CASE AUTH/3418/11/20

CONTACTABLE PHARMACEUTICAL PHYSICIAN v LEO

Leo UK Disclosure and website issue

A complainant who described him/herself as a pharmaceutical physician working in the pharmaceutical/health industry, complained about a number of aspects of Leo Pharma's website (www.leo-pharma.co.uk) including the lack of information about clinical trials, the company's transparency with patient organisations, and the information it had provided on Disclosure UK.

The detailed response from Leo is given below.

1 Information about clinical trials

The complainant alleged that Leo did not have details on its website's home page as to where clinical trial information could be found.

The Panel did not agree with Leo's submission that the Code was ambiguous in this regard; the clinical trial information could be included on a UK or non-UK site, whereas details as to where such information could be found was required to be included on the home page of a company's website. The Panel noted that although information as to where the details of Leo's clinical trials could be found was provided on the company's global website (www.leo-pharma.com) there was, as acknowledged by the company, no such information on the home page of the UK website (www.leo-pharma.co.uk). Breaches of the Code were ruled including that high standards had not been maintained. The Panel but did not consider that the matter warranted a ruling of a breach of Clause 2 and no breach was ruled.

2 Patient organisation disclosures

The complainant noted that the list of patient organisations with which Leo had engaged had been published on the website; the list was dated September 2019 and the document entitled 'List of Patient Organisations to which Leo Pharma UK/IE had provided financial support 2018/2019'. The document provided varied levels of information per transfer of value. With respect to the dates of transfer, one provision of support appeared to be from 2017 so it was not clear if the title of the document accurately reflected the information in the document. The complainant alleged that the document contained incomplete information to enable the average reader to form an understanding of the significance of the support.

The complainant further noted that no transfers had been published for 2019, and the 6 month timeframe for disclosure had passed in 2020 for disclosure of 2019 data and in that regard he/she asked if Leo could confirm that it had not engaged with any patient organisations in 2019.

The complainant alleged that it was unclear if the 2017 and 2018 data related to patient organisation funding from Leo was made public at least once a year as per the 2016 Code given 2017 data appeared in a document dated September 2019. The complainant asked Leo to demonstrate the dates on which funding for 2016, 2017 and 2018 payments to patient organisations were made public.

The Panel considered that the 2016 Code was applicable to the complainant's allegation that it was unclear if payments to patient organisations in 2016, 2017 and 2018 were made public at least once a year.

The Panel noted Leo's submission that all of the transfers of value listed on the document entitled 'List of Patient Organisations to which Leo UK/IE had provided financial support 2018/2019' and dated September 2019 were made in 2018.

The Panel noted that the 2016 Code did not stipulate how long transfers of value to patient organisations had to remain in the public domain. The Panel considered that the complainant had not discharged his/her burden of proof that a breach of the Code had occurred in relation to disclosure of payments made to patient organisations in 2016 and 2017 and therefore the Panel ruled no breach of the Code.

In relation to payments made to patient organisations in 2018, the Panel noted Leo's submission that the list of disclosures dated September 2019 was first approved in June 2019 and then re-approved in September 2019 following a correction to one of the values. The Panel noted Leo's submission that it had fulfilled the requirement to make the disclosure in the first six months after the end of the calendar year in which the transfers of value were made, which was a requirement of the 2019 Code. However, as noted above, the Panel considered that the 2016 Code was the relevant Code for disclosure of payments made to patient organisations in 2018.

The Panel noted that the list of patient organisations to which Leo had provided support, which was approved in June 2019, included some payments that were made in January and May 2018. The Panel had no information before it as to what, if anything, was disclosed prior to June 2019. Leo made no submission in that regard. The Panel noted the lack of a definitive timeframe in the 2016 Code and considered that on the evidence before it, the complainant had not discharged his/her burden of proof that the disclosure in June 2019 of payments made to patient organisations in 2018 did not comply with the 2016 Code and no breach of the Code was ruled.

In relation to the description of the support given to patient organisations for payments made in 2018, the Panel noted that the list stated, in alphabetical order, the name of the patient organisation, a brief description of the project or initiative for which the support had been given and its monetary value. The Panel noted that the complainant considered that it was not clear what the funding went towards but it considered that it was possible that some of the payments were for core funding of the projects/initiative in question as opposed to specific related activities. The Panel noted Leo's submission that where a payment was not a corporate sponsorship or was a corporate sponsorship associated with a particular project, that had been made clear. 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 the significance of the support. No breach of the 2016 Code was ruled.

In relation to the payments to patient organisations made in 2019, the Panel noted that 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. The Panel noted Leo's submission that transfers of value had been made to four patient organisations in 2019 but that when this complaint was submitted (November 2020) no disclosure of such had been made. The Panel therefore ruled a breach of the Code as acknowledged by Leo. High standards had not been maintained and a further 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 when it received this complaint in November 2020. The Panel noted that those transfers of value were subsequently disclosed in December 2020, more than 5 months later than the date required by the Code. 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, on balance, that Leo had reduced confidence in the industry for its failure to publicly disclose any of its 2019 transfers of value to patient organisations in the time period required by the 2019 Code and it ruled a breach of Clause 2 which was appealed by Leo.

The Appeal Board considered that it was most regrettable that Leo was more than 5 months late in disclosing its 2019 transfers of value to patient organisations, but it noted that Leo's failures in this regard appeared to be confined to a single year and that the reporting period might have been impacted by the Covid-19 pandemic. There had been no change for the reporting period for patient organisation disclosures. There had been a delay in the disclosure process for health professionals and healthcare organisations due to a decision to avoid contacting them about disclosure at a very busy time. The Appeal Board considered, on balance, that the Panel's ruling of a breach above was sufficient in relation to the 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.

3 Links on LEO UK website

The complainant noted a number of occasions upon which a reader was redirected from the Leo UK website without notice.

The Panel noted that in each of the scenarios described by the complainant the user was being directed from one Leo website to another. The Panel considered that it was sufficiently clear, from the screenshots provided by Leo, that the user was being directed to another Leo website which was stated on the website to which the user was being directed. The Panel therefore ruled no breaches of the Code.

The Panel noted Leo's submission that if a link on the Leo UK website went to an external website, a pop-up appeared which informed viewers that they were about to leave a Leo website and go to a third-party website outside of the control of Leo. The Panel noted its comments and rulings above and considered that the complainant had

not shown that Leo had failed to maintain high standards in relation to links on its UK website as alleged and no breach of the Code was ruled. Consequently, no breach of Clause 2 was ruled in that regard.

4 Certification/Recertification

The complainant noted that the 'News' section of the Leo website contained some very old articles and alleged that some of those articles fell under educational material for the public or patients relating to disease and so should be certified before use and should be certified at no less [sic] than 2 year intervals.

The complainant referred to three specific items in the 'News' section.

The Panel noted Leo's submission that the three press releases in question were housed in a section of the corporate website named 'News' in the 'About Us' tab; the text in the 'News' landing page referred to media enquiries and provided the contact details for the Leo communications team.

In the Panel's view, it was not necessarily unacceptable to have press releases within a clearly labelled section of a corporate website which made the intended audience (media) clear. The Panel queried if it was sufficiently clear that the 'News' section was only intended for the media, prior to accessing it. However, the Panel noted Leo's submission that the website in question had separate sections for patients and health professions under the 'Supporting You' tab.

In the Panel's view, from the evidence before it, the press releases appeared to be within a section of the website which was intended for the media. The Panel did not consider that in such circumstances the material was educational material for the public or patients issued by companies which related to diseases or medicines or any other type of material that required certification. Nonetheless, the Panel noted Leo's submission that all three press releases were certified, rather than examined. No breach of the Code was ruled in relation to each of the three press releases.

The Panel considered that it would be good practice for companies to review all information on their corporate websites regularly, including that which did not require certification under the Code, to assess if it was still appropriate for the intended audience. The Panel noted that the press releases were ordered by date and grouped by the year in which they were released, which was clearly labelled within the 'News' section of the website. The Panel noted its comments above and considered that as there was no requirement to certify the three press releases in question, regardless of whether they were certified or examined originally, there was no requirement to re-certify them and therefore no breach of the Code was ruled in relation to each.

In the Panel's view the press releases were not intended for patients taking a Leo medicine and therefore the side effect reporting statement was not required. The Panel ruled no breach of the Code in that regard in relation to each of the three press releases.

The Panel noted its comments above and considered that the complainant had not provided any evidence to suggest that Leo had failed to maintain high standards with

regard to the availability of the three press releases in question within the 'News' section of its corporate website and no breaches of the Code were ruled including Clause 2.

5 Information published on Disclosure UK

The complainant stated that he/she could not locate where Leo had disclosed the number of health professionals which shared in the aggregated payments to see what the average type of payment was. The complainant asked if Leo could confirm that information had been published and if so, where.

The complainant alleged that with regard to disclosure of funding to healthcare organisations, it was impossible in many cases to see who the real beneficiary of the funding provided by Leo was, as Leo had disclosed against many non-healthcare organisations and middle parties.

The complainant alleged that for 33 named organisations, monies disclosed by Leo which could be found under the 'Healthcare Organisation' tab on Disclosure UK for 2017 and/or 2018, Leo had failed to meet the requirements of the Code as the recipient of the funding was not a healthcare organisation or a health professional but a healthcare organisation or health professional might have been the beneficiary given the amount of 'event sponsorships' the company had disclosed.

The complainant asked if Leo could explain why the beneficiaries of the funding had not been disclosed to the public.

The complainant stated that he/she could see from Disclosure UK that Leo provided funding towards joint working in 2018 to a university but could not locate where the company had published an executive summary of the joint working agreement or if the project had been completed, a short summary of the outcomes and lessons learned.

The Panel noted the complainant's allegation that he/she could not locate where Leo had disclosed the number of health professionals which shared in the aggregated payments as per the Code. It was unclear to the Panel which disclosure year the allegation was in relation to and therefore which was the applicable Code. The Panel noted Leo's submission that the information as required by the 2019 Code was published and accessible on the Disclosure UK website. The Panel therefore ruled no breach of the 2019 Code.

The Panel noted Leo's submission that it had not conducted a joint working project in recent years and that the payment was made to the university by Leo Global for a research and development activity, which was erroneously categorised as joint working and that Leo would ask for it to be corrected on Disclosure UK. The Panel considered that as there was no evidence that it had been a joint working project, no breach of the 2016 Code was ruled.

The Panel noted that the complainant provided information from Disclosure UK in relation to 33 named organisations and over 200 transfers of values made to those organisations in 2017 and/or 2018. In the Panel's view, it was not necessarily a breach of the Code to disclose a payment made to organisations other than healthcare organisations on Disclosure UK as long as it did not breach any other codes, laws and

regulations. However, the Panel considered that, for example, it would likely be a breach of the Code if an indirect transfer of value was disclosed against an intermediate or third party where the pharmaceutical company knew or could identify the healthcare organisation or health professional that had benefitted from the transfer of value; in such situations the transfer of value should be disclosed against the known final recipient.

The Panel noted Leo's submission that the organisations cited by the complainant had in most cases received a transfer of value for the purposes of a stand meeting, sponsorship of an educational meeting or a grant. The Panel further noted Leo's submission that where payments related to indirect transfers of value to a health professional or a healthcare organisation, then that would be declared against the health professional or healthcare organisation in question and that it had no evidence or reason to believe that the transfers of value called into question by the complainant would pertain to indirect transfers of value.

Whilst the Panel queried whether some of the named organisations in the list provided by the complainant were healthcare organisations as defined by the Code, it had no evidence before it that they were intermediaries such that they were not the final beneficiaries and that the payments disclosed had in fact gone to identifiable individual health professionals or healthcare organisations. The Panel considered that the complainant had provided no evidence to suggest that any of the more than 200 payments in question on Disclosure UK were anything other than direct payments to the organisations named. In that regard the Panel did not consider that the complainant had discharged his/her burden of proof that the transfers of value in question were indirect payments to health professionals or healthcare organisations known to Leo as alleged. The Panel therefore ruled no breach of the 2016 Code in relation to transfers of value made in 2017 and 2018 for each of the 33 organisations named.

The Panel considered that the complainant had not shown that Leo had failed to maintain high standards with regard to information published on Disclosure UK and no breaches of Code was ruled. The Panel consequently ruled no breach of Clause 2.

A complainant who described him/herself as a pharmaceutical physician working in the pharmaceutical/health industry, complained about a number of aspects of Leo Pharma's website (www.leo-pharma.co.uk) including the lack of information about clinical trials, the company's transparency with patient organisations, and the information it had provided on Disclosure UK. The complainant stated that he/she was not an employee or consultant to pharmaceutical companies and had no direct or indirect interest in Leo Pharma.

Leo stated that it welcomed scrutiny and was proud to abide by the requirements of the Code, but was once again disappointed by the nature of this particular complaint, now the third from what appeared to be the same complainant (see Case AUTH/3397/10/20 and Case AUTH/3405/10/20). As previously, the majority of the points raised were not opinion, but 'what if' scenarios; in Leo's view that suggested that the intent of the exercise was to tie up the resources of both Leo and the PMCPA for non-genuine reasons.

Leo considered that it was not in the spirit, letter or the Constitution and Procedure for a complaint to be tested through debating hypotheses; rather that the burden of proof fell to complainants to establish their complaints on the balance of probabilities. It was unreasonable to accept complaints based on purely theoretical scenarios rather than reasonable assumption.

The targeted, somewhat obsessive, actions of this complainant, whether parts of his/her complaint were upheld or not, was an abuse of the spirit and intent of the openness of self-regulation.

Leo stated that it would, of course, answer the points raised by the complainant but would do so succinctly where possible, and not engage in discussions around hypothetical or imagined breaches of the Code; Leo would provide more information on specific points if required. Leo repeated its request that the veil of secrecy concerning the complainant's connections with the industry be lifted. The sheer scale of the case and the efforts put into this and the previous complaints, strongly suggested that the complainant had a vested interest. While the concerns raised did, in some instances, address genuine Code matters, in many instances they did not, and the motivation should not be hidden. Leo requested that the Authority actively look into that aspect of this series of complaints.

Leo noted that the complainant described him/herself as a pharmaceutical physician but one that was neither employed by a pharmaceutical company nor a consultant to one. By definition, that was impossible; to be a pharmaceutical physician he/she must have (or have had) an affiliation with one or more pharmaceutical companies. Leo therefore respectfully requested that the potential conflicts of interest were made visible to all readers of the eventual report on this case.

Leo noted that the complainant had raised a great many issues within this wide-ranging complaint. Whilst Leo admitted one breach of the Code below, it did not believe it had breached the Code in the other, numerous, and in many cases, superfluous instances cited by the complaint.

When writing to Leo, the Authority asked the company to consider the requirements of Clauses 1.9, 13.1, 14.3, 14.5, 20, 24.1, 24.9, 26.3, 27.7 and 28.6 as cited by the complainant. The company was also asked to bear in mind the requirements of Clauses 9.1 and 2 in relation to each of the five topics outlined below.

On receipt of Leo's response, the case preparation manager determined that in relation to some of the complainant's comments at Points 2 and 5 below, no *prima facie* case had been established and those comments should not be referred to the Panel for consideration; the parties were so informed and the decision was accepted by the complainant. The remainder of the complainant's comments were referred to the Panel.

1 Information about clinical trials

COMPLAINT

The complainant noted that the supplementary information to Clause 13.1 stated that companies must include on the home page of their website information as to where details of their clinical trials could be found. That detail appeared to have been omitted from the home page of Leo's website (www.leo-pharma.co.uk) in breach of Clause 13.1.

RESPONSE

Leo submitted that it was correct that the home page of its website did not have information as to where details of its clinical trials could be found. However, the company noted that the supplementary information to Clause 28.5 of the Code also stated:

> '**Information on clinical trials** as agreed in the current Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases and the current Joint Position on the Publication of Clinical Trial Results in the Scientific Literature may **be available at a UK or a non-UK website**.
>
> Attention is drawn to Clause 13.1 and its supplementary information.'
>
> (emphasis added by Leo)

Leo submitted that whilst it was correct that the information was not on the leo-pharma.co.uk website, information as to where the details of Leo's clinical trial registration could be found, in line with the requirements of the supplementary information to Clauses 13.1 and 28.5, was provided on the company's global website (www.leo-pharma.com).

Leo stated that in light of the ambiguity that existed in the Code in relation to the direction provided in the supplementary information to Clauses 13.1 and 28.5, it considered that it had fulfilled the requirements of the Code and refuted the alleged breach of Clause 13.1.

PANEL RULING

The Panel noted that the supplementary information to Clause 13.1, Details of Clinical Trials, stated that companies must include on the home page of their website information *as to where* details of their clinical trial results could be found. The supplementary information to Clause 28.5, Information on Clinical Trials, stated that information on clinical trials as agreed in the current Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases and the current Joint Position on the Publication of Clinical Trial Results in the Scientific Literature *might be available* on a UK or on a non-UK site. The Panel did not agree with Leo's submission that ambiguity existed between Clauses 13.1 and 28.5; the clinical trial information could be included on a UK or non-UK site, whereas details as to where such information could be found was required to be included on the home page of a company's website. The Panel noted that although information as to where the details of Leo's clinical trials could be found was provided on the company's global website (www.leo-pharma.com) there was, as acknowledged by the company, no such information on the home page of the UK website (www.leo-pharma.co.uk). A breach of Clause 13.1 was ruled. High standards had not been maintained and a breach of Clause 9.1 was ruled.

The Panel noted its rulings above but did not consider that the matter warranted a ruling of a breach of Clause 2 which was a sign of particular censure and reserved for such use. No breach of Clause 2 was ruled.

2 Patient organisation disclosures

COMPLAINT

The complainant noted that the list of patient organisations with which Leo had engaged had been published on the website; the list was dated September 2019 and the document entitled

'List of Patient Organisations to which Leo Pharma UK/IE had provided financial support 2018/2019'. The document provided varied levels of information per transfer of value. With respect to the dates of transfer, one provision of support appeared to be from 2017 so it was not clear if the title of the document accurately reflected the information in the document.

The document contained insufficiently complete information to enable the average reader to form an understanding of the significance of the support as per Clause 27.7. For example, 'Patient Information Forum Corporate Membership 2018 Monetary Amount: £12,000' or 'Patients Association Annual Corporate Sponsorship Monetary Value: £5,000' or 'Thrombosis UK Stand at Manchester Healthcare Professional 'Management of VTE' Conference, 3 May 2018 Monetary Value £500'.

The complainant submitted that it was not clear to the public what the funding went towards or the significance of the support to the patient organisation - a term like 'corporate sponsorship' did not clarify the significance of the support to the patient organisation or Leo.

The complainant noted that Clause 27.7 stated that the list of organisations being given support must be disclosed annually and disclosure must be made within the first six months after the end of the calendar year in which the transfers of value were made. The complainant further noted that no transfers had been published for 2019, and the 6 month timeframe for disclosure had passed in 2020 for disclosure of 2019 data and in that regard he/she asked if Leo could confirm that it had not engaged with any patient organisations in 2019 - otherwise it would appear that it was in breach of Clause 27.7.

The complainant alleged that it was unclear if the 2017 and 2018 data related to patient organisation funding from Leo was made public at least once a year as per Clause 27.7 of the 2016 Code given 2017 data appeared in a document dated September 2019. The complainant asked if Leo could demonstrate the dates on which funding for 2016, 2017 and 2018 payments to patient organisations were made public.

RESPONSE

Leo noted that the complainant had queried the list of patient organisation disclosures available on its website which was dated September 2019 and entitled 'List of Patient Organisations to which Leo UK/IE had provided financial support 2018/2019'. Leo stated that with regards to timelines for 2018 disclosures, that occurred at the transition between the 2016 and 2019 Codes, but with the 2019 Code applicable for the large part. The 2016 Code required simply an annual updated list of organisations supported. For the 2019 Code, the requirement became much more specific, with the requirement for a disclosure in respect of each calendar year, and within the first six months after the end of the calendar year in which the transfers of value were made.

Leo submitted that the list of patient organisation disclosures dated September 2019 was first approved in June 2019 in order to disclose 2018 transfers of value to patient organisations. That was in line with the 2019 Code and fulfilled the requirement to make the disclosure in the first six months after the end of the calendar year in which the transfers of value were made. All the disclosures were for the year 2018 – that was, where a transfer of value to a patient organisation was made in 2018.

There were no 2019 transfers of value on the list. Though the individuals involved in the creation and approval of the list at the time were no longer with the organisation, Leo could only surmise that the title of the list referred to 2018/2019 because although the payment in all instances was made in 2018, some of the payments were for activities occurring in 2018, in 2019, or in 2018 and 2019. Therefore, the title of the document reflected when the payment was made and when the related activity occurred.

Leo noted that the list on the website when this complaint was made was dated September 2019 – the June version was corrected and reapproved in September following a request from Thrombosis UK for a correction to one of the transfer of values. That correction was duly made, and the list reapproved and uploaded. No additional payments were included on the list.

Leo submitted, therefore, that when the complaint was submitted no disclosure had yet been made on its website with regards to 2019 transfers of value to UK patient organisations. An internal investigation had discovered that there appeared to be four UK patient organisations to which a transfer of value had taken place in 2019: Anticoagulation UK, the National Eczema Society, the Patients Association and the Psoriasis Association. Leo submitted that as the transfers of value to these four patient organisations took place in 2019, it appeared that the six-month timeframe for disclosure of them in 2020 had passed. Leo therefore, with regret, admitted that a disclosure of transfers of value for patient organisations had not yet been made for 2019, in breach of Clause 27.7. Leo submitted that the situation had been rectified as a matter of urgency, and the 2019 patient organisation disclosures were now live on its website. Leo did not consider the breach of Clause 27.7 warranted a ruling of a breach of Clause 9.1 or of Clause 2, a ruling reserved as a sign of particular censure.

Leo stated that it would investigate why its procedures, which appeared to work adequately in 2019, clearly appeared to have failed in 2020. Leo considered that it was due to a restructure and shift in responsibilities for the activity from one individual to another. It was possible that some confusion arose with regards to the Covid-19 related delay to the disclosure process for health professionals and healthcare organisations in 2020. Leo stated that it would look into the matter and its processes as a matter of priority.

Leo noted that the complainant also asserted that:

> '…document contained insufficiently complete information to enable the average reader to form an understanding of the significance of the support as per Clause 27.7.'

The complainant also went on to express confusion over terms such as 'corporate sponsorship'. Leo disagreed with that entirely subjective opinion. The term 'sponsorship' was itself, not defined in the Code. Sponsorship of organisations was however, generally well understood, and indeed, the word itself was used within Clause 27. The declaration of sponsorship by Leo in the documentation was sufficiently prominent and clearly presented to ensure readers were aware of the company's involvement from the outset. In addition, inclusion of 'Support for Raising Awareness of CAT [cancer associated thrombosis]' and for example 'Donation to match the amount raised in a private capacity by a Leo employee' provided sufficient context for readers to understand the nature for the provision of the support to the patient organisation. Where a payment was not a corporate sponsorship or, was a corporate sponsorship associated with a particular project, that had been made clear. Leo therefore denied a breach of Clause 27.7.

Leo noted that the complainant had also queried the dates on which declarations pertaining to payments to patient organisations for the years 2016 and 2017 were made public. As per Clause 27.7 of the Code, the requirement was for an annual disclosure. There was no guidance on how many years' retrospective declarations should be kept public, unlike in Clause 24.5 about disclosures with health professionals and healthcare organisations.

Therefore, given the hypothetical or 'what if' scenario described by the complainant, Leo declined to engage with that aspect of the complaint. The payment to the Irish Skin Foundation labelled as 2017 in the list discussed above, was intended for 2017, but was actually made in 2018 due to an internal delay in making the payment, which was why it appeared in the 2018 list. In any case, that 2017 payment was to an Irish patient organisation, so would not fall within scope of the Code.

Following a request for further information, Leo provided a revised version of the document entitled. 'UK/IE Patient Organisations to which LEO Pharma has provided support in 2018/2019', which included transfers of value for 2018 and 2019, including the month each payment was made (ref UK/IE MAT- 42294, June 2021).

PANEL RULING

The Panel considered that the 2016 Code was applicable to the complainant's allegation that it was unclear if payments to patient organisations in 2016, 2017 and 2018 were made public at least once a year.

The Panel noted that Clause 27.7 of the 2016 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 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 form an understanding of the significance of the support. The list of organisations being given support must be updated at least once a year.

The Panel noted Leo's submission that all of the transfers of value listed on the document entitled 'List of Patient Organisations to which Leo UK/IE had provided financial support 2018/2019' and dated September 2019 were made in 2018 including the transfer of value in respect of sponsorship in 2017 of the Irish Skin Foundation Nurse Helpline.

The Panel noted that the 2016 Code did not stipulate how long transfers of value to patient organisations had to remain in the public domain. The Panel considered that the complainant had not discharged his/her burden of proof that a breach of Clause 27.7 had occurred in relation to disclosure of payments made to patient organisations in 2016 and 2017 and therefore the Panel ruled no breach of Clause 27.7 in relation to each of these years.

In relation to payments made to patient organisations in 2018, the Panel noted Leo's submission that the list of disclosures dated September 2019 was first approved in June 2019 and then re-approved in September 2019 following a correction to one of the values. The Panel noted Leo's submission that it had fulfilled the requirement to make the disclosure in the first six months after the end of the calendar year in which the transfers of value were made, which was a requirement of the 2019 Code. However, as noted above, the Panel considered that the 2016 Code was the relevant Code for disclosure of payments made to patient organisations in 2018.

The Panel acknowledged that it was not entirely clear in the 2016 Code whether as a minimum companies could update their lists on a certain date once a year covering the previous twelve months of payments in which case no payment would ever be disclosed more than twelve months after it was made or whether the annual update could be by no later than a fixed date each year in relation to payments made at any time in the previous calendar year. The position had been clearer in the relevant supplementary information in the 2012 Code second edition which required a list of patient organisations including the monetary value of support regardless of its level to be made publicly available by the end of the first quarter of each year in relation to payments made in the previous calendar year and in the 2019 Code which required that disclosure must be in the first six months after the end of the calendar year in which the transfers of value were made. The Panel noted that, under the 2016 Code, as a minimum, the published list of patient organisations had to be updated annually. The Panel considered that it would have been helpful if the approach adopted by a company had been made clear on its website.

The Panel noted that the list of patient organisations to which Leo had provided support, which was approved in June 2019, included some payments that were made in January and May 2018. The Panel had no information before it as to what, if anything, was disclosed prior to June 2019. Leo made no submission in that regard. The Panel noted the lack of a definitive timeframe in Clause 27.7 in the 2016 Code as described above and considered that on the evidence before it, the complainant had not discharged his/her burden of proof that the disclosure in June 2019 of payments made to patient organisations in 2018 did not comply with the 2016 Code and no breach of Clause 27.7 was ruled.

In relation to the description of the support given to patient organisations for payments made in 2018, the Panel noted that the list described by the complainant (dated September 2019) stated, in alphabetical order, the name of the patient organisation, a brief description of the project or initiative for which the support had been given and its monetary value. The Panel noted that the complainant considered that it was not clear what the funding went towards but it considered that it was possible that some of the payments were for core funding of the projects/initiative in question as opposed to specific related activities. The Panel noted Leo's submission that where a payment was not a corporate sponsorship or was a corporate sponsorship associated with a particular project, that had been made clear. 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 the significance of the support. The Panel noted that the supplementary information to Clause 27.7 stated that an indication of a patient organisation's total income and/or the company's support as a percentage of the patient organisation's total income might be given although neither was obligatory. No breach of Clause 27.7 of the 2016 Code was ruled.

In relation to the payments to patient organisations made in 2019, the Panel noted that Clause 27.7 of the 2019 Code (which came into force on 1 January 2019) 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. The Panel noted Leo's submission that transfers of value had been made to four patient organisations in 2019 but that when this complaint was submitted (November 2020) no disclosure of such had been made. The Panel therefore ruled a breach of Clause 27.7 of the 2019 Code as acknowledged by Leo. High standards had not been maintained; a breach of Clause 9.1 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 when it received this complaint in November 2020. The Panel noted that those transfers of value were subsequently disclosed in December 2020, more than 5 months later than the date required by the Code. 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, on balance, that Leo had reduced confidence in the industry for its failure to publicly disclose any of its 2019 transfers of value to patient organisations in the time period required by the 2019 Code and it ruled a breach of Clause 2.

APPEAL FROM LEO

Leo appealed the Panel's ruling of a breach of Clause 2.

Leo noted that the complaint received in November 2020, as had been the case for the majority of the last 11 complaints, was lengthy and wide ranging, covering a range of allegations, all pertaining to the Leo Pharma UK/IE corporate website. The majority of the allegations were ruled not in breach of the Code.

Leo submitted on receipt of this complaint however, and upon further investigation, it became apparent that disclosure of transfers of value to patient organisations had not yet been made for the year 2019. Leo submitted that it acknowledged this in its response, and so admitted to a regrettable breach of Clause 27.7. 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 HCPs and HCOs. Leo accepted the ruling of the Panel with regards to a breach of Clause 9.1, as it was entirely fair to say that high standards had not been maintained for the company's 2019 patient organisation disclosures.

Leo submitted that it was also well aware that there had been subsequent issues identified with the 2019 patient organisation disclosures, as per Case AUTH/3498/3/21 and its voluntary admission of Case AUTH/3527/6/21. Case AUTH/3498/3/21 was the subject of an appeal, which would be handled separately, and Case AUTH/3527/6/21 was yet to be ruled upon. To avoid confusion, Leo would refrain from bringing these two cases into the discussion below.

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 was described as:

> '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 *sh*ort 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 exhaustive. However, in terms of the specifics of this case, the subject of disclosures was not on this list. The failure of Leo Pharma UK 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 of transfers of value. As stated earlier, there were potential reasons why this occurred, and Leo had taken steps to ensure that robust procedures and oversight were in place for disclosures of transfers of value for patient organisations from 2020 and moving forward. These steps included capture of patient organisation activities (both local and global) in an online approval system, as well as the appointment of a senior compliance executive.

Leo submitted that it should also be taken into consideration that prior to the 2019 Code, the requirement in Clause 27.7 was for companies to make publicly available, a list of patient organisations to which support had been provided, and for this list to be updated at least once a year. In the ruling, the Panel noted that Clause 27.7 of the 2019 Code (which came into force on 1 January 2019) 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. The Panel noted that those transfers of value were subsequently disclosed in December 2020, more than 5 months later than the date required by the Code. Therefore, the failure to disclose the 2019 patient organisation transfers of value at this later time period would not have been in breach of Clause 27.7 of the 2016 Code, however, was in breach of the 2019 Code. Therefore, Leo challenged whether a breach of this refinement to Clause 27.7 in the 2019 Code, was enough to genuinely ‘bring discredit upon, or reduce confidence in, the pharmaceutical industry’?

Leo stated that it would not be appealing this ruling if its investigations had found that Leo Pharma 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 a breach of Clause 27.7 pertaining to one calendar year, a breach of Clause 2 was disproportionate and this Panel ruling had somewhat lost sight of what was meant by a breach of a Clause 2.

Leo submitted 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. Leo submitted it strongly believed that a breach of Clause 2 should be reserved for the most serious instances of misconduct by pharmaceutical companies. Inappropriate and overuse of a breach of Clause 2, as had happened here, and increasingly in other instances, not only served to diminish the perceived severity of Clause 2, but in itself leads to a reduced confidence in and discredit to the industry.

In summary, whilst Leo Pharma UK had regrettably breached Clause 27.7, and had failed to maintain high standards so breaching Clause 9.1, it submitted that the disclosure of transfers of value to patient organisations 5 months later than required to do so by the 2019 Code, did not, in any meaningful way, 'bring discredit upon, or reduce confidence in, the pharmaceutical industry'.

COMMENTS FROM COMPLAINANT

There was no response from the complainant on the appeal.

APPEAL BOARD RULING

The Appeal Board noted that Leo only became aware that it had not disclosed any of its 2019 payments to patient organisations when it received this complaint in November 2020. The Appeal Board noted that those transfers of value were subsequently disclosed in December 2020, more than 5 months later than the date required by the Code. 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 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 5 months late in disclosing its 2019 transfers of value to patient organisations, but it noted that Leo's failures in this regard appeared to be confined to a single year and that the reporting period might have been impacted by the Covid-19 pandemic. There had been no change for the reporting period for patient organisation disclosures. There had been a delay in the disclosure process for health professionals and healthcare organisations due to a decision to avoid contacting them about disclosure at a very busy time. The Appeal Board considered, on balance, that the Panel's ruling of a breach of Clause 9.1 was sufficient in relation to the 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.

3 Links on LEO UK website

COMPLAINT

The complainant noted the following occasions upon which a reader was redirected from the Leo UK website without notice:

(i) In the 'Our Focus', Skin Conditions, Psoriasis section, it was not made clear when users were leaving the company's site and being directed to another site as per Clause 28.6, when clicking on the word 'QualityCare' within the 'Emotional' section. Viewers were brought to another website without any wording to indicate that they were being redirected.

(ii) Within the same section called 'Emotional', it was not made clear when users were leaving the company's site and being directing to another site as per Clause 28.6, when clicking on the word 'MINDBOOST'. Viewers were brought to another website without any wording to indicate that they were being redirected.

(iii) Within the 'Our focus', Thrombotic Conditions section, under 'Tackling Thrombotic Conditions', a link from the word 'CancerClot' took viewers to another website without making that clear as per Clause 28.6. The website which viewers were taken to was a website on psoriasis from Leo.

(iv) Within the 'Supporting Patients' section under 'Qualitycare', the link to Qualitycare in the first paragraph took viewers to another website without making that clear as per Clause 28.6.

(v) Within the 'Supporting Patients' section, under 'Helping Sarah', the link to Qualitycare in the last paragraph took viewers to another website without making that clear as per Clause 28.6.

RESPONSE

Leo noted that Clause 28.6 stated:

> 'It should be made clear when a user is leaving any of the company's sites, or sites sponsored by the company, or is being directed to a site which is not that of the company.'

and the supplementary information to 28.6 stated:

> 'Sites linked via company sites are not necessarily covered by the Code.'

Leo provided several relevant highlighted screenshots of its website to illustrate the complainant's concerns.

Leo noted the allegations in points i and ii above and stated that with regard to the links from QualityCare and MINDBOOST, in all instances described by the complainant, the link directed viewers to another, clearly labelled, Leo UK website. Users were not leaving any of the company's sites, or sites sponsored by the company. Leo submitted that the screenshots provided showed that there was extensive text, outlining the nature of the resource to which viewers were being directed. The text stated:

> 'We [Leo] understand that the emotional and day-to-day impact of living with psoriasis can be as damaging as the physiological effect, which was why we provide QualityCare providing free resources and confidential advice which encourage people with psoriasis to rethink how they can best manage and treat their condition.'

Leo submitted that the text around the link to QualityCare, which was a patient disease website, clearly outlined a bespoke resource for patients affected by psoriasis. In the part of the sentence '…we provide QualityCare…', it was obvious that 'we' referred to Leo. It was clear that QualityCare was a bespoke Leo resource, which could be accessed via the link. Therefore, Leo considered that it was implicit that viewers would be moving from one Leo website, to another. Clicking the link took viewers to the QualityCare website (screenshot provided) which was clearly labelled as a Leo UK website from the outset, both in the header ('Created by Leo Pharma in the UK and Ireland') and footer (company name and UK and Ireland addresses). Leo stated that although the URL for QualityCare was different from the Leo UK website, it was still a Leo website.

With regard to the MINDBOOST link, Leo noted that the text around that stated:

> 'Within QualityCare is MINDBOOST, a customisable stress-reduction programme of physical and mental exercises for psoriasis sufferers, with the exercises grouped into three areas: confidence, mood and focus. MINDBOOST was developed in collaboration with Marie-Amélie de Potter, an anti-stress consultant with over 20 years of experience in stress management initiatives.'

Leo submitted that again, this was clearly described as a resource existing within QualityCare, implying that this was a bespoke, Leo resource, distinct from the corporate website. Leo noted, however, that MINDBOOST was removed from the QualityCare website in June 2020; the Leo website would be updated to reflect that, shortly.

Leo noted that the complainant was concerned about the link from CancerClot (point iii above) (screenshot provided). Leo submitted that due to a technical error, that link wrongly linked to the Leo QualityCare psoriasis website, but now correctly linked to www.cancerclot.com, again, a clearly labelled Leo website. The accompanying text around the link stated:

> 'Leo is proud of our disease awareness and support programmes that help people to have the confidence to take control of their conditions. CancerClot offers support to people living with cancer associated thrombosis (CAT)'.

Again, Leo contended that the text clearly outlined a distinct Leo resource for patients affected by cancer associated thrombosis; it was clear that it was a bespoke Leo resource (from the words 'our disease awareness and support programmes') from the corporate website, which could be accessed via the link. Leo considered that it was implicit that viewers were moving from one Leo website to another, but not leaving Leo sites. Leo provided a screenshot of the CancerClot website and noted that it was clearly labelled as a Leo website from the outset, both in the header ('Created by Leo Pharma, for audiences in the UK and Ireland) and footer (company name and UK and Ireland addresses). Although the URL for CancerClot.com was different from the corporate Leo UK website, it was still a Leo website.

Leo noted that the complainant had the same assertions regarding the link to QualityCare, which appeared elsewhere on the Leo UK website. Leo provided a highlighted screenshot to illustrate point iv of the complaint and noted that QualityCare was clearly described as a patient support resource, that was a distinct Leo resource.

Leo provided a screenshot of a webpage specifically dedicated to a description of the QualityCare site. In the text, QualityCare was described as a 'free service to support people living with psoriasis' as well as being described as 'Leo Pharma's platform to support people living with psoriasis' and a 'holistic resource'. Leo stated that, as with the other scenarios described above, it considered that it was implicit that the link was to that of further Leo content.

Finally, on the section about 'Helping Sarah' (point v above), Leo noted that the text in the screenshot provided described QualityCare as a 'free and confidential…support program'. Again, it was implicit that the link would go to a Leo website.

Leo noted that where a link on its website went to an external website, a pop-up appeared to alert viewers that they were about to leave a Leo website and go to a third-party website, which

was outside of the control of Leo (screenshot provided). Leo contended that the pop-up was both in keeping with the letter of Clause 28.6 of the Code, but as importantly, the spirit of it.

Leo noted that in Case AUTH/3166/2/19, where, with regards to Clause 28.6 and a tweet sent by Sanofi UK, 'The Panel noted that the tweet linked to @IMMDSReview. It considered that it would be clear to readers that this was the IMMDS Review Twitter handle and not a Sanofi site. The Panel therefore ruled no breach of the requirement to be clear when leaving a company site'. Leo considered that a similar principle applied here. On no occasion described, did viewers leave a Leo website, nor were they directed to a third-party website without a pop-up appearing. Leo contended that in all the instances described above, the links, all of which went to clearly labelled, Leo UK owned patient disease awareness and support websites, the accompanying text on the Leo UK website was sufficient to make it obvious to viewers that they were visiting another Leo-owned, dedicated resource.

Leo submitted that viewers had a reasonable role to play in reading the text, before clicking on an accompanying link, and, as such, there was no additional requirement in this particular circumstance under the Code to notify them of this. Therefore, Leo refuted a breach of Clause 28.6 in the instances cited.

PANEL RULING

The Panel noted that Clause 28.6 stated that it should be made clear when a user was leaving any of the company's sites, or sites sponsored by the company, or was being directed to a site which was not that of the company. The Panel noted that in each of the scenarios described above by the complainant (points i to v) the user was being directed from one Leo website to another (that was so even in point iii above where a Leo CancerClot link erroneously linked to a Leo psoriasis website). The Panel considered that it was sufficiently clear, from the screenshots provided by Leo, that the user was being directed to another Leo website which was stated on the website to which the user was being directed. The Panel therefore ruled no breach of Clause 28.6 in relation to each of points i to v.

The Panel noted Leo's submission that if a link on the Leo UK website went to an external website, a pop-up appeared which informed viewers that they were about to leave a Leo website and go to a third-party website outside of the control of Leo. The Panel noted its comments and rulings above and considered that the complainant had not shown that Leo had failed to maintain high standards in relation to links on its UK website as alleged and no breach of Clause 9.1 was ruled. Consequently, no breach of Clause 2 was ruled in that regard.

4 Certification/Recertification

COMPLAINT

The complainant noted that the 'News' section of the Leo website contained some very old articles. Some of those articles fell under Clause 14.3, educational material for the public or patients relating to disease and so should be certified before use and should be certified at no less [sic] than 2 year intervals as per Clause 14.5.

The complainant submitted that the information in the following items appeared to be quite old and he/she asked if Leo could provide evidence that the content within those items were currently certified for use as they were live on its website.

The items were:

(i) 'Don't 'putt' yourself at risk of sun damage, play it safe and protect your skin' was found within the news section for 2013 and contained the article 'Leo Pharma UK launched golfing sun safe campaign' - date 17 June 2013. The complainant alleged that the information which had been provided to the public did not contain the mandatory wording as per Clause 26.3.

(ii) 'WHO Resolution: Psoriasis now on the Global Health Agenda' was found within the news section for 2014 and contained what would initially appear as an article called 'Psoriasis now on the global health agenda'. However, the line under that title stated 'For UK MEDIA ONLY'. The complainant submitted that if that information was only intended for the media, it should not be on a publicly accessible site under 'News'. It was not clear what type of media the item was intended for - consumer or medical. The complainant asked whether Leo had reviewed the item in the context of information to the media or educational information about a disease to the public. The complainant alleged that the information which had been provided to the public did not contain the mandatory wording as per Clause 26.3.

(iii) 'PSO what? Report highlights true personal and public cost of psoriasis' was found within the News 2017 section and contained a link to a press release called 'New report highlights true personal and public cost of psoriasis and spotlights variation in GPs' time, capacity and skills to help'. The complainant asked if that was a press release, had it been certified in the context of being on a corporate website and becoming educational information on a disease and requiring certification as such. The complainant again alleged that the information which had been provided to the public did not contain the mandatory wording as per Clause 26.3.

RESPONSE

Leo noted that the complaint had referred to the following three news items, which were press releases:

2013 – Don't 'putt' yourself at risk of sun damage
2014 – WHO Resolution: Psoriasis now on the Global Health Agenda
2017 – PSO what? Report highlights true personal and public cost of psoriasis

Leo stated that none of the press releases cited above, indeed, none of the press releases in the 'News' section of the website, discussed any medicines on any occasion. The press releases in the 'News' section either related to disease area and public health, or staff recruitment announcements.

Leo noted that Clause 14.3 listed certain non-promotional material which must be certified in advance in a manner similar to that provided for by Clause 14.1, namely:

- educational material for the public or patients
- material relating to working with patient organisations as described in Clause 27 and its supplementary information
- material relating to joint working between the NHS and the pharmaceutical industry as described in Clause 20 and its supplementary information

- material relating to patient support programmes involving the provision to health professionals of items to be passed on to patients as described in Clause 18.2 and its supplementary information
- non-promotional material for patients or health professionals relating to the provision of medical and educational goods and services, including relevant internal company instructions, as described in Clause 19.1 and paragraph 8 of its supplementary information.

Supplementary information to Clause 14.3 'Examination of Other Material' stated:

> 'Other material issued by companies which relates to medicines but which is not intended as promotional material for those medicines *per se*, such as corporate advertising, press releases, market research material, financial information to inform shareholders, the Stock Exchange and the like, and written responses from medical information departments or similar to unsolicited enquiries from the public etc, should be examined to ensure that it does not contravene the Code or the relevant statutory requirements.'

Leo submitted that the three press releases in question thus did not fall into the categories of non-promotional material requiring certification described in Clause 14.3, but rather, required examination as per the supplementary information to 14.3 and the requirements for recertification at intervals of no longer than two years, did not apply in that instance. Leo denied a breach of Clause 14.

Leo stated that for complete transparency, all three press releases were formally certified, rather than examined, as part of a 'belt and braces' approach to approval. However, that did not change the fundamental nature of the items in question, in that they were press releases, without a requirement to certify. Therefore, if there was no requirement to certify the press releases initially there must also be no requirement for (re)certification at the 2-year timepoint regardless of whether the original approval of the material took place through examination or certification.

Leo noted that the complaint had also alleged that the presence of the press releases on a corporate website meant that they had become educational information on a disease, requiring certification. Leo submitted that the press releases were clearly housed in a section named 'News' . The text in the 'News' home page clearly referred to media enquiries and provided the contact details for the Leo communications team. Therefore, there could be no doubt that the 'News' section, and the press releases housed within, were intended for the media. Indeed, the Leo website had separate sections for patients and health professionals, under 'Supporting You'. Therefore, again, there could be no doubt that the 'News' section was aimed specifically at the media, not at patients. Leo stated that its position was also backed up by Case AUTH/3011/1/18 where, with regards a press release on a company's website, specific reference was made by that company to the supplementary information in Clause 14.3; the company submitted that the press release on its website did not fall within the materials for which certification was required by Clause 14, and therefore no certificate was produced. No comment was made by the Panel on the clauses relevant to that part of the submission.

Leo noted that the complaint had also alleged breaches of Clause 26.3. That was irrelevant as Clause 26.3 concerned requirements for wording on reporting of side effects on patient

materials relating to a specific medicine. None of the three press releases in question discussed any medicine. Therefore, Leo denied a breach of Clause 26.3.

PANEL RULING

The Panel noted that Clause 14.3 stated, *inter alia*, that the following must be certified in advance in a manner similar to that provided for by Clause 14.1: educational material for the public or patients issued by companies which related to diseases or medicines but was not intended as promotion for those medicines. The supplementary information to that clause stated, *inter alia*, that other material issued by companies which related to medicines, but which was not intended as promotional material for those medicines *per se*, such as press releases, should be examined to ensure that it did not contravene the Code or the relevant statutory requirements.

The Panel noted Leo's submission that the three press releases in question were housed in a section of the corporate website named 'News' in the 'About Us' tab; the text in the 'News' landing page referred to media enquiries and provided the contact details for the Leo communications team.

In the Panel's view, it was not necessarily unacceptable to have press releases within a clearly labelled section of a corporate website which made the intended audience (media) clear. The Panel queried if it was sufficiently clear that the 'News' section was only intended for the media, prior to accessing it. However, the Panel noted Leo's submission that the website in question had separate sections for patients and health professions under the 'Supporting You' tab.

The Panel noted its comments above including the layout of the corporate website; in the Panel's view, from the evidence before it, the press releases appeared to be within a section of the website which was intended for the media. The Panel did not consider that in such circumstances the material was educational material for the public or patients issued by companies which related to diseases or medicines or any other type of material that required certification under Clause 14.3. Nonetheless, the Panel noted Leo's submission that all three press releases were certified, rather than examined, as part of a 'belt and braces' approach to approval. No breach of Clause 14.3 was ruled in relation to each of the three press releases.

The Panel considered that it would be good practice for companies to review all information on their corporate websites regularly, including that which did not require certification under the Code, to assess if it was still appropriate for the intended audience. The Panel noted that the press releases were ordered by date and grouped by the year in which they were released, which was clearly labelled within the 'News' section of the website. The Panel noted its comments above and considered that as there was no requirement to certify the three press releases in question, regardless of whether they were certified or examined originally, there was no requirement to re-certify them and therefore no breach of Clause 14.5 was ruled in relation to each.

In the Panel's view the press releases were not intended for patients taking a Leo medicine and therefore the side effect reporting statement as required by Clause 26.3 was not required. The Panel ruled no breach of Clause 26.3 in relation to each of the three press releases.

The Panel noted its comments above and considered that the complainant had not provided any evidence to suggest that Leo had failed to maintain high standards with regard to the availability

of the three press releases in question within the 'News' section of its corporate website and no breach of Clause 9.1 was ruled; subsequently no breach of Clause 2 was ruled.

5 Information published on Disclosure UK

COMPLAINT

The complainant stated that he/she could not locate where Leo had disclosed the number of health professionals which shared in the aggregated payments as per Clause 24.9 to see what the average type of payment was. The complainant asked if Leo could confirm that information had been published and if so, where.

With regard to disclosure of funding to healthcare organisations, it was impossible in many cases to see who the real beneficiary of the funding provided by Leo was, as Leo had disclosed against many non-healthcare organisations and middle parties. This did not make for a transparent picture of the relationship between the pharmaceutical industry and healthcare organisations.

The complainant noted that Clause 1.9 defined the term 'healthcare organisation' as either 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.

Clause 24.1 required companies to document and publicly disclose certain transfers of value made directly or indirectly to health professionals and healthcare organisations located in Europe.

The complainant alleged that for each of the below monies disclosed by Leo which could be found under the 'Healthcare Organisation' tab on Disclosure UK for 2017 and/or 2018, Leo had failed to meet the requirements of Clause 24.1 as the recipient of the funding was not a healthcare organisation or a health professional but a healthcare organisation or health professional might have been the beneficiary given the amount of 'event sponsorships' the company had disclosed.

The complainant provided details of thirty three organisations, including information from Companies House, websites and Facebook, and over 200 payments listed on Disclosure UK. The complainant alleged that each organisation identified was not a healthcare organisation as defined by Clause 1.9 and queried which health professional/healthcare organisation had benefited from each payment.

The organisations named and numbers of payments are summarised for the case report as follows. The complainant also provided details of the amounts disclosed.

Organisation **Classification highlighted by complainant (where given)**	**Number of payments**	
	2017	**2018**
Dovetail Healthcare Events Limited Other business support service activities not elsewhere classified	12	3
Haymarket Media Group Publishing of consumer and business journals and periodicals	1	1
Kayonesse Consulting	3	4
Mediconf UK Ltd Activities of Conference Organisers	17	36
Morph Consultancy Ltd Management of consultancy activities other than financial management	0	2
Meetings Management Other business support service activities not elsewhere classified	9	1
Pharmaclub 89	0	1
South West Health Events Educational support services	1	0
African Caribbean Health Information Conferences	1	0
Which When Why Ltd Other Education not elsewhere classified	2	6
WP Event Management Facilitating and managing medical educational meetings and events as well as working with Healthcare teams within Primary, Secondary and Community Care	1	5
Rodeley Consulting and Training Management consultancy activities other than financial management	1	4
Essentially Medical Independent company that specialises in organising meetings between primary health professionals and disease area specialists	6	4
GP Forum Ltd Other education not elsewhere classified	22	20

GP Simulation Ltd Other education not elsewhere classified	1	1
Keynote Conference Ltd Activities or conference organisers	5	6
Medical Update Ltd Other education not elsewhere classified	0	3
Cogora Ltd Advertising agencies	1	1
Essex Equip Ltd Other business support service activities not elsewhere classified/Other education not elsewhere classified	3	4
Effective Consulting Risk and damage evaluation	1	2
Co & Associates Ltd Other business support service activities not elsewhere classified	0	2
Aliqua Events Ltd Activities of conference organisers	3	1
ABCD Dermatopathology Course Limited Other business support service activities not elsewhere classified	0	1
All-Party Group on Skin	0	1
GP Meetings	0	1
Health Learning Partnership Other education not elsewhere classified	0	5
SM Meetings	0	1
Vidya Health Ltd Other business support service activities not elsewhere classified	0	2
Xpert Learning Ltd Management consultancy activities other than financial management	0	5
Barnet Pharmacists Study Group	1	0
Shropshire and Powys Skin Club	3	2

St Austell Printing Company Printing not elsewhere classified	1	0
The Dowling Club The foremost educational and social club for UK dermatologists [The complainant queried why the funds were not given to the British Association of Dermatologists (BAD) rather than the Dowling Club which was within the auspices of BAD]	1	0

The complainant asked if Leo could explain why the beneficiaries of the funding had not been disclosed to the public for the examples he/she had provided.

The complainant stated that he/she could see from Disclosure UK that Leo provided funding of £19,923 towards joint working in 2018 to University of Sheffield. He/she could not locate where the company had published an executive summary of the joint working agreement (if the project was still ongoing that should be available for the duration of the project at a minimum) or if the project had been completed, a short summary of the outcomes and lessons learned. Could Leo demonstrate it had complied with Clause 20 with respect to its transparency and publication requirements required for joint working?

RESPONSE

Leo noted the complainant's comment that he/she had been unable to locate where it had disclosed the number of health professionals within the aggregated payments as per Clause 24.9 to see what the average type of payment was. Leo stated that that data was published and accessible. Leo suggested that if the complainant had trouble locating it, he/she could contact the ABPI for assistance in navigating the Disclosures UK website.

Leo noted that the complainant had listed payments to thirty three organisations, alleging that they were not bona fide healthcare organisations but had not provided any evidence as to why not. The complainant had made serious, unsubstantiated allegation against the companies in question, based purely on their status on the Companies House website. Leo submitted that the status of a healthcare organisation was, however, not determined by its description or status on the Companies House website. Clause 1.9 of the Code described a healthcare organisation as:

> *'…*either 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 is in Europe or an organisation through which one or more health professionals or other relevant decision makers provide services.' (emphasis added by Leo)

Leo stated that it had underlined the latter part of the definition, to outline the rationale for categorising the organisations listed above as healthcare organisations. The organisations cited by the complainant had in most cases, received a transfer of value for the purposes of a stand meeting, sponsorship of an educational meeting or a grant. Taking the example of meetings, by means of being organisations through which health professionals or other decision makers delivered educational meetings and content, this qualified them as healthcare

organisations, even if the remit of some of the companies was broader than being only a healthcare organisation.

Leo submitted that the principles of disclosure relied on pharmaceutical companies acting in good faith and making sure that they had fully disclosed. In some cases, this might mean categorising an organisation as a healthcare organisation, which might not be its primary role on a day-to-day basis, but had nevertheless on a specified occasion, carried out the duties of a healthcare organisation by undertaking an activity which would enhance patient care or benefit the NHS whilst maintaining patient care. That satisfied the requirement of a healthcare organisation as defined by the Code. It would be a breach of the Code to under disclose or fail to disclose. It was not a breach of the Code to inadvertently over disclose.

Again, Leo UK had acted in good faith in categorising the organisations cited as healthcare organisations and disclosing against them. In the absence of actual evidence that, on a balance of probabilities, a breach of the Code had occurred, Leo would not engage with the accusation any further, and refuted all accusations of a Code breach.

Leo noted the complainant's final reference to the company's funding of £19,923 towards joint working in 2018 to University of Sheffield, and the failure of Leo to publish an executive summary of that joint working. Leo submitted that the payment had been miscategorised as joint working. Leo UK had not conducted a joint working project in recent years. The payment was made to the University of Sheffield by the Leo Global organisation for a research and development activity, which was described in a payment and reimbursement form as a research and development collaboration. Leo stated that this was why the activity was erroneously categorised as joint working, a term which was specific to the UK. Leo stated that it would ask for this to be corrected on Disclosures UK. Leo therefore refuted a breach of Clause 20 of the Code.

Following a request for further information, Leo submitted that its standard procedure was that where payments related to indirect transfers of value to a health professional or a healthcare organisation, then this would be declared against the health professional or healthcare organisation in question. Leo had no evidence or reason to believe that the transfers of value called into question by the complainant would pertain to indirect transfers of value. Leo stated that if there was any substantiating evidence that suggested otherwise on any individual payment, it would investigate.

PANEL RULING

The Panel noted the complainant's allegation that he/she could not locate where Leo had disclosed the number of health professionals which shared in the aggregated payments as per Clause 24.9 of the Code. It was unclear to the Panel which disclosure year the allegation was in relation to and therefore which was the applicable Code. The Panel noted Leo's submission that the information as required by Clause 24.9 of the 2019 Code was published and accessible on the Disclosure UK website. The Panel therefore ruled no breach of Clause 24.9 of the 2019 Code.

The Panel noted that the 2016 Code was applicable to the allegation that a joint working executive summary had not been published in relation to a payment made in 2018. The Panel noted Leo's submission that it had not conducted a joint working project in recent years and that the payment was made to the University of Sheffield by Leo Global for a research and

development activity, which was erroneously categorised as joint working and that Leo would ask for it to be corrected on Disclosure UK. The Panel considered that as there was no evidence that it had been a joint working project, Clause 20 was not relevant and so no breach was ruled.

The Panel noted the complainant's allegation that in relation to disclosure of transfers of value made to healthcare organisations, it was impossible in many cases to see who the real beneficiary of the funding provided by Leo was, as Leo had disclosed against many non-healthcare organisations and middle parties. The Panel noted that the complainant provided information from Disclosure UK in relation to 33 named organisations and over 200 transfers of values made to those organisations in 2017 and/or 2018. The Panel noted that the 2016 Code was therefore applicable.

Clause 24.1 stated that companies must document and publicly disclose certain transfers of value made directly or indirectly to health professionals and healthcare organisations located in Europe.

The Panel noted that Clause 1.9 of the 2016 Code stated that the term 'healthcare organisation' meant either 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.

A health professional was defined in Clause 1.4 of the Code as including members of the medical, dental, pharmacy and nursing professions and any other persons who in the course of their professional activities might administer, prescribe, purchase, recommend or supply a medicine.

The Panel noted that Clause 1.10 of the 2016 Code stated that the term 'transfer of value' meant a direct or indirect transfer of value, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development or sale of medicines. A direct transfer of value was one made directly by a company for the benefit of a recipient. An indirect transfer of value was one made on behalf of a company for the benefit of a recipient or through an intermediate and where the company knew or could identify the recipient that would benefit from the transfer of value.

In the Panel's view, it was not necessarily a breach of the Code to disclose a payment made to organisations other than healthcare organisations on Disclosure UK as long as it did not breach any other codes, laws and regulations. However, the Panel considered that, for example, it would likely be a breach of the Code if an indirect transfer of value was disclosed against an intermediate or third party where the pharmaceutical company knew or could identify the healthcare organisation or health professional that had benefitted from the transfer of value; in such situations the transfer of value should be disclosed against the known final recipient.

The Panel noted Leo's submission that the organisations cited by the complainant had in most cases received a transfer of value for the purposes of a stand meeting, sponsorship of an educational meeting or a grant. The Panel further noted Leo's submission that its standard procedure was that where payments related to indirect transfers of value to a health professional or a healthcare organisation, then that would be declared against the health

professional or healthcare organisation in question and that it had no evidence or reason to believe that the transfers of value called into question by the complainant would pertain to indirect transfers of value.

The Authority was not an investigatory body and the Panel's rulings were made on the evidence provided by both parties; the complainant bore the burden of proving his/her complaint on the balance of probabilities. Whilst the Panel queried whether some of the named organisations in the list provided by the complainant were healthcare organisations as defined by the Code, it had no evidence before it that they were intermediaries such that they were not the final beneficiaries and that the payments disclosed had in fact gone to identifiable individual health professionals or healthcare organisations. The Panel considered that the complainant had provided no evidence to suggest that any of the more than 200 payments in question on Disclosure UK were anything other than direct payments to the organisations named. In that regard the Panel did not consider that the complainant had discharged his/her burden of proof that the transfers of value in question were indirect payments to health professionals or healthcare organisations known to Leo as alleged. The Panel therefore ruled no breach of Clause 24.1 of the 2016 Code in relation to transfers of value made in 2017 and 2018 for each of the 33 organisations named.

The Panel considered that the complainant had not shown that Leo had failed to maintain high standards with regard to information published on Disclosure UK and no breach of Clause 9.1 was ruled. The Panel consequently ruled no breach of Clause 2.

Complaint received **11 November 2020**

Case completed **18 November 2021**