adjudicated upon and so the Panel had to consider all of the matters raised in this case even if they were the same or similar to those raised in the previous case. The Panel further noted that it had no evidence before it that the complainant in Case AUTH/3418/11/20 was the same as in the current case (Case AUTH/3498/3/21); different complainants might provide different reasons for complaining about the same matter or appealing the same ruling.

1 Disclosure UK website disclosure for National Eczema Society in 2018

The Panel noted Leo's submission that a transfer of value of £1,000 made in 2018 to the National Eczema Society and published on Disclosure UK, was for the sponsorship of three training events for health professionals in return for which Leo would have a stand at each event. The Panel further noted Leo's submission that for the purposes of that activity, it regarded the National Eczema Society as a healthcare organisation and disclosure was made on Disclosure UK under Clause 24.2.

The Panel noted that the 2016 Code did not define a patient organisation although Clause 27.1 referred to companies interacting with disability organisations, carer or relative organisations and consumer organisations to support their work, including assistance in the provision of appropriate information to the public, patients and carers. A healthcare organisation was defined in Clause 1.9 of the same Code as a healthcare, medical or scientific association or organisation such as a hospital, clinic, foundation, university or other teaching institution or learned society whose business address, place of incorporation or primary place of operation was in Europe or an organisation through which one or more health professionals or other relevant decision makers provided services. The Panel considered that it was possible, depending upon the activity in question, that an organisation could fulfil either the role of a patient organisation or the role of a healthcare organisation. On the evidence before it, the Panel considered that the complainant had not discharged his/her burden of proof that the disclosure of this particular transfer of value to the National Eczema Society on Disclosure UK as opposed to on the list of payments made to patient organisations on the Leo website was inappropriate as alleged and no breach of Clause 27.7 of the 2016 Code was ruled.

2 'Trekfest' charitable donation to National Eczema Society in 2019

In relation to the charitable donation made to the National Eczema Society in 2019, the Panel noted Leo's submission that it had matched the amount raised by its employees (£5,217.43) from family and friends for participating in a sponsored walk called 'Trekfest'; a total charitable donation of £10,434.86 was announced on the Leo UK/Ireland Twitter feed in September 2019. The Panel noted, however, that the Code required companies to publish, at a national or European level, a list of patient organisations to which they had provided support; individual announcements of payments on Twitter and the like were not sufficient in that regard. The Panel noted that Leo's payment to the National Eczema Society with regard to 'Trekfest' was not included in the list of payments made to patient organisations in 2019 on the company's website (ref UK/ IE MAT 42294, dated January 2021). The Panel therefore ruled a breach of Clause 27.7 of the 2019 Code in relation to that payment.

3 Allegations on timeliness of 2018 and 2019 patient organisation disclosures

The Panel noted that as stated by the complainant the list of patient organisations to which Leo Pharma UK/IE had provided support in the years 2018 and 2019 had two successive versions in recent times on the Leo UK Website, one dated December 2020 (ref UK/IE MAT 41615) and a subsequent document with the same title dated January 2021 (ref UK/IE MAT 42294). The Panel noted Leo's submission that the list was updated between December 2020 and January 2021 because three payments made to Thrombosis UK in 2019 had been missed off the list in December 2020. In that regard Leo referred to its response to Case AUTH/3418/11/20 (made in December 2020) in which it assured the Panel that its failure to disclose payments made to four patient organisations in 2019 had been rectified as a matter of urgency, and that the 2019 patient organisation disclosures were now live on the Leo Pharma UK/IE website.

The Panel noted that the complainant stated that he/she could not tell if Leo had disclosed funding to patient organisations for 2018 and 2019 in a time frame in accordance with Code requirements; in that regard, he/she had only referred to three specific payments made to Thrombosis UK in 2019. The complainant had alleged that whilst those three payments were included on the list dated January 2021, they were not included on the December 2020 version of the list and so had been disclosed outside the first six months after the end of 2019. The Panel therefore made its ruling in relation to the three payments specifically highlighted by the complainant.

In relation to the three payments made to Thrombosis UK in 2019, the Panel noted that Clause 27.7 of the 2019 Code stated that disclosure must be in the first six months after the end of the calendar year in which the transfers of value were made ie by the end of June 2020. The Panel noted that these payments had not been disclosed until January 2021 and thus the Panel ruled a breach of Clause 27.7 of the 2019 Code in relation to each payment. Leo accepted one breach of Clause 27.7 and it appealed the remaining two breaches of that clause.

In relation to the description of the three payments made to Thrombosis UK in 2019 on the list dated January 2021, the Panel noted that Clause 27.7 of the 2019 Code stated, *inter alia*, 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' and that 'The published information must include the monetary value of financial

support and of invoiced costs. For significant non-financial support that cannot be assigned a meaningful monetary value, the published information must describe clearly the non-monetary value that the organisation receives.' The supplementary information to Clause 27.7 stated that whilst an indication of the patient organisation's total income and/or the company's support as a percentage of the patient organisation's total income might be given, neither was obligatory. The Panel noted that the record of payments to Thrombosis UK included the name of the organisation, a brief description of the project or initiative for which the support had been given and its monetary value. The Panel considered that it was possible that the payments were for core funding of the projects or initiatives at issue as opposed to specific related activities; the complainant had provided no evidence otherwise and Leo had made no submission in that regard. On the basis of the information before it, the Panel did not consider that the complainant had shown, on the balance of probabilities, that the description of the nature of the support was not sufficiently complete to enable the average reader to form an understanding of its significance as alleged; no breach of Clause 27.7 of the 2019 Code was ruled in relation to each of the three payments to Thrombosis UK.

The Panel was concerned to note that the three payments to Thrombosis UK were missing from the December 2020 list on Leo's website given that in November 2020 Leo was made aware of issues with its disclosure of payments made in 2019 to patient organisations as part of Case AUTH/3418/11/20. The Panel was further concerned to note that Leo had twice updated its list following that complaint (December 2020 and January 2021) but its donation to the National Eczema Society for Trekfest was still missed. The Panel considered that Leo had failed to maintain high standards in this regard and a breach of Clause 9.1 of the 2019 Code was ruled.

Clause 2 was a sign of particular censure and was reserved for such use. The Panel noted that Leo only became aware that it had not disclosed any of its 2019 payments to patient organisations as required by the Code on notification of Case AUTH/3418/11/20 in November 2020 and had subsequently disclosed some but not all of the payments in December 2020, more than 5 months later than the date required by the Code. Furthermore, three payments to Thrombosis UK were not disclosed until January 2021 and Leo only became aware that its donation to the National Eczema Society in relation to Trekfest in 2019 had not been disclosed on its website when it was notified of this complaint (Case AUTH/3498/3/21) in March 2021. In the Panel's view, transparency in relation to transfers of value to patient organisations was an important means of building and maintaining confidence in the pharmaceutical industry. The Panel considered that Leo had reduced confidence in the industry in this regard and it ruled a breach of Clause 2 of the 2019 Code. This ruling was appealed by Leo.

With regard to the complainant's general observation that many of the other amounts of funding on the January 2021 list did not provide a clear description of the significance of the funding or what the money was for, the Panel considered that it was not for it to make out the complaint and identify the funding at issue. In that regard, however, the complainant had specifically referred to a 'Donation to match the amount raised in a private capacity by a Leo Pharma employee' being used to describe giving 'Changing Faces' £1408.20 in June 2018. The Panel noted that Clause 27.7 of the 2016 Code was similar to the 2019 Code with regard to the description of the support required. The Panel noted that the record of the payment to Changing Faces included the name of the organisation, a statement that the payment was to match an amount raised by an employee in his/her private capacity and its monetary value. The Panel considered that it was possible that the payment was for core funding as opposed to specific activities; the complainant had provided no evidence otherwise and Leo had made no submission in that regard. The Panel did not consider that the complainant had shown, on the

balance of probabilities, that the description of the nature of the support of the payment to Changing Faces was not sufficiently complete to enable the average reader to form an understanding of the significance of the support as alleged and no breach of Clause 27.7 of the 2016 Code was ruled. The Panel noted its comments and rulings here and above at Point 1 and consequently ruled no breach of Clauses 9.1 and 2 of the 2016 Code.

APPEAL BY LEO

Leo appealed the Panel's rulings in relation to Point 3 regarding multiple breaches of Clause 27.7 (x2) and the overall breach of Clause 2. Leo's reasons for appeal were outlined below.

Background

Leo submitted that this complaint was received in March 2021, and Leo believed it to be one in a series of complaints brought against Leo Pharma UK by the same complainant or complainants. This topic was addressed as part of a complaint received towards the end of last year, Case AUTH/3418/11/20. Leo submitted it could only assume that this complaint was from the same complainant, and that this person had been monitoring the content of the Leo Pharma UK/IE website over many months. Although the Authority had confirmed that these two complaints originated from different email addresses, this did not exclude the high likelihood of them originating from the same individual(s). The list of disclosures on the Leo Pharma UK/IE website to which this complaint referred was updated in light of Case AUTH/3418/11/20. In Leo's response to the latter, dated 18 December 2020, Leo made the admission that disclosures of support to patient organisations for the year 2019 had not been made within the required 6-month timeframe in 2020 as required by the 2019 Code and admitted to a breach of Clause 27.7.

Leo submitted that the patient organisation disclosure list for 2019 which was published in mid-December 2020, was updated approximately 3 working weeks later in mid-January with three Thrombosis UK 2019 transfers of value which had been missed off the list in December, due to individuals with knowledge of these payments being on holiday over the Christmas period. The list was updated in good faith, and in the interests of full transparency. The complainant, obviously monitoring the Leo Pharma UK website, reported this update in the patient organisation disclosure list to the PMCPA.

Leo submitted that additionally, in 2019, Leo Pharma UK employees participated in an event called 'Trekfest', where employees walked the distance of a marathon (26.2 miles) along the Thames Path, in order to raise money for the National Eczema Society. Leo Pharma UK employees managed to raise £5217.43 for the National Eczema Society – this amount was then matched by an additional £5217.43 from Leo, bringing the total charitable donation to £10,434.86. Leo sent out a Tweet on the Leo Pharma UK/IE Twitter feed announcing this – the complainant was aware of this donation as a result of examining Leo Pharma UK's Twitter feed, and also reported this to the PMCPA. This payment did not represent the typical patient organisation sponsorship or financial support which would normally go through Leo's External Affairs department as part of its wider external stakeholder engagement programme for the year. Therefore, this payment was not included in the list of patient organisations supported in 2019. Leo had made the details of this donation publicly available, by the fact that Leo had posted this on Twitter. It was therefore clear that there was no effort to hide or conceal this donation – indeed, the complainant would not have been in a position to know about this donation otherwise.

Leo submitted that it also stated in its original reply, that it was in the process of revising its procedures on this important Code requirement, which had clearly been inadequate in 2020. The reason for the omission was partly due to a considerable turnover in staff at the time and the responsibility for this activity shifting from one person to another. It was also possible that some confusion arose owing to the impact of COVID-19 on the disclosure process for health professionals and healthcare organisations. Leo also stated that while it could not retrospectively apply a new process or procedure to this matter, the important point would be making sure that for 2020 disclosures, which were due by the end of June 2021 and were now published, that moving forwards, its procedures were robust, and not dependent on changes in personnel or individual knowledge.

Additional two breaches of Clause 27.7

Leo Pharma accepted a finding of a breach of Clause 27.7 as it pertained to the failure to disclose initially in December 2020, the three transfers of value to the patient organisation, Thrombosis UK. However, Leo did not understand why the Panel had ruled three breaches of Clause 27.7, one for each of the three payments to the same patient organisation. The requirement of Clause 27.7 was to publish a list of patient organisations to which companies provided support. Clause 27.7 did not refer to individual payments. It therefore followed, that this update to the list, which was made in January and pertained to a single patient organisation, should constitute one breach of Clause 27.7, not three. It would be reasonable to award three breaches of Clause 27.7 had the list been updated on three occasions. Indeed, the Panel had adhered to this principle in its ruling of a single breach of Clause 27.7 in Case AUTH/3418/11/20, so Leo was puzzled as to why the approach had differed here.

Overall finding of Clause 2

Leo submitted that the overall finding of a breach of Clause 2 in this instance was inappropriate, and excessive.

Clause 2 in the 2019 Code stated:

'Discredit to, and Reduction of Confidence in, the Industry

Activities or materials associated with promotion must never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry

Supplementary information:

A ruling of a breach of this clause is a sign of particular censure and is reserved for such circumstances. Examples of activities that are likely to be in breach of Clause 2 include prejudicing patient safety and/or public health, excessive hospitality, inducements to prescribe, unacceptable payments, inadequate action leading to a breach of undertaking, promotion prior to the grant of a marketing authorization, conduct of company employees/agents that falls short of competent care and multiple/cumulative breaches of a similar and serious nature in the same therapeutic area within a short period of time.'

Leo submitted that it appreciated that the list given in the supplementary information was not an exhaustive list. However, in terms of the specifics of this case, the subject of disclosures was

not on this list. The initial failure of Leo to disclose transfers of value to patient organisations for 2019, was regrettable, but was confined to the one year, and not indicative of a wider systemic issue with disclosures in other years. It was clear that with regards to patient organisation disclosures for 2019 specifically, there had been issues with capturing this in a systematic manner. For full transparency, Leo had made a voluntary admission, again with regards to the 2019 patient organisation disclosures list, with the discovery of payments made by the Global organisation to UK patient organisations (Case AUTH/3527/6/21). As stated above, the reason for the omission was partly due to a considerable turnover in staff at the time and the responsibility for this activity shifting from one person to another. It was also possible that some confusion arose owing to the impact of COVID-19 on the disclosure process for health professionals and healthcare organisations. Leo submitted that it had taken steps to ensure that for the years ahead, that was, disclosures for 2020 onwards, that robust procedures and oversight was in place. This included capture of patient organisation activities (both local and global) in an online approval system, as well as the appointment of a head of compliance and medical governance.

As stated above, Leo submitted that the patient organisation disclosure list for 2019 which was published in mid-December 2020, was updated in mid-January with three Thrombosis UK 2019 transfers of value which had been missed off the list in December, due to individuals with knowledge of these payments being on holiday over the Christmas period. The list was updated in good faith, in the interests of full transparency. Additionally, the 'Trekfest' donation to the National Eczema Society though publicly declared on Twitter, was not captured in Leo's list of disclosures because of the fact that this did not go through Leo's usual external stakeholder engagement channels but was a corporate donation.

However, Leo submitted that it challenged whether the 'Trekfest' donation to the National Eczema Society, publicly declared on social media, and consequently viewed by many more people than would visit the Leo Pharma corporate website, or the late, yet voluntary addition to the list of three transfers of value to a single patient organisation, Thrombosis UK, of the value of £2400, £325.60 and £800, three working weeks later, was enough to genuinely 'bring discredit upon, or reduce confidence in, the pharmaceutical industry'?

Leo submitted that it would not appeal this ruling, were Leo found to have had systemic issues with patient organisation disclosures over two or more years, or if Leo had breached a signed undertaking and assurance in such a matter. However, for the purposes of breaches of Clause 27.7 pertaining to one calendar year, a Clause 2 ruling was disproportionate and this ruling by the Panel had somewhat lost sight of what was meant by a breach of Clause 2 ruling.

Leo submitted that it was important that all parties involved, be it patients, health professionals, patient organisations, or pharma companies themselves had confidence in the rulings and sanctions imposed by self-regulation. A Clause 2 ruling should be reserved for the most serious instances of misconduct by pharmaceutical companies. Inappropriate and overuse of a Clause 2 ruling, as had happened here, and increasingly in other instances, not only served to diminish the perceived severity of a Clause 2, but in itself led to a reduction of confidence in and discredit to the industry. Therefore, in summary, whilst Leo had regrettably breached Clause 27.7, and had failed to maintain high standards in so breaching Clause 9.1, the matters in this case did not in any meaningful way, 'bring discredit upon, or reduce confidence in, the pharmaceutical industry' and so Leo appealed the ruling of a breach of Clause 2 in this instance

COMMENTS FROM THE COMPLAINANT

There was no response from the complainant on the appeal.

APPEAL BOARD RULING

The Appeal Board noted that three payments made to Thrombosis UK in 2019 had not been disclosed until January 2021 and thus the Panel had ruled a breach of Clause 27.7 of the 2019 Code in relation to each payment. The Appeal Board noted that Leo had accepted a single ruling of a breach of Clause 27.7, and it had appealed the remaining two breaches of that clause. The Appeal Board noted that the requirement of Clause 27.7 was to publish 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 was sufficiently complete to enable the average reader to understand the significance of the support. The Appeal Board considered that the late disclosure of the three payments in question made in 2019 to Thrombosis UK only amounted to one breach of Clause 27.7 which had been accepted by Leo and ruled accordingly. The appeal on this point was successful.

The Appeal Board noted that Leo only became aware that it had not disclosed any of its 2019 payments to patient organisations as required by the Code on notification of Case AUTH/3418/11/20 in November 2020 and had subsequently disclosed some but not all of the payments in December 2020, more than 5 months later than the date required by the Code. Furthermore, three payments to Thrombosis UK were not disclosed until January 2021 and Leo only became aware that its donation to the National Eczema Society in relation to Trekfest in 2019 had not been disclosed on its list of disclosures to patient organisations on its website when it was notified of this complaint (Case AUTH/3498/3/21) in March 2021. In the Appeal Board's view, transparency in relation to transfers of value to patient organisations was an important means of building and maintaining confidence in the pharmaceutical industry.

The Appeal Board noted the sequence of events above and it was very disappointed that Leo had made further errors in its disclosure of payments made to patient organisations in 2019.

The Appeal Board noted Leo's submission that it now had robust procedures and oversight in place. The Appeal Board considered that it was most regrettable that Leo was more than 6 months late in disclosing payments made to patient organisations in 2019. This was the second time that Leo had not met the requirements of the Code in this regard. The Appeal Board noted that Leo's failures in this regard appeared to be confined to a single year, 2019, and that the reporting period may have been impacted by the Covid-19 pandemic. The Appeal Board considered, on balance, that the Panel's ruling of a breach of Clause 9.1 was sufficient in relation to the second failure to publish the patient organisation payments in the requisite time period. Consequently, the Appeal Board ruled no breach of Clause 2. The appeal on this point was successful.

Complaint received **29 March 2021**

Case completed **18 November 2021**