

**CASE AUTH/3397/10/20**

## **ANONYMOUS CONTACTABLE COMPLAINANT v LEO**

### **Online interviews with Leo staff**

An anonymous complainant complained about a number of interviews with executives from Leo Pharma which had been published on pharmaboardroom.com over a period of several years. The complainant stated that he/she was a pharmaceutical physician who was not an employee of a pharmaceutical company or a consultant to pharmaceutical companies but did work in the pharmaceutical/healthcare industry.

### **COMPLAINT**

The complainant explained that pharmaboardroom.com was a website with information and updates from the pharmaceutical industry; the company was registered in the UK and based in London. The readership of the website included medical journalists, communications agencies, pharmaceutical company employees and members of the public in the UK. Health professionals featured within all of these categories.

The complainant noted that Clause 1.11 required pharmaceutical companies to comply with all codes, laws and regulations to which they were subject and alleged that given the activity in question, Leo did not appear to have abided by the Code.

The complainant alleged that from the answers provided, the interviewees appeared not to be conversant with the UK Code as per Clause 16.1.

The media outlet did not appear to have been briefed on the Code requirements either, despite the company being responsible for information about its products which was subsequently issued as per Clause 26.5.

The complainant noted that promotional material required certification as per Clause 14.1 and the interviews could not have been certified with any validity in line with the Code given their content.

The complainant also noted that promotional material placed on the internet for a UK audience must comply with the Code as per Clause 28.1 and this did not appear to be the case in the interviews in question.

In the complainant's view it was possible for the executives to answer questions about areas like growth, pipeline and acquisitions within Leo without making product claims and naming specific medicines, however they had chosen not to do this.

The complainant also alleged that the interviews may have been sponsored by Leo (paid placement as some of the answers were not typical of an interview format) but this was not declared, possibly breaching Clause 9.10.

When writing to Leo, the Authority asked it to consider the requirements of various clauses of the Code in relation to ten points subsequently ruled by the Panel not to be in scope of the Code and therefore not in breach of the Code, and separately, Clauses 9.1 and 2 in relation to the cumulative effect of the other matters raised by the complainant in addition to the clauses cited by the complainant and detailed below.

## **BACKGROUND FROM LEO**

Leo Pharma noted that the complaint referred to 11 interviews provided to pharmaboardroom.com, an independent third party website, by senior Leo Pharma executives from around the world over a period of 7 years (2013 to 2020) and alleged breaches seemingly of the 2019 Code.

### **Pharmaboardroom.com factual background**

Leo Pharma stated that the interviews which were the subject of the complaint were solicited by Focus Reports Limited for the purpose of preparing reports on particular countries by collecting interviews with the general managers or presidents of all the largest pharmaceutical companies in that country.

Focus Reports Limited was incorporated in the UK, although it traditionally worked with consultants and freelancers globally in order to produce interviews and analyses catering to the awareness and communication needs of executive thought leaders in the global pharma and biopharma space. The owners of the company were not resident in the UK. Pharma Boardroom (previously pharma.focusreports.net) was a global online business-to-business platform owned by Focus Reports Limited and provided information and insight on business strategy for a professional audience of senior executives in the life sciences industry. This audience had been confirmed by user registration data.

The intention of the reports was to define how pharmaceutical companies worked strategically and how company products fitted with that company's strategy. In general, interviewees were asked the same questions: background of the individual; company strategy; areas of focus; resources and product pipeline as it related to the company strategy.

The interviews were published by Focus Reports Limited on its website, pharmaboardroom.com. Extracts from the interviews, selected by Focus Reports Limited, were included in country reports published on the website. The interviews were also published in a magazine, Pharmaceutical Executive circulated to subscribers globally. Pharmaboardroom.com provided industry trends, news and reports related to the life sciences industry around the world. The site was intended 'for senior professionals who want to understand local and global markets' and described itself as 'the premier website for C-Level executives, consultants, regulators and vendors working in Healthcare & the Life Sciences globally'.

As demonstrated by analytics data supplied by Focus Reports Limited, during the six months from 1 May 2020 to 1 November 2020, the USA represented the single largest source of users (15.01%), followed by India (13.00%) and UK (6.33%). Furthermore, the most engaged users

(most extensive usage) were from the Ukraine (20.88%) followed by Spain (13.33%) and USA (11.78%). The site was not therefore directed towards health professionals or patients or a UK audience in general; it had no UK focus, save that the registered address for Focus Reports Limited was in London and was published from a UK server. A copy of the pharmaboardroom.com 'about us' landing page was provided together with a copy of a letter and analytics data from Focus Reports Limited.

Leo Pharma stated that the interviews were not sponsored by life sciences companies and involved no payment either by or to Focus Reports Limited. Accordingly, while the content of the transcript of an interview was generally confirmed with the interviewee to ensure accuracy, it was the property of Focus Reports Limited. Following approval of the transcript, the interviewee had no further involvement or control over any publication by Focus Reports Limited and was not notified of the extracts of the interview selected and used for the purposes of country reports. Companies were, however, generally offered the option of purchasing an advertisement (this was always a corporate rather than a product advertisement) to be published in the completed report; there was no requirement for companies to purchase an advertisement, but Leo Pharma understood that around 1 in 4 companies did so.

Focus Reports Limited was incorporated in 2012 however it had informed Leo Pharma that there had not previously been a complaint under the Code arising from its business approach. Similarly, while the earliest interview identified by the complainant was now over 7 years old, no previous complaint had been notified to Leo.

Leo submitted that it was clear that any finding that the digital activities of independent third party companies, directed globally and not specifically to a UK audience, were subject to the Code, simply because their parent company was located in the UK, was stretching the relevance of the UK to such activities. Such a finding would, moreover, discourage businesses from establishing in the UK, to the detriment of UK business and without any corresponding benefit to UK society.

### **The website and the interviews at issue did not fall within the scope of the Code**

Leo stated that in its view the Code was not applicable to the pharmaboardroom.com website or to the interviews identified by the complainant. The website was non-promotional. It was not directed towards health professionals, other relevant decision makers or patients, but was intended to provide strategic business information to the life sciences industry. The website was not directed towards a UK audience within the scope of Clause 28.1 of the Code but was intended to provide information on a global basis.

a) The pharmaboardroom.com website did not promote medicines to health professionals or other relevant decision makers

Clause 1.1 stated that 'this Code applies to the promotion of medicines to members of the United Kingdom health professions and to other relevant decision makers'.

'Promotion' was defined at Clause 1.2 as 'any activity undertaken by a pharmaceutical company or with its authority which promoted the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines'.

Leo stated that the website was not designed to promote medicines, but to provide business information to a specialized audience of senior executives working in the life sciences industry. Furthermore, the website was clearly not directed towards health professionals or other relevant decision makers. The intended audience (senior life sciences executives) was clearly communicated to anyone who accessed the site. Any reference to individual medicines simply illustrated information regarding business practices and trends in the industry. This context was central to whether a promotional purpose or effect might reasonably be construed; Leo submitted that in circumstances where legitimate business information was provided to senior industry executives and was not intended for health professionals or other relevant decision makers, the definition of promotion as set out in Clause 1.2 was not met.

b) The pharmaboardroom.com website did not promote medicines to the general public but provided business information to a specialized audience

Leo recognized that, for the purposes of the Code, individuals were generally categorized into those who were health professionals and those who were not, with the latter being classed together as 'members of the public'. The Code however recognized that 'members of the public' might have widely divergent characteristics and the type of information which might be viewed as promotional when presented to certain individuals might, in contrast, be viewed as non-promotional when presented to others; therefore the type of information which might legitimately be provided to patients prescribed a particular medicine was different to that which might be provided to the general public. Leo submitted that similar considerations applied when information was provided for non-promotional purposes in the context of a business discussion to a specialized audience who had a proper business interest in, and need to see, such information.

The website was not intended to promote medicines at all, but to provide information on business strategy. Therefore, it was explicitly not intended for the public generally, but for a specialized audience of senior executives in the life sciences industry. The nature of this specialized audience meant that information regarding a particular medicine might be required to provide context for the consideration of associated business strategy without being promotional. In particular, information provided through this website for this particular specialized audience did not encourage members of the public to ask their health professional to prescribe such medicines - the principal reason why information regarding prescription only medicines should not be provided to members of the general public - but simply provided illustration for a business presentation.

c) The content of the pharmaboardroom.com website did not fall within the category of non-promotional information within the scope of the Code

Clause 1.1 stated that 'the Code also applies to a number of areas which are non-promotional including information made available to the public about prescription only medicines'. The examples given in the supplementary information to Clause 1.1 comprised 'declarations of sponsorship in Clause 9.10, clinical trials and non-interventional studies in Clause 13, certain aspects of the provision of medicines and samples in Clause 17, donations, grants and fees for services in Clauses 19.2 and 21, the use of consultants in Clause 23, the provision of information to the public in Clause 26 and relations with patient organisations in Clause 27.

Therefore 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', 'material

relating to joint working between the NHS and the pharmaceutical industry', 'material relating to patient support programmes' and 'non-promotional material for patients or health professionals relating to the provision of medical and educational goods and services'.

The categories listed above were materially different to information intended to inform senior industry executives (as distinct from the public generally) about local business environments and practices (where the information was not 'about medicines', even if references to medicines might be used to illustrate business scenarios) and there was no suggestion in the Code that its provisions were applicable to the type of material published by pharmaboardroom.com. Leo considered that if such information was viewed as falling within the scope of the Code, this needed to be stated explicitly – which it was not.

d) The pharmaboardroom.com website was not directed to a UK audience

Clause 28.1 of the Code stated that 'promotional material about prescription only medicines directed to a UK audience which was provided on the Internet must comply with all relevant requirements of the Code'.

The website was intended for 'C-Level executives, consultants, regulators and vendors working in Healthcare & the Life Sciences globally'. The website was not directed towards persons in the UK and its international focus was clearly communicated to anyone who accessed the site. None of the interviews identified by the complainant had related to the UK or were relevant to the UK as demonstrated by the fact that the 'TAGS' on the left hand side, near the top of the published interviews relate to the country of origin and not the UK.

The global nature of the audience was evidenced by the data provided by pharmaboardroom.com in relation to its readership, with only a small proportion of people accessing the site from the UK (copy provided).

e) In these circumstances the requirements of the Code were not generally applicable to publications on pharmaboardroom.com

In particular:

- While all Leo personnel within the scope of Clause 16.1 were conversant with the Code, there was no requirement for interviewees from affiliated companies providing interviews which were not directed to a UK audience or subject to the Code, to have a detailed knowledge of its provisions;
- Pharma Boardroom did not obtain or publish interviews under contract with Leo and there was accordingly no requirement for Leo to ensure that Pharma Boardroom was trained on the provisions of the Code in accordance with Clause 16.1;
- Pharma Boardroom was not a public relations agency retained by Leo and therefore Leo had no responsibility for information published by Pharma Boardroom under Clause 26.5; and
- In circumstances where interviews published by Pharma Boardroom were not intended to promote specific medicines and/or were not subject to the Code, there was no requirement for them to be certified in accordance with Clause 14.1 (or, for completeness, as material within the categories listed at Clause 14.3 which were required to be certified in a similar manner to that provided for by Clause 14.1).

**The dates when the interviews were published**

Leo Pharma was concerned by the duration of time since a number of the interviews identified by the complainant were published, which in some cases was well over 7 years. This delay inevitably resulted in difficulty in conducting a proper investigation and therefore prejudice to the company.

Leo stated that it was aware of the decision of the Panel in Case AUTH/3200/5/19, which involved events in 2002. It was unclear from the report of that case whether the Panel reached any conclusion as to the interval of time after which historic cases should not be considered, as a matter of fairness or if the basis for the Panel's decision to allow the allegations in that case to proceed was that the company was able to provide a response, albeit with difficulty.

It was inevitably the case that the interval of time following publication in these cases meant that it was difficult for Leo Pharma to respond in a comprehensive way or, in some cases, at all; relevant personnel no longer worked for Leo Pharma Group companies and documents (often email correspondence) would have been destroyed in the normal course of business.

Where material required to be certified for the purposes of the Code, Clause 14.6 provided that such certificates and associated material should be retained for at least 3 years. Leo Pharma stated that it respectfully suggested that the Code should therefore consider carefully whether it was appropriate to consider complaints relating to activities or material which were more than 3 years old, particularly in cases where the company was unable to respond to such allegations or in relation to matters (such as breaches of Clauses 14.1 and 16.1) where evidence was unlikely to be available after the time that has elapsed.

### **Response to interviews identified by the complainant**

Without prejudice to its position that the interviews published on pharmaboardroom.com did not fall within the scope of the Code, Leo nonetheless responded in relation to the complainant's allegations of breaches of the Code. In each case, Leo had documented the date when the interview was 'written' as stated by pharmaboardroom.com, which was the date of publication and followed shortly after the date of the interview.

In relation to each identified interview, the complainant had alleged various breaches of the Code and, in addition, had claimed that all of the interviews were potentially in breach of Clause 9.1 (on the basis that some might have been sponsored by Leo Pharma). The clauses of the Code identified by the complainant in relation to each identified interview as well as the allegations in respect of Clause 9.1 were addressed in each case.

In addition to the above, the complainant alleged breaches of the following clauses of the Code in relation to each of the identified interviews: Clause 16.1 (on the basis that the interviewees were not conversant with the Code), Clause 26.5 (on the basis that Pharma Boardroom was not briefed on Code requirements), Clause 14.1 (in relation to certification requirements) and Clause 28.1 (on the basis that promotional material placed on the internet for a UK audience must comply with the Code). Leo Pharma's responses to those allegations were provided above, in the section of this response which explained why 'The website and the interviews did not fall within the scope of the Code'

Leo stated that its response in relation to each of the clauses of the Code identified by the complainant should not be construed as indicating its acceptance that the Code in general, or such clauses in particular, were applicable.

### **Historic breaches of the Code and adherence to undertakings**

Leo provided comment in relation to how/whether it recorded historic breaches of the Code and ensured that, if such cases were relevant, current material reflected any undertakings given.

### **Overall analysis of the interviews identified by the complainant**

Leo stated that the interviews identified by the complainant, covering a 7-year period were initiated by Focus Reports Limited/Pharma Boardroom and involved Leo affiliates outside the UK. None of the reports were sponsored or paid for by any Leo Pharma Group company. Leo Pharma stated that the interviews were, in each case requested for the purpose of a country specific Healthcare and Life Sciences Review being undertaken by Focus Reports Limited/Pharma Boardroom. The interviews and reviews were subsequently published by Focus Reports Limited/Pharma Boardroom for use by senior 'C-level' executives in the life sciences industry globally. They were not intended for health professionals or other relevant decision makers and had a strictly business focus. While senior executives in the life sciences industry were not health professionals and might, to that extent, be viewed as members of the public, they were clearly a specialist group, distinct from the 'general public'. The interviews and country specific Healthcare and Life Sciences Reviews were intended for an international audience and there was no reference in any of the identified material to UK health professionals or to use of medicines in the UK. All of the identified interviews stated clearly the country of focus, where the interviewee was located. Similarly, the pharmaboardroom.com website was global in focus and only a small proportion of individuals who accessed the site were UK based.

Overall, the content of the interviews was non-promotional and business focused. Any references to specific products were limited and could be justified in the context of the business discussion in which they appeared. Nevertheless, there were a small number of errors which were regrettable and in some circumstances the approach was not consistent with what would be standard practice in the UK in accordance with the Code.

However, in the context described above, Leo Pharma respectfully submitted that the interviews did not fall within the scope of the Code. They were not promotional within the definition at Clauses 1.1 and 1.2 and they did not fall within areas of non-promotional activity identified in the Code. They were not aimed at health professionals or other persons in the UK and the entire focus was international. The only connection with the UK was the fact that the company which commissioned the interviews and published them on an international website, had a UK address. Leo did not believe that this was sufficient to bring the interviews within the scope of the Code, when all other factors argued against it.

In circumstances where the interviews which were the subject of this complaint did not fall within the scope of the Code, it was necessarily the case that there had been no breach of the undertaking given in Case AUTH/2583/3/13 and the matters raised by the complainant cumulatively did not fall within Clauses 9.1 or 2.

Finally, Leo noted that this very substantial complaint had involved considerable investigation by Leo. In a number of instances, the allegation by the complainant had been poorly defined and,

while Leo had made efforts to understand the issues raised, this had not always been easy. Therefore, if Leo could provide further clarification of any of the points raised, it would.

## **PANEL RULING – GENERAL COMMENTS**

The complainant raised a number of concerns about interviews with a number of senior executives of various Leo affiliates published on pharmaboardroom.com.

The Panel noted Leo's submission that the pharmaboardroom website was a global online business-to-business platform which was open to all and did not appear to be directed at a particular country. There were contributions from a broad range of countries and it appeared that the content was for a global audience which would of course include the UK.

The Panel first had to decide whether the published interviews fell within the scope of the UK Code.

The Panel noted Leo's submission that the interviews were solicited by Focus Reports Limited which was incorporated in the UK and were published by Focus Reports Limited on its website, pharmaboardroom.com which was published from a UK server. In the Panel's view, the content on pharmaboardroom.com resulting from the interviews with pharmaceutical company staff was therefore potentially within the scope of the Code. A relevant factor would be the role of the pharmaceutical company.

The Panel noted that Clause 28.1 stated that promotional material about prescription only medicines directed to a UK audience which is provided on the Internet must comply with all relevant requirements of the Code.

The Panel noted Leo's submissions that the interviews were requested for the purpose of a country specific Healthcare and Life Sciences Review and that extracts from the interviews, selected by Focus Reports Limited, were included in these country specific reports. It appeared to the Panel that the full interviews were published on the In Focus section of the website which was not country specific.

The Panel noted Leo's submission that analytics data supplied by Focus Reports Limited, from 1 May 2020 to 1 November 2020, demonstrated that the USA represented the single largest source of users (15.01%) of the website in question, followed by India (13.00%) and UK (6.33%). There was no data provided covering the dates of the interviews at issue. The Panel considered that it was not likely that the readership changed that much over that time but there was no way of being certain from the information provided.

The Panel further noted Leo's submission that the site was not therefore directed towards health professionals or patients or a UK audience in general; it had no UK focus, save that the registered address for Focus Reports Limited was in London and the material was published from a UK server.

The Panel noted Leo's submission that all of the identified interviews on the website stated clearly the country of focus, where the interviewee was located and had 'TAGS' on the left hand side, near the top of the published interviews, related to the country of origin. The Panel noted, however, that whilst that was the case for most of the interviews which appeared on the non-country specific In Focus section of the website, one interview had no country TAGS and



another referred to 'R&D Leo Pharma'. In general the pages referred to the country and many of the questions included the country name. The country specific reports were labelled as such and appeared to be accessible only via country specific sections on the website. The Panel noted that according to Leo, the interviews were also published in a magazine, Pharmaceutical Executive circulated to subscribers globally.

The Panel noted Leo's submission that Pharmaboardroom.com provided industry trends, news and reports related to the life sciences industry around the world. The site was intended 'for senior professionals who want to understand local and global markets' and described itself as 'the premier website for C-Level executives, consultants, regulators and vendors working in Healthcare & the Life Sciences globally'. In the Panel's view the website in question, and the associated magazine, was aimed at senior pharmaceutical company executives rather than health professionals, patients or members of the general public. The Panel understood that senior company executives might also be health professionals or considered as members of the public, and that the website was open access; however, in the Panel's view, visitors to pharmaboardroom.com would likely be looking for industry insights and not for information to help them make treatment decisions. The Panel further noted that there was no evidence that content from pharmaboardroom.com had been distributed by Leo UK or by Leo to organisations or individuals in the UK. The Panel noted that some of the language published in some of the interviews if it had been as stated by the interviewee from Leo might be of concern if the UK Code applied given the general quality standards in the Code for information.

Bearing in mind its general comments above the Panel then went on to consider each interview as follows.

#### **Interview with a senior Leo Pharma Ireland executive**

The complainant noted that the question 'You mentioned that Leo Pharma was recently honoured with a number of awards in the UK for unrolling programs that were in some ways inspired by your efforts in Ireland. Can you tell us more about these honours?' Elicited the following:

'The awards came about because we launched a product called Dovobet Gel in the UK - and Ireland - in early 2011. The product has been very successful but the drug itself was only part of the launch.'

The complainant alleged that the answer promoted Dovobet Gel to the public, in breach of Clauses 26.1, 4.1, 4.2, 4.3, 4.4, 4.6, 4.8 and 4.9.

#### **RESPONSE**

Leo noted that the interview was given on 7 December 2012.

Leo stated that at the time of the interview, the employee had recently been appointed to a senior role at Leo UK and Ireland which became effective in 2013. Details were given. In 2012 the employee was based in Ireland. In 2012, Leo Pharma Ireland and Leo Pharma UK were separate legal entities (the single legal entity was not formed until 1 January 2013). It was Leo's primary position that the interview did not fall within the scope of the Code.

Leo explained that the employee was contacted requesting an interview for the purposes of a report on the Irish Healthcare and Pharmaceutical Industry being prepared by Focus Reports. Prior to the interview a list of suggested topics was sent to the employee including an overview of Leo Pharma's Irish product portfolio and how this complemented the specific needs of Irish patients and synergies that Leo had built between the Irish and UK markets. The interview involved a second employee also based in Ireland.

Leo stated that a draft transcript of the interview was sent for approval and minor amendments were returned and it was understood that the approved transcript of the full interview would be uploaded onto a dedicated portal in the Ireland section. Extracts would be used for the final printed report. The interview was not sponsored by Leo Pharma Ireland and, after returning the amended transcript, Leo Pharma Ireland had no further opportunity to amend or revise the material published. Leo Pharma Ireland did not pay for the interview, for publication of the transcript on the Ireland section of the [pharma.focusreports.net](http://pharma.focusreports.net) website (subsequently [pharmaboardroom.com](http://pharmaboardroom.com)) or for inclusion of extracts from the interview in the Healthcare and Life Sciences Review on Ireland. However, Leo Pharma Ireland was offered the option to purchase a corporate advertisement, to be published in the Review. While the purchase of the advertisement was not a condition of publication, the option was accepted by Leo Pharma Ireland. Copies of documents relevant to the interview were provided.

Leo Pharma understood that the Second 2012 ABPI Code, effective from July 2012 applied to this interview.

Leo Pharma did not agree that the interview breached Clause 26.1 of the 2019 Code (Clause 22.1 of the Second 2012 Code). The use of the brand name of one medicine on one occasion in the context of an interview of over 3,300 words, did not mean that the content of the interview was promotional within the meaning of Clause 1.2. The brand name was used to provide context for a specific scenario raised in a question by the interviewer and was not the focus of the discussion. The interview would not therefore have been in breach of Clause 22.1 of the Second 2012 Code, even if it had been directed towards members of the general public. In fact however, the interview was not directed to members of the general public, but to a specialist audience of senior executives in the life sciences industry. In the circumstances described above, the single reference to the name of the product was necessary and appropriate.

Leo noted that Clause 4.1 required that prescribing information should be provided in all promotional material for a medicine (save for abbreviated advertisements). Promotional material, consistent with Clause 1.1 of the Code, constituted material promoting medicinal products to members of the UK health professions or other relevant decision makers. As explained [pharmaboardroom.com](http://pharmaboardroom.com) was not directed towards members of the health professions or other relevant decision makers or to a UK audience. The inclusion of UK prescribing information in association with the interview addressed to senior executives in the life sciences industry was therefore clearly not required and would, furthermore, have been wholly inappropriate. Accordingly, there could be no breaches of Clauses 4.1, 4.2, 4.3, 4.6, 4.8 (Clause 4.9 of the Second 2012 Code) or 4.9 (Clause 4.10 of the Second 2012 Code).

Leo noted the complainant's allegation of a breach of Clause 4.4, which referred to digital material. Clause 4.4 of the Second 2012 Code instead referred to audio visual material, such as films, DVDs and suchlike and was therefore not applicable to the publication of the interview on the [Pharmaboardroom.com](http://Pharmaboardroom.com) website.

Leo submitted that the interview was not promotional, as explained above and there was, accordingly, no obligation to certify it in accordance with Clause 14.1 of the Code. Leo Pharma had not accessed the archive (which required specific permission from Zinc) in order to confirm whether this provided evidence of certification of the interview. While this was unlikely, in any event, Clause 14.6 of the Code required certificates and relevant accompanying material to be preserved for only three years and there was accordingly no obligation for Leo Pharma to retain such material over seven years later.

## **PANEL RULING**

The Panel noted its general comments above.

The Panel noted Leo's submission that at the time of the interview, while the employee had recently been appointed to a Leo UK and Ireland role, the role only became effective in 2013. In 2012, the employee was based in Ireland and the interview was requested in her capacity at Leo Pharma Ireland. The Panel noted Leo's assertion that the interview did not fall within the scope of the Code.

The Panel disagreed with Leo's submission that there was no reference in any of the identified material to UK health professionals or to use of medicines in the UK; the employee stated in the interview, and noted by the complainant, that:

'The awards came about because we launched a product called Dovobet Gel in the UK - and Ireland - in early 2011. The product has been very successful but the drug itself was only part of the launch.'

The Panel noted that this sentence was followed by the statement:

'Our work was about changing people's lives in psoriasis: we focused on awareness and support. It was very much a holistic approach to a product launch.'

The Panel further noted, from the material provided by Leo, that the employee made a number of references to the UK in the interview including references to the integration of the roles and that 'Having worked in the UK for six months, what I see immediately is that the hurdles for market access are certainly more challenging there than in Ireland.'

In the Panel's view, it was very likely that content from a company that discussed use of its medicines in the UK or statements from employees working for a UK based company fell within the scope of the Code. Context as well as content was important. Noting its comments above the Panel considered that the interview did come within the scope of the Code.

The Panel noted that the complainant appeared to refer to the clauses in the 2019 Code. The interview had taken place in 2012 so the Panel considered that the relevant Code was the 2012 Code Second Edition.

The Panel considered that whilst the interview did refer to use of medicines in the UK, the publication of the interview on a website for senior pharmaceutical executives globally meant that the interview was not advertising a prescription only medicine to UK health professionals, other relevant decision makers or members of the public. The Panel therefore ruled no breach of the relevant clauses in the 2012 Code, Second Edition which were similar to the clauses cited

by the complainant. These being Clauses 24.1 (similar to Clause 28.1 of the 2019 Code) 22.1 and 22.5 (similar to Clauses 26.1 and 26.5 of the 2019 Code), 14.1, 4.1, 4.2, 4.3, 4.4 (with regard to its reference to interactive data systems), 4.6, (similar in the 2012 and 2019 Codes), 4.9 (similar to Clause 4.8 in the 2019 Code) and 4.10 (similar to Clause 4.9 of the 2019 Code).

The Panel noted that Clause 9.10 stated that material relating to medicines and their uses, whether promotional or not, and information relating to human health or diseases which was sponsored by a pharmaceutical company must clearly indicate that it has been sponsored by that company.

The Panel noted Leo's submission that the interview was not sponsored by Leo Pharma Ireland and, after returning the amended transcript, Leo Pharma Ireland had no further opportunity to amend or revise the material published by Focus Reports/Pharma Boardroom. Leo Pharma Ireland did not pay for the interview, for publication of the transcript on the Ireland section of the pharma.focusreports.net website (subsequently pharmaboardroom.com) or for inclusion of extracts from the interview in the Healthcare and Life Sciences Review on Ireland. The Panel further noted Leo's submission that while the offer to purchase a corporate advertisement to be published in the review was not a condition of publication, the option was accepted by Leo Pharma Ireland.

There was no evidence before the Panel that the interview in question was sponsored by Leo as alleged and no breach of Clause 9.10 (similar in the 2012 and 2019 Codes) was ruled.

The Panel did not consider that the complainant had proved on the balance of probabilities that relevant personnel were not conversant with the Code as alleged and no breach of Clause 16.1 (similar in the 2012 and 2019 Codes) was ruled.

The Panel noted its comments and rulings above and did not consider that the interview meant that Leo had not maintained high standards or had brought discredit upon the industry and no breach of Clauses 9.1 and 2 (similar in the 2012 and 2019 Codes) were ruled.

With regard to the alleged breach of Clause 1.11 (2019 Code), which required pharmaceutical companies to comply with all codes, laws and regulations to which they were subject, the Panel noted that when writing to Leo, the Authority asked it to consider the requirements of the clauses cited by the complainant and provided a list. Clause 1.11 was excluded from that list. The Panel noted that whilst Leo had not responded in relation to Clause 1.11, it had responded in relation to all of the other clauses raised. The Panel noted its rulings of no breaches of the Code and therefore considered that there was no evidence of a breach of Clause 1.11 (similar to Clause 1.8 in the 2012 Code Second Edition which was the applicable Code) and ruled no breach of Clause 1.8 of the 2012 Code Second Edition accordingly.

#### **APPEAL FROM THE COMPLAINANT (first email, 23 April 2021)**

The complainant stated that he/she would like to correct what appeared to be a key fact provided by Leo and considered by the Panel in relation to when the employee in question started with Leo in the UK. Details were provided including a LinkedIn page and there was evidence in the public domain which contradicted Leo's response.

In the interview the launch of the prescription only medicine (POM) 'Dovobet' in the UK was described. Leo did not market 'Dovobet' in India. In the USA, Leo marketed 'Dovobet' under a different brand name, Taclonex.

The complainant alleged that based on the metrics of users visiting the Pharmaboardroom website, provided by Leo, the main audience for whom this information was relevant were UK users of this website.

The complainant alleged that cases were assessed based on evidence and relied on trust - given this basic information provided from the company was incorrect and misleading, it did not provide a level playing field and this was not in keeping with the spirit of the Code. It raised questions as to the accuracy of Leo's response in general.

The complainant noted that the Panel ruling described a new group of individuals who were not described in the current or previous codes - 'senior pharmaceutical executives'. In the ruling, this group had been separated from UK health professionals, other relevant decision makers or members of the public. As the Code did not define or mention this group currently, the ruling should reflect the categories of individuals already described or mentioned in the Code.

The complainant alleged that if the Panel wanted to define 'senior pharmaceutical executives' as a unique group, this should be reflected in the future Code but this definition was not currently applicable nor had it been applicable in previous Code editions and should therefore be set aside. As the Panel noted, the users of this site might be health professionals, other relevant decision makers (ORDM) or members of the public, but working with the current categories in the Code, users must be defined broadly as members of the public. It was worth considering that if this case was ruled, the definition of 'senior pharmaceutical executives' becomes precedent and very similar arguments could be made for other categories of professional individuals. For example, staying within the dermatology area, an article published on a UK server on a professional hairdressing website discussing a POM for scalp psoriasis could be ruled as not within scope of the Code as the viewer (eg hairdressing professional) might be looking for industry insights about managing customers with scalp health issues and psoriatic scalp.

Another example, drawing direct parallels with this case, which might be ruled as being outside of the Code might be a senior pharmaceutical executive providing promotional information about a yet to be authorised POM in aesthetic medicine to a professional makeup artist audience on a makeup artist professional website, published from a UK server.

The complainant alleged that these examples did not appear to be in line with legislation, the Code or the spirit of the Code, but would use this case as precedent in the event of a complaint. The ruling of the Panel made 'senior pharmaceutical executives' a special group in the Code. The intention of looking for 'industry insights' was very far reaching as medicines cross into many industries and professional groups who were not health professionals or ORDMs as he/she described in his/her examples. It placed senior pharmaceutical employees in an elevated and unique status within the Code which was a very unusual stance for a self-regulating industry.

The complainant alleged that the definition and interpretation of who a 'senior pharmaceutical executive' was also varied greatly depending on the size and structure of a pharmaceutical company and was a term subject to interpretation; when did one become a 'senior' executive -

was it based on years of experience, title, span and control of management, certain cultural reforms influence seniority or some other factors. The only group which all 'senior pharmaceutical executives' fitted in to in the current Code was as 'members of the public' and the case should be assessed as such.

### **FURTHER COMMENTS FROM THE COMPLAINANT (second email 30 July 2021)**

Following the appeal of another part of this case and the findings of the independent referee, the complainant clarified that he/she would like to appeal specific points on the interview related to Clauses 1.11, 2 and 9.1 of the Code. [Due to a typographical error the Panel minute referred to Clause 1.11, but as this was considered under the 2012 Code Second Edition the relevant Clause was Clause 1.8.]

The complainant stated that as noted by the Panel, content from a company that discussed use of its medicines in the UK or statements from employees working for a UK based company fell within the scope of the Code but context as well as content was important. The complainant stated that he/she would now present the publicly available facts of the case. With regard to context, Leo had provided a specious defense.

The complainant alleged that Leo's primary defense that the start date in the UK of the employee in question was after the interview to support its submission that the interview did not fall within the scope of the Code was erroneous and evidence in the public domain proved this. It demonstrated that the company was willing to distort reality to avoid possible censure. Details were provided including reference to the employee's LinkedIn page and other information that was in the public domain.

Leo was a member of the ABPI and therefore as per the Constitution and Procedure, should provide a complete response to the matters of complaint. The omission of the information regarding the employee's start date in the UK (approximately 6 months *in situ* at the time of interview) represented a breach of Clause 1.8 (2012 Code Second Edition).

The complainant alleged that by saying that the employee was not in a UK role at the time of information represented a falsehood and was not in line with the letter or spirit of the Constitution which they had agreed to abide by. The misrepresentation of the facts in this case to create a defense did not maintain high standards, breaching Clause 9.1. The facts in this case had been obscured by Leo to enable a better outcome and this lack of transparency and integrity brought the pharmaceutical industry into disrepute (Clause 2).

The PMCPA reviewed both of the emails submitted by the complainant (23 April and 30 July 2021) in relation to his/her appeal. The first email did not raise any clauses for the Appeal Board to consider whereas the second email referred to specific clauses of the Code. The PMCPA informed the complainant that his/her reasons for appeal in the two emails had some overlap but that the second email did not include the points raised about promotion of prescription only medicines which had only been made in his/her first email; the Authority asked the complainant to confirm if both emails were intended to form the appeal or if the second email was intended to supersede the first. The Authority received no response from the complainant, so Leo was asked to consider both emails as part of the appeal.

### **RESPONSE FROM LEO**

## Background

Leo submitted that this case was part of a series of complaints made by this complainant against Leo Pharma UK, each case raising multiple allegations of breaches of the Code and requiring extensive investigation and commitment in terms of time and resources on the part of both Leo Pharma UK and the PMCPA. The overwhelming majority of the allegations made by the complainant were without foundation, and so Leo questioned whether the complainant's strategy, which aimed to disrupt Leo Pharma UK's business, was consistent with the spirit and purpose of the Code and represented an appropriate use of the PMCPA's resources.

## Response to the appeal

Leo responded as follows:

As stated in Leo's response to the complaint, in 2012, when the PharmaBoardRoom interview was given, Leo Pharma Ireland and Leo Pharma UK were separate legal entities. This continues to be the situation today. However, from 1 January 2013 commercial operations for the two companies were combined and run from Leo Pharma UK and therefore from that date the employee in question could describe herself as having a 'combined' role.

Leo submitted that contrary to the complainant's allegation, it did not state, in its response to the complaint that the employee was not effective in a UK role, simply his/her Leo Pharma UK and Ireland responsibilities became effective only on 1 January 2013 when the combined commercial operation was formed. Before that time the responsibilities were separate. The interview with PharmaBoardroom was given in Ireland, solely in the employee's role at Leo Pharma Ireland.

Leo accepted that whilst further details of the employment arrangements could have been provided in its original response and it was incorrect to state that the employee was exclusively based in Dublin in 2012 or that the two legal entities combined in January 2013, the employee had no combined role for the UK and Irish entities prior to 1 January 2013, when the commercial operations were joined. The interview with PharmaBoardroom was requested in the context of a focus report on Ireland and was given from his/her office in Dublin in the context of a role at Leo Pharma Ireland.

Leo submitted that it strongly objected to the complainant's allegation that its response to the original complaint was false or that this breached Clause 9.1 of the Code.

Leo submitted that Annex 1 to Leo Pharma UK's original response to the complaint provided analytics data during the six months from 1 May 2020 to 1 November 2020, demonstrating that the PharmaBoardroom site was a genuinely international site and was not focused on UK or any other single country. Those data showed that, while the USA represented the single largest source of users (15.01%), followed by India (13.00%), UK users comprised only 6.33% of the total. Furthermore, the most engaged users (most extensive usage) were from Ukraine (20.88%) followed by Spain (13.33%) and USA (11.78%). Therefore, irrespective of the fact that the product referenced by the employee was not supplied by Leo Pharma in India and was supplied under a different brand name in the US, the data did not suggest that the interview was focused on UK rather than having an international focus. In particular, the website had a business focus and reference to individual products was not intended to promote those products but to illustrate particular business strategies and experiences.

Leo agreed that senior pharmaceutical executives were a sub-set of the category of members of the public. However, the significance of their role was that they had a particular business interest in medicinal products and in that discussion reference to particular medicines should not be assumed to be promotional but rather a necessary part of a legitimate business discussion in the context of the pharmaceutical industry. In these circumstances the information provided in the PharmaBoardroom interviews did not breach either the applicable legislation or the Code.

Leo submitted that for completeness, the complainant's suggestion that treating senior pharmaceutical executives as different to other members of the public could result in similar arguments being made for other groups lacked merit.

- Hairdressers had no business or professional need to discuss prescription only medicines. They did not prescribe, supply, administer, buy or sell such products and, if any client of a hairdresser had a scaly scalp the appropriate advice would be to consult a doctor or other health professional.
- Similarly, make-up artists had no business or professional need to discuss prescription only medicines. They did not prescribe, supply, administer, buy or sell such products and, if any client of a make-up artist requested medical aesthetic treatment, they should be advised to consult a doctor or other health professional.

#### **FINAL COMMENTS FROM THE COMPLAINANT**

There were no comments from the complainant on Leo's response to his/her appeal.

#### **APPEAL BOARD RULING**

The Appeal Board noted that the complainant had submitted two emails (23 April and 30 July 2021) in relation to his/her appeal. The complainant's email dated 30 July raised some of the same points as in his/her email of 23 April but did not raise the points in relation to promotion of prescription only medicines which he/she had only referred to in his/her email of 23 April.

The Appeal Board noted that the complainant's email of 23 April did not associate the points raised with any clauses of the Code and considered that it was for the complainant to make clear the basis for his/her appeal, which clauses were being appealed and why. The Appeal Board noted that the PMCPA had asked the complainant to clarify the position and no further response had been received. The Appeal Board therefore determined that the scope of the appeal would be limited to the complainant's second email, dated 30 July 2021, where the points raised by the complainant were linked to particular clauses of the Code for the Appeal Board to consider. The Appeal Board, therefore, determined that the only point for consideration in this appeal was in relation to the complainant's allegation that Leo had incorrectly stated that the employee's role in the UK became effective in January 2013, which was not so. The Appeal Board noted that this aspect became apparent to the complainant following notification of the Panel ruling in the case.

The representatives of Leo submitted that, regrettably, due to the wide scope of this complaint and the other complaints which Leo had to respond to, details regarding the employee's start date in a UK role were not entirely accurate; Leo had relied on the employee's memory for his/her start date. On receipt of the complainant's appeal, Leo checked employment records, which clarified that the employee worked for Leo Pharma UK on a part time basis for a period of time from July 2012.



The Appeal Board considered that it was careless that Leo had only relied on the employee's recollection of events from 8 years ago, rather than checking employment records, when it provided its response to the PMCPA. Although the Appeal Board was concerned about the error and considered that Leo should have taken greater care when responding to this complaint, it did not consider that on balance Leo's response to the complaint in this regard amounted to a breach of the Code as alleged. The Appeal Board therefore upheld the Panel's ruling of no breach of Clauses 1.8, 9.1 and 2 of the 2012 Code Second Edition. The appeal on this point was unsuccessful.

### **Interviews with other senior Leo Pharma executives**

The Panel ruled no breach of numerous clauses in relation to ten other points raised by the complainant concerning interviews given by senior executives of various Leo Pharma affiliates as it considered that the matter of complaint was not within the scope of the Code. The complainant appealed this ruling to an independent referee under Paragraph 7.6 of the Constitution and Procedure. The independent referee decided that these points were not within the scope of the Code. The details are thus not included.

**Complaint received      6 October 2020**

**Case completed         22 October 2021**