CASE AUTH/3311/2/20

COMPLAINANT v LEO

Media Advisory Board for Kyntheum

An anonymous, non-contactable individual complained about a media advisory board for Kyntheum (brodalumab) held by Leo Pharma Laboratories Ltd. Kyntheum was indicated for the treatment of moderate to severe plaque psoriasis in adults who were candidates for systemic therapy.

The complainant provided a copy of a report published by the Medicines and Healthcare Products Regulatory Agency (MHRA) about its investigation into the media advisory board in question.

The report stated that nine UK-based journalists attended a media advisory board organised by Leo in June 2017 where they were paid to advise Leo on securing media interest on psoriasis, its effect on patients and on Leo's approach to disseminating newsworthy information on Kyntheum. The agenda included a presentation which featured significant content describing the benefits of Kyntheum which was yet to receive a marketing authorisation and the MHRA considered that the advisory board was designed to promote an unlicensed medicine to the attendees. Leo agreed to issue a corrective statement to attendees, at the request of the MHRA.

The complainant stated, referring to the MHRA report, that he/she did not believe that the matter had been assessed under the Code and requested that the PMCPA do so.

The detailed response from Leo Pharma is given below.

The Panel noted that this would be the fourth time the apparently same matter was raised with a regulatory body. The Panel noted that it had to consider all complaints in accordance with its Constitution and Procedure and thus it had to consider and rule upon matters referred to it. The Panel noted that this was the first time however that the matters had been considered in relation to the requirements of the Code.
The Panel first had to decide whether the advisory board was promotional. The Panel considered that it was acceptable to hold advisory boards for journalists so long as the overall arrangements complied with the Code. In this regard particular care had to be taken to ensure that the overall arrangements and content were appropriate for journalists. The status of the journalists, whether they were also health professionals, and whether they worked for consumer or health care professional publications would be relevant.

The Panel noted the business questions which the company stated that it needed to address and queried whether those which covered general psoriasis matters (What aspects of new medical/scientific information on psoriasis treatments were most newsworthy and how to communicate on psoriasis and its complications within a media

environment which more commonly covered other chronic diseases) were *bona fide* business requirements given Leo's long- standing heritage in this area. In the Panel's view, given the limited information before it, those business questions about brodalumab did not appear to be unreasonable requirements for the business.

The Panel did not accept Leo's submission that delegates were among a limited community of media experts experienced in reporting on a range of health issues within the national consumer press and it was on this basis that each was chosen. The Panel noted that according to the invitation Leo originally intended to invite health journalists from consumer and medical publications in the UK. This was echoed in other materials including the meeting agenda which referred to seeking advice from consumer, medical and trade journalists. The Panel noted that ultimately the advisory board participants were all freelance journalists, one of whom was a doctor and one of whom was also an agony aunt. All appeared to contribute primarily to consumer media. The Panel queried whether Leo could therefore be sufficiently confident that the majority of the participants had the requisite expertise to address the business questions insofar as they related to medical and trade publications. In this regard, the Panel noted from the executive summary of the meeting that it appeared to cover matters primarily related to the consumer press. This disparity was also echoed in the relatively fewer comments participants made in relation to trade and medical press as recorded in the meeting report. The Panel also queried whether the number of delegates with consumer media expertise was appropriate given the breadth of advice sought covered medical, trade and consumer press.

The Panel noted the detailed scientific presentation about brodalumab which comprised 16 slides covering its mechanism of action and the clinical trial programme. The Panel noted Leo's view that a summary about brodalumab would enable participants to provide better quality counsel. The Panel queried whether the detail was appropriate for participants advising in relation to the consumer press. The Panel noted that speaker notes from the presentation stated that 'There are current studies investigating brodalumab's potential in treating psoriatic arthritis and so far results are positive. We expect to initiate a phase 3 study for this indication in Europe, but we do not wish to publish any timing on this yet'. The Panel queried whether this information was necessary in order for the attendees to be able to answer the required questions.

Taking all of the above circumstances into account the Panel considered, on balance, that the advisory board insofar as it concerned non health professional journalists writing for the consumer media did not satisfy the requirements for an advisory board and was thereby promotional.

The Panel noted that Kyntheum, was not classified as a prescription only medicine when the media advisory board at issue was held and thus on this very narrow technical point it ruled no breaches of the Code in this regard.

The Panel noted its comments above in relation to the promotional nature of the advisory board and considered that brodalumab had been promoted prior to the grant of its marketing authorisation and a breach of the Code was ruled.

The Panel ruled that high standards had not been maintained in breach of the Code.

In the Panel's view the arrangements for the advisory board demonstrated a lack of care, and awareness of the Code on matters that reflected UK law. The Panel noted its comments above in relation to the consumer expertise of participants and that the participants had been paid to attend what the Panel considered to be a promotional meeting. The Panel noted that the supplementary information to Clause 2 included promotion prior to the grant of a marketing authorization as an example of an activity that was likely to be in breach of that clause. The Panel considered, on balance, that Leo had thus brought discredit upon, and reduced confidence in, the pharmaceutical industry and a breach of Clause 2 was ruled.

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The report stated that nine UK-based journalists attended a media advisory board organised by Leo on 26 June 2017 where they were paid to advise Leo on securing media interest on psoriasis, its effect on patients and on Leo's approach to disseminating newsworthy information on Kyntheum. The agenda included a presentation which featured significant content describing the benefits of Kyntheum which was yet to receive a marketing authorisation and the MHRA considered that the advisory board was designed to promote an unlicensed medicine to the attendees. Leo agreed to issue a corrective statement to attendees, at the request of the MHRA.

COMPLAINT

The complainant stated, referring to the MHRA report, that he/she did not believe that the matter had been assessed under the Code and requested that the PMCPA do so.

When writing to Leo, the Authority asked it to consider the requirements of Clauses 26.1, 26.2, 9.1, 3.1 and 2 of the Code.

RESPONSE

Leo Pharma stated that it took compliance with the Code extremely seriously and had detailed processes for compliance with it.

By way of background, Leo explained that:

- Brodalumab was a recombinant human monoclonal antibody indicated for the treatment of moderate to severe plaque psoriasis in adult patients who were candidates for systemic therapy.

- Brodalumab was granted a marketing authorisation on 17 July 2017.

- Prior to the grant of the marketing authorisation, there had been historic public discourse around the potential relationship between brodalumab and suicidality.

- Leo held an advisory board on 26 June 2017 to gain specialist advice from national health journalists including, but not limited to, how best to present information suitable for the general public without causing undue alarm or reassurance, in the context of safety data for brodalumab and perceived links to increased suicidality.

- Following the advisory board, Leo became aware of a brief article in an 'opinion column' first published in July 2017 in an Irish newspaper (authored by a journalist who had been given a copy of the invitation to attend the advisory board by another journalist). In the article, the author expressed surprise at receiving such an invitation (although it had not been sent to him/her directly by Leo) and the article appeared critical in tone.

- In line with Leo's value and commitment to transparency it proactively notified the Irish Pharmaceutical Healthcare Association (IPHA) about the article and the Association took the matter up as a complaint. Following its initial rulings, Leo appealed, after which the matter was finally ruled to be in breach of Clauses 2.1, 3.1 and 20.1 of the IPHA Code.

- In addition, following a pre-notification of the advisory board to the Irish Healthcare Products Regulatory Authority (HPRA) by Leo, the HPRA separately investigated and considered the matter under the Medicinal Products (Control of Advertising) Regulations 2007. The Authority concluded that there had been breaches of regulations 6, 7b and 9 of S.I No 541 of 2007. In addition, the HPRA notified the MHRA of the advisory board.

- Leo received correspondence about the matter from the MHRA in September 2017. Following discussions with the Advertising Standards Unit, Vigilance and Risk Management of Medicines, the following took place:

    - The MHRA concluded a provisional view that Leo was in breach of regulation 279 of Part 14 of the Human Medicines Regulations 2012 on the summary grounds that the MHRA considered the advisory board was designed to promote an unlicensed medicine and that this had the potential to lead to the subsequent promotion of a prescription only medicine to the public.

    - Leo revised its internal procedures to ensure that all activities, including, but not limited to, advisory boards involving the media, were compliant with the Code and The Human Medicines Regulations 2012.

    - Leo, as required by and in agreement with the MHRA, issued a corrective statement to all the UK advisory board attendees stating, *inter alia*, Leo's commitment to comply with The Human Medicines Regulations 2012.

    - Leo provided a corrective statement to the MHRA, to be placed on its website, regarding the advisory board activity. This statement summarised the MHRA's conclusions and stated that Leo had not intended that the advisory board should have any promotional elements and that the company had acted in good faith.

- Leo acted on the outcomes from the MHRA scrutiny that were described above. For the purposes of this response, Leo noted the PMCPA's request to consider the requirements of Clauses 26.1, 26.2, 9.1, 3.1 and 2 of the Code (2016 edition since this advisory board took place in 2017) and had included full details of the original Leo consideration of the advisory board, its review and approval process and why it was considered to comply with the Code.

In response to the complaint, Leo stated that it took compliance with the Code extremely seriously and had processes in place for compliance with it. These were used in full throughout the planning and execution of the advisory board in question to control the activities and documents from the pre-approval stage through to adviser selection, invitation, contracting, meeting facilitation, presentations and summary minutes of the meeting.

Leo conducted the advisory board to seek specialist advice from a small number of expert health journalists, to help shape an effective approach on a legitimate activity: securing media interest in psoriasis, its complications and the later dissemination of newsworthy information on brodalumab. Leo believed that the advisory board was non-promotional in its intent, its activities and its effect. Rather, its purpose was to seek advice on the later drafting by Leo of press releases on brodalumab and psoriasis to a general audience. The materials circulated to all parties were designed to reflect this intent so that they would have been clear on the intended purpose of the activity (as contracted). Potential attendees would also have been clear that they had been chosen on the basis of their expertise and that they were being asked to attend in order to advise the company. Attendees were given no documents with information on brodalumab to take away from the meeting or provided with such before the meeting. No attendee was given the impression that he/she was being encouraged to write any consumer or other article and nor did any do so as a consequence of the advisory board. Instead, the activity was undertaken to seek expert advice for a legitimate business purpose.

Brodalumab presented a unique set of challenges for Leo; in addition to it being the company's first biologic medicine, the nature of the historic public discourse around it had differed from that of most new product launches and had shaped the context in which Leo brought the medicine to market. With particular reference to safety data on suicidality, Leo had a responsibility to help ensure any information about brodalumab was understood by audiences, including journalists, in a factual and balanced manner.

Leo stated that it was legitimate, and in the public interest, for companies to inform the public about medical and scientific progress. Companies sent such information to journalists who were in a position to judge newsworthiness and relevance to their audience. Such new and newsworthy information on medicines presented to journalists, and in the public interest was not promotion. Leo noted that the advisory board at issue was not used to issue any press release or announce any news. No documents with information on brodalumab were provided to the attendees to take away from the meeting or provided before the meeting. No attendee was given the impression that they were being encouraged to write any consumer or other article and nor did any do so as a consequence of the advisory board. Instead, the purpose of this media advisory board was to secure expert advice in the shaping of the content of press releases and media materials planned for the future.

Marketing authorisation was planned to be the first newsworthy milestone at which Leo would communicate directly to lay audiences about brodalumab. Leo identified a risk that safety data on brodalumab might be misreported by lay media at this milestone and through the advisory

board it sought expert advice on how to mitigate that risk and other advisory questions related to the clear communication of information and newsworthy information for a general audience.

Leo stated that it was generally accepted that companies might, at times, need external expert advice when the relevant expertise did not exist within the company (for example health professional advisory boards). Such advice was customarily sought through formally constituted advisory boards, whose participants were recognised experts in the relevant field or subject matter. Such activities, and all materials relating to them, were entirely non-promotional. In this context, Leo engaged the attendees in their capacity as experienced health journalists who could provide the company with specialist advice, and not as members of the public. The delegates were among a limited community of media experts, all with experience of reporting on a range of health issues within the UK or Irish national consumer press and it was on this basis that each was chosen as an advisor. Eight delegates from the UK and two from Ireland participated (as well as a GP who was a broadcaster and who attended for the purpose of presenting the background on psoriasis) and were provided with a written briefing for this purpose. The Irish attendees participated remotely online.

Leo provided a list of UK invitees and a description of the relevant experience which merited their invitation as experts.

Attendees for Leo included two personnel from communications for whom the advice was most pertinent, the medical director and three agency facilitation staff (one online).

The office of Leo's agency partner was chosen as the venue, due to its central location, to enable convenient travel for delegates and eliminate the need for accommodation.

A sufficient number of slides were presented, on psoriasis and brodalumab, only in order to give the advisers enough information to answer the stated questions. These slides (including the slide notes) were intended to be a factual summary of brodalumab and its pivotal studies and were balanced with regard to efficacy and safety. Neither the slides nor any other documents with information on brodalumab were provided to the attendees to take away from the meeting (nor provided before the meeting).

Leo stated that the agency facilitator could use a facilitation guide to ensure that the meeting covered all of its advisory agenda. This document clearly, and in detail, set out the business advice that was required and that factual information on brodalumab from published data should be presented for this purpose and that there should be no reference to the brand name.

Leo minuted and used the advice received from this small selection of experts when it later drafted press materials relating to the grant of the marketing authorization for brodalumab. The press releases for lay and health professional media relating to the grant of the marketing authorization were subsequently vetted by the MHRA (and amended in response to its comments) through standard procedures concerning a new product entering the UK market. The advisory board was not used to disseminate 'news' about brodalumab, and no such articles were written by the attendees as a consequence of the advisory board, all of whom had signed contracts with confidentiality clauses.

In the course of proposing, planning and convening the advisory board, Leo adhered to detailed internal processes to ensure compliance with all relevant codes and regulations and to ensure that the activity reflected Leo's genuine intent to seek specialist advice. Detailed documentation

was generated by the communications department and approved independently by the medical department.

The process started with the generation of a pre-approval form which was completed prior to initiating any part of the activity. This form set out the compliant intent and objectives of the meeting, the rationale for choice of advisors, and the arrangements for the meeting, which were all scrutinised for compliance before proceeding with any part of the project.

This was followed by approval of meeting-related materials and content, including an approved invitation to attendees. Control was maintained over the activity through the use of contracts (which included a confidentiality clause) and pre-read to the advisors in which the advisory intent and objectives of the advisory board were clear.

The detailed advice obtained from the delegates at the meeting was recorded as an audio file to facilitate the production of a meeting summary report. This was a detailed report with substantive advisory actions for the attention of Leo and the company took this advice into consideration when later drafting press materials.

Clause 3.1

Leo stated that the context of the advisory board related to media announcements, and in the pre-licence phase of any new product there were specific newsworthy milestones at which companies were able to compliantly communicate. Leo stated that the advisory board in question was not used to issue any press release or announce any news. The date of the advisory board meeting was dictated by the timing of the opinion announcement from the Committee for Medicinal Products for Human Use (CHMP) for two reasons: 1) so that the content of the CHMP opinion could be taken into account when considering the company's approach for marketing authorization media materials, and, 2) to ensure the advisory board meeting took place with sufficient time remaining to implement the expert advice received ahead of the marketing authorization being granted. It was therefore necessary to implement the advisory board within the standard anticipated 60-day window between CHMP opinion and the granting of the marketing authorization.

The purpose of the meeting was to secure expert advice on the following:

- How to frame the language of a scientific press release in a manner that could be readily understood in the context of the novel mode of action of brodalumab.
- What aspects of new medical/scientific information on psoriasis treatments were most newsworthy.
- How to communicate on psoriasis and its complications within a media environment which more commonly covered other chronic diseases.
- How to present information suitable for the general public without causing undue alarm or reassurance, in the context of safety data for brodalumab and perceived links to increased suicidality.
- How to report on complex issues such as suicidal ideation and behaviour (SIB) in a transparent, understandable, and responsible manner.

Leo stated that the attendees were chosen on the basis of their expertise to address the above questions and were briefed and contracted accordingly. The balance of the agenda provided more than sufficient time for them to provide advice and included separate breakout sessions for the UK and Irish delegates, where further general and country-specific advice was sought.

The Leo attendees consisted of two personnel from communications for whom the advice was most pertinent, the medical director and three agency facilitation staff (one online).

During the course of the meeting, the agency facilitator could use a facilitation guide to ensure that the meeting covered all of its advisory agenda. That document clearly, and in detail, set out the business advice that was required and that factual information on brodalumab from published data should be presented and that there should be no reference to the brand name.

Leo submitted such an activity was non-promotional, whether undertaken before or after the grant of a marketing authorisation. Leo used the advice received from the small selection of experts when later drafting press materials relating to the marketing authorisation grant for brodalumab. The advisory board was not used to disseminate 'news' about brodalumab. No documents with information on brodalumab were provided to the attendees to take away from the meeting or provided before the meeting. No attendee was given the impression that he/she was being encouraged by to write any consumer or other article and nor did any do so as a consequence of the advisory board.

The slides used to facilitate the discussions included only sufficient factual data related to brodalumab so that attendees were appropriately informed to provide specific answers to the questions posed. Neither the slides nor any other documents with information on brodalumab were provided to the attendees to take away from the meeting (nor provided before the meeting).

The advisory board was not used for the purpose of issuing any press release to those present, nor did Leo ask the delegates to publish any information of any kind, whether in relation to brodalumab or psoriasis and nor did any do so as a consequence of the advisory board.

Moreover, all the advisers attended under a contract which specified the advisory purpose of their attendance and the nature of their relationship with Leo for the purposes of this advisory board. This contract included a confidentiality clause.

However, the MHRA concluded a provisional view that Leo was in breach of regulation 279 of Part 14 of the Human Medicines Regulations 2012 on the summary grounds that the advisory board was considered to be designed to promote an unlicensed medicine. On that basis Leo accepted a breach of Clause 3.1.

Leo reiterated that the intent of this advisory board was non-promotional; it was convened to seek expert advice from attendees in their capacity as experienced health journalists and not as members of the public. The questions posed to the attendees included (but were not limited to) the five matters set out above.

Leo stated that, as with all of those engaged as consultants for an advisory board, the contracted advisors were engaged to provide their expertise (as would be the case for a health professional advisory board). The media advisors were not engaged or considered by Leo as

members of the public (just as contracted health professional advisors would not be considered as members of the public for the purposes of a confidential advisory board nor with any intent to influence their individual prescription habits) but instead to provide their professional insights. They were invited and contracted with documents in which the advisory intent and objectives of the advisory board were clear.

Leo Pharma stated that during the course of the meeting, the agency facilitator could use a facilitation guide to ensure that the meeting covered all of its advisory agenda. That document clearly, and in detail, set out the business advice that was required and that factual information on brodalumab from published data should be presented and that there should be no reference to the brand name.

A sufficient number of slides were presented, on psoriasis and brodalumab in order to provide the advisers with enough information to answer the stated questions. These slides (including the slide notes) were intended to be a factual summary of brodalumab and its pivotal studies; they were supported by the evidence and were balanced and did not mislead with regard to efficacy and safety. All information within the materials could be further substantiated upon request and underwent a check for scientific accuracy as part of the approval process by the Leo Pharma medical team. Neither the slides nor any other documents with information on brodalumab were provided to the attendees to take away from the meeting (nor provided before the meeting).

With regard to the balanced nature of the information presented, the very intent and purpose of the advisory board demonstrated Leo's efforts to adequately focus on the safety profile of the medicine, not only during the advisory board but also in subsequent materials generated based on the advice of the attendees.

Leo submitted that the significant focus on the safety profile of brodalumab reflected the stated intent to receive advice on the communication of this sensitive information. In addition, the information about brodalumab was only provided to allow the attendees to have sufficient context to permit them to provide valuable expert insights. Leo also noted that not only was it the company's intent that publications did not arise based on the medicines discussed and content provided during the advisory board, at no time between the advisory board taking place and the attendees being notified of the MHRA conclusions (nor since) had such a publication been made by the attendees as a consequence of the advisory board.

The attendees each signed a contract which included a confidentiality clause and were not requested explicitly or implicitly to publish any information pertaining to the content of the advisory board and none had done so as a consequence of the advisory board (bound as they were by the confidentiality clause in the agreement they each signed).

The MHRA concluded a provisional view that Leo was in breach of regulation 279 of Part 14 of the Human Medicines Regulations 2012 on the summary grounds that the advisory board was considered to be designed to promote an unlicensed medicine. Furthermore, the MHRA considered that the advisory board might potentially lead to the promotion of a prescription only medicine to the public. On that basis, Leo accepted a breach of Clause 26.1.

Leo submitted, however, that as no information on brodalumab reached the public or patients as a consequence of the advisory board, there was no potential for unfounded hopes of successful

treatment to be raised nor for the public or patients to be misled with regard to the safety of the product. Leo thus denied a breach of Clause 26.2.

Clause 9.1

Leo stated that the advisory board was undertaken in the exceptional circumstances of the need to prepare media materials for a product that presented a complex and nuanced communication challenge that the company had not encountered before.

Throughout the course of proposing, planning, convening and concluding this advisory board, Leo adhered to detailed internal processes to ensure compliance with all relevant codes and regulations and ensured that the activity reflected its genuine intent to seek specialist advice. Processes for approval and conduct of the advisory board included:

- Detailed documentation (pre-approval, invitations, pre-reading, agenda, slides, minutes) generated by the communications department and approved independently by the medical department in line with the relevant standard operating procedure (SOP) in use at the time.

- The process started with the generation of a pre-approval form which was completed before starting any part of the activity. The form set out the compliant intent and objectives of the meeting, the rationale for choice of advisors, and the arrangements for the meeting which were all scrutinised for compliance before proceeding with any part of the project.

- The most relevant expertise required for the advisory board was that of a highly experienced, national health journalist. In this context, Leo engaged the attendees in their capacity as experienced health journalists who could provide specialist advice, and not as members of the public. The delegates were among a limited community of media experts experienced in reporting on a range of health issues within the national consumer press and it was on this basis that each was chosen.

- Leo estimated an appropriate service fee for these experts (detail provided), in anticipation of their commitment to the meeting which would last 2.25 hours, as well as to the 1.75 hours of detailed pre-reading they were recommended to undertake (the invitation highlighted a useful resource for delegates to gather some context on the condition ahead of the meeting, the 'PSO What?' Report (with information on psoriasis produced by Leo)). There were no externally published or agreed fair market value (FMV) rates for expert journalists so Leo relied upon estimation to reach this figure, which was commensurate with rates for other professions.

- The meeting was held at the office of Leo's communications agency partner due to its central location to enable convenient travel for delegates and eliminate the need for accommodation to be provided. No accommodation was offered or provided to any delegate. Since the meeting took place in the evening (6 – 8:15pm), delegates were offered a light buffet of sandwiches, cold snacks and soft drinks. No additional hospitality was offered before, during or after the meeting. Delegates were reimbursed for reasonable travel expenses.

- During the course of the meeting, the agency facilitator could use of a facilitation guide to ensure that the meeting covered all of its advisory agenda. That document clearly, and in detail, set out the business advice that was required and that factual information on brodalumab from published data should be presented for that purpose and that there should be no reference to the brand name.

- The presentations used during the advisory board were designed to be factual, non-promotional and intended to equip the contributors with sufficient information to address the advisory questions posed, and the agenda was set up to allow for a majority of the time at the meeting to be available for Leo to receive that advice. The information was only presented and not provided as a takeaway item nor provided to attendees before the meeting. No other materials were presented or provided apart from the 'PSO What?' Report mentioned above, which was sent as a pre-read.

- The advice received from the small selection of experts was later used to draft press materials relating to the marketing authorization grant for brodalumab.

- The advisory board was not used to disseminate news about brodalumab, and no such news articles were written as a consequence of the advisory board.

- Control was maintained over the activity through the use of contracts and written briefings to the advisors. The detailed advice obtained from the delegates at the meeting was recorded as an audio file and summarised to facilitate the production of a meeting report which was acted upon.

Leo stated that during correspondence with the MHRA, it took the opportunity to review its internal processes and had since updated these to ensure they were as robust as possible in order to strengthen its commitment to comply with the Human Medicines Regulations 2012, the Code and any other relevant regulations.

Leo had a clearly identified need for external expertise that was not available in the company and suitably qualified advisers were identified, invited, and contracted (with confidentiality requirements). The detailed advice received at the meeting was used for the intended purpose of informing the later drafting of press materials. Critically, none of the media advisers at the meeting published any news or other articles on brodalumab as a consequence of the advisory board, demonstrating the compliant intent and diligent control over the conduct of this meeting.

Given the exhaustive diligence and process applied to this activity and given that no information on brodalumab was disseminated by the attendees to the public as a consequence of the advisory board, the standards applied by Leo was clearly adequate to the task of ensuring that the meeting fulfilled the legitimate and only purpose of securing expert advice to meet a business need. Therefore, Leo did not accept a breach of Clause 9.1.

Clause 2.

Leo stated that it took the concerns of complainants, the PMCPA, as well as compliance with the Code, extremely seriously. As stated above, it accepted breaches of Clauses 3.1 and 26.1 but not of Clauses 26.2 or 9.1.

Leo stated that it recognised that breaches of this nature might in many circumstances warrant a breach of Clause 2. However, its intention with the advisory board was only to seek advice. Leo stated that it had not intended that the advisory board should have any promotional elements and the company acted in good faith, as stated in its corrective statement that was published by the MHRA. Moreover, given the exhaustive diligence with which the advisory board was prepared and executed, given that Leo had (and had further refined) processes for the application of such diligence for advisory boards and given that, not only did the advisory board meet its business purpose of securing actionable expert advice, but that no information on brodalumab was published by the attendees to the public or patients as a consequence of this advisory board, the company did not believe the circumstances warranted an application of Clause 2.

PANEL RULING

The Panel noted that this would be the fourth time the apparently same matter was raised with a regulatory body. The Panel noted that it had to consider all complaints in accordance with its Constitution and Procedure and thus it had to consider and rule upon matters referred to it. The Panel noted that this was the first time however that the matters had been considered in relation to the requirements of the Code.

The Panel noted Clause 3.1 prohibited the promotion of a medicine prior to the grant of its marketing authorisation. Once the marketing authorisation had been granted Clause 26.1 prohibited the promotion of prescription only medicines to the public.

The Panel first had to decide whether the advisory board was promotional. The Panel considered that it was acceptable to hold advisory boards for journalists so long as the overall arrangements complied with the Code. In this regard particular care had to be taken to ensure that the overall arrangements and content were appropriate for journalists. The status of the journalists, whether they were also health professionals, and whether they worked for consumer or health care professional publications would be relevant.

The Panel noted the business questions which the company stated that it needed to address and queried whether those which covered general psoriasis matters (What aspects of new medical/scientific information on psoriasis treatments were most newsworthy and how to communicate on psoriasis and its complications within a media environment which more commonly covered other chronic diseases) were *bona fide* business requirements given Leo's long- standing heritage in this area. In the Panel's view, given the limited information before it, those business questions about brodalumab did not appear to be unreasonable requirements for the business.

The Panel did not accept Leo's submission that delegates were among a limited community of media experts experienced in reporting on a range of health issues within the national consumer press and it was on this basis that each was chosen. The Panel noted that according to the invitation Leo originally intended to invite health journalists from consumer and medical publications in the UK. This was echoed in other materials including the meeting agenda which referred to seeking advice from consumer, medical and trade journalists. The Panel noted that ultimately the advisory board participants were all freelance journalists, one of whom was a doctor and one of whom was also an agony aunt. All appeared to contribute primarily to consumer media. The Panel queried whether Leo could therefore be sufficiently confident that the majority of the participants had the requisite expertise to address the business questions

insofar as they related to medical and trade publications. In this regard, the Panel noted from the executive summary of the meeting that it appeared to cover matters primarily related to the consumer press. This disparity was also echoed in the relatively fewer comments participants made in relation to trade and medical press as recorded in the meeting report. The Panel also queried whether the number of delegates with consumer media expertise was appropriate given the breadth of advice sought covered medical, trade and consumer press.

The Panel noted the detailed scientific presentation about brodalumab which comprised 16 slides covering its mechanism of action and the clinical trial programme. The Panel noted from the meeting approval form Leo's view that a summary about brodalumab would enable participants to provide better quality counsel. The Panel considered that it was not unacceptable to present scientific data to journalists from whom one was seeking expert advice but considered that the presentation should bear in mind their status (health professional or consumer) and expertise. The Panel queried whether the detail was appropriate for participants advising in relation to the consumer press. The Panel noted that speaker notes from the presentation stated that 'There are current studies investigating brodalumab's potential in treating psoriatic arthritis and so far results are positive. We expect to initiate a phase 3 study for this indication in Europe, but we do not wish to publish any timing on this yet'. The Panel queried whether this information was necessary in order for the attendees to be able to answer the required questions.

Taking all of the above circumstances into account the Panel considered, on balance, that the advisory board insofar as it concerned non health professional journalists writing for the consumer media did not satisfy the requirements for an advisory board and was thereby promotional.

The Panel noted that the product, Kyntheum, was not classified as a prescription only medicine when the media advisory board at issue was held. Clauses 26.1 and 26.2 only applied to prescription only medicines. On this very narrow technical point the Panel ruled no breach of Clauses 26.1 and 26.2 of the Code.

The Panel noted its comments above in relation to the promotional nature of the advisory board and the application of Clause 3.1. The Panel considered that brodalumab had been promoted prior to the grant of its marketing authorisation and a breach of Clause 3.1 was ruled.

The Panel noted its comments about the advisory board set out above and considered for those reasons high standards had not been maintained a breach of Clause 9.1 was ruled.

In the Panel's view the arrangements for the advisory board demonstrated a lack of care, and awareness of the Code on matters that reflected UK law. The Panel noted its comments above in relation to the consumer expertise of participants and that the participants had each been paid to attend what the Panel considered to be a promotional meeting. The Panel noted that the supplementary information to Clause 2 included promotion prior to the grant of a marketing authorization as an example of an activity that was likely to be in breach of that Clause. The Panel considered, on balance, that Leo had thus brought discredit upon, and reduced confidence in, the pharmaceutical industry and a breach of Clause 2 was ruled.

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Complaint received	**18 February 2020**
Case completed	**25 February 2021**