ANONYMOUS, NON CONTACTABLE HOSPITAL CONSULTANT v GW PHARMACEUTICALS

Alleged promotion of Epidiolex

An anonymous, non-contactable complainant, who described themselves as a consultant neurologist, complained about the pre-licence promotion of Epidiolex (cannabidiol) by GW Pharmaceuticals at a hospital meeting in February 2018. An application for a marketing authorization had been submitted to the European Medicines Agency (EMA) for its use as an adjunctive treatment for seizures associated with Lennox-Gastaut Syndrome and Dravet Syndrome.

The complainant had attended the multi-disciplinary team meeting at which GW Pharmaceuticals hosted a presentation on Epidiolex treatment. The complainant stated that after the presentation, he/she was informed that Epidiolex was unavailable to prescribe as it was not currently licensed in the UK or Europe.

The detailed response from GW Pharmaceuticals is given below.

The Panel noted that GW Pharmaceuticals referred to a third party organisation that employed managers to represent GW Pharmaceuticals. The Panel noted that it was an established principle under the Code that companies were responsible for the acts/omissions of third parties acting on their behalf.

The Panel noted that an application for a marketing authorization for Epidiolex was submitted to the EMA on 29 December 2017; its proposed indications were as adjunctive treatment for seizures associated with Lennox-Gastaut Syndrome and Dravet Syndrome, each forms of child onset epilepsy.

The Panel noted that the slides provided by the parties in relation to the meeting in February differed. The complainant provided photographs of nine slides, some of which were such that the full slide could not be seen, whilst GW Pharmaceuticals provided thirty-two slides. The Panel noted GW Pharmaceuticals' detailed submission about the slides including that those provided by the complainant were not those used at the meeting. It was difficult in such circumstances to establish which set of slides was used. The complainant could not be contacted for more information. The Panel however noted that a photograph taken by GW Pharmaceuticals at the meeting of a particular slide appeared to be consistent with that slide as provided by the company as part of its response; both appeared to contain the header 'Cannabidiol is an investigational product and is not licensed in the EU'.

The Panel examined the slides provided by both parties and noted that while most of the 32 slides provided by GW Pharmaceuticals stated that cannabidiol was not EMA approved, the nine slides provided by the complainant did not. The Panel noted that the slides provided by GW Pharmaceuticals discussed cannabidiol, Phase III trial data including Dravet Syndrome and Lennox-Gastaut Syndrome and GW Pharmaceuticals' cannabidiol pharmaceutical production.

The Panel noted GW Pharmaceuticals' submission that the meeting in question was the legitimate exchange of medical and scientific information in response to an unsolicited enquiry about the development of cannabidiol. The Panel noted that the Code prohibited the promotion of a medicine prior to the grant of its marketing authorization; supplementary information stated that the legitimate exchange of medical and scientific information during the development of a medicine was not prohibited provided that this did not constitute promotion which was prohibited by the Code. The Panel queried whether a product subject to Phase III trials, and for which licence applications had been submitted, would be considered an investigational molecule or otherwise in development. The Panel noted that the GW Pharmaceuticals' slides included the proposed indications, usage and dosage. In the Panel's view and given the content of the presentations provided by each party, health professionals were likely to view Epidiolex as a pre-licence product. The Panel considered that its view was supported by the list of questions asked by those present which included questions about cost, shelf life, storage and others relevant to the product's use. There did not, on the information before the Panel, appear to be an exchange of medical and scientific information about the development of the product. In the Panel's view, the presentation could not take the benefit of the supplementary information in the Code.

With regard to GW Pharmaceuticals' submission that the presentation was provided in response to an unsolicited enquiry, the Panel noted that the Code provided an exemption to the definition of promotion stating that replies made in response to individual enquiries from members of the health professions or other relevant decision makers or in response to specific communications from them whether of enquiry or comment, were excluded from the definition of promotion, but only if they related solely to the subject matter of the letter or enquiry, were accurate and did not mislead and were not promotional in nature. The Panel noted that the exemption only applied to unsolicited enquiries, an enquiry made without any prompting from the company. If an enquirer subsequently

requested further information this could be provided and would be exempt from the Code provided the additional information met the requirements of this exemption. The Panel noted that when relying on this limited exemption in relation to a meeting about an unlicensed product, documentation was very important.

The Panel noted GW Pharmaceuticals' submission that the presentation was provided in response to an unsolicited verbal request from health professionals for a medical presentation on updated clinical data and properties of cannabidiol in December 2017 during a meeting between two managers representing GW Pharmaceuticals and two doctors from the hospital in question. The Panel noted that GW Pharmaceuticals provided some evidence in support of its position. The general points covered in the presentation provided by GW Pharmaceuticals appeared to be consistent with the points raised by the health professionals. When asked if the presentation was scientific or promotional in nature, one of the doctors stated that it was scientific in nature, as new scientific data which he/she had not seen before was shared. The doctor stated that he/she was particularly interested to hear more about study results, safety information, side-effects, efficacy and also to get an update on recent trial data, when market approval might be expected and whether prescriptions on a named patient basis might be a possibility. The Panel noted the list of 12 attendees. From the evidence before the Panel, it appeared that in requesting the meeting the two health professionals, rather than GW Pharmaceuticals, had decided that the content was appropriate for the small specialized departmental group.

Whilst the Panel had some concerns about the meeting, including the lack of formal documentation, it noted that based on the company's account there was no evidence that the meeting went beyond the original information requested by the two doctors. The Panel noted that the complainant bore the burden of proof and had not established that the meeting was promotional and not in response to an unsolicited request. On the evidence before it, the Panel considered that, on balance, GW Pharmaceuticals could take the benefit of the exemption of the definition of promotion in the Code in relation to unsolicited requests and therefore did not consider on the particular facts of this case, that the meeting promoted Epidiolex prior to the grant of its license as alleged. The Panel therefore ruled no breaches of the Code.

An anonymous non-contactable complainant who described him/herself as a consultant neurologist complained about the pre-licence promotion of Epidiolex (cannabidiol) by GW Pharmaceuticals at a hospital meeting in February 2018. An application for a marketing authorization had been submitted for its use as an adjunctive treatment for seizures associated with Lennox-Gastaut Syndrome and Dravet Syndrome.

COMPLAINT

The complainant submitted that he had attended a multi-disciplinary team meeting at a named hospital at which GW Pharmaceuticals hosted a presentation on Epidiolex treatment. Pictures of some of the slides were provided. The complainant stated that after the presentation, he/she was informed that Epidiolex was unavailable to prescribe as it was not currently licensed in the UK or Europe.

When writing to GW Pharmaceuticals it was asked to bear in mind the requirements of Clauses 3.1, 9.1 and 2 of the Code. The case preparation manager stated that Clause 15.2 might also be relevant.

RESPONSE

GW Pharmaceuticals noted that the anonymous complainant had provided little detail and while it was thus difficult to respond, it had nonetheless investigated the issues raised and was comfortable that the complaint had no basis. It trusted that the level of diligence was reflected in its detailed response.

GW Pharmaceuticals explained that in response to an unsolicited request and invitation by health professionals in December 2017, managers representing GW Pharmaceuticals' attended the named hospital in February 2018 to exchange scientific and medical information about the development of cannabidiol. There was no formal agenda but the intention of what would be addressed at the meeting was set out in emails between one of the managers (A) and health professionals at the hospital (copy provided) and contemporaneous notes. The purpose of the meeting was to present tailored and appropriate data on cannabidiol in response to the unsolicited request. There was no promotional intent. A full list of attendees was provided.

As part of its investigation, GW Pharmaceuticals had obtained statements (copies provided) from manager A, who arranged the meeting/presentation in question, and manager B who attended the presentation. The company also provided a signed summary/record of a telephone call on 23 March 2018 between the health professional who requested and attended the presentation in February, and two other senior employees from the third party organisation.

GW Pharmaceuticals submitted that manager (A) who had arranged the meeting, in particular had provided a rigorous and detailed account of the presentation, backed by robust supporting materials, including a number of records of his/her interactions with health professionals at, and prior to, the presentation. The manager had satisfied GW Pharmaceuticals that the presentation at issue was not promotional. The manager was highly experienced and qualified and, in GW Pharmaceuticals' view, an eminently sensible and conscientious medical affairs professional. He/she was fully aware of the Code and his/her responsibilities under it. His/her account was backed by: (i) contemporaneous

records of his/her communications with health professionals with whom he/she interacted as a result of unsolicited requests at a meeting with named health professionals in December 2017, and at the presentation in question; (ii) his/her contemporaneous photograph of the presentation slides used at the February meeting; (iii) the slides themselves; and (iv) briefing materials on which he/she was well-trained. Manager B's statement corroborated entirely manager A's detailed account. The summary/record signed by one of the health professionals further corroborated these accounts. Together these statements and the accounts and supporting materials provided a clear, comprehensive and credible account of the meeting on 7 February 2018 and the background to it.

GW Pharmaceuticals stated that it had re-assessed in the context of the complaint, all relevant material, procedures, processes and instructions which might pertain to the alleged events, including anything which might have prompted promotional statements to be made or promotional material to be presented in error. The briefing and training materials given to manager A, along with his/her account of any instructions he/she received, was also reviewed. Similarly, GW Pharmaceuticals had considered manager B's professional background, experience and training records provided in his/her statement. The slides which were presented at the February 2018 meeting had been reviewed, including photographic evidence of the same, along with manager A's detailed account and the corroborative accounts of manager B and a health professional. Any material, where relevant, was provided as exhibits to manager A's statement.

Having thoroughly investigated the complaint, GW Pharmaceuticals considered that the allegations were entirely unfounded; the company denied any wrong-doing or impropriety on its part or by its managers. A number of factual issues and inconsistencies in the complaint, as set out below, led the company to suspect that the complaint was unfounded and/or fabricated.

GW Pharmaceuticals submitted that it had never implicitly, or directly, promoted or encouraged the promotion of any unlicensed medicine, including Epidiolex. Indeed, the company considered that it went to particular lengths to ensure that the alleged claims would not happen even by reason of genuine error. In that regard GW Pharmaceuticals referred to statements by manager A which constituted the company's standard responses to enquiries on cannabidiol.

GW Pharmaceuticals stated that, unprompted, health professionals had requested a medical presentation on updated clinical data and properties of cannabidiol which was what was provided at the presentation. The request was corroborated by the email exchange between manager A and the requesting health professionals which stated: 'Thanks for your request to present an update on cannabidiol data and progress'.

According to GW Pharmaceuticals, the basis and nature of the presentation was clear from the email exchange and the disclaimer on slide 2 which stated; 'This slide deck is being presented following an unsolicited request from a healthcare professional'. One health professional also clearly confirmed that he/she and another health professional had invited GW Pharmaceuticals to make a presentation, the first health professional being 'particularly interested to hear more about study results, safety information, side effects, efficacy and also to get an update on recent trial data, when market approval might be expected and whether prescriptions on a named patient basis might be a possibility'.

Manager A stated 'Great care was taken to ensure that the presentation was balanced, noting trial design and balancing any efficacy data with safety data including laboratory findings, common adverse events and serious treatment emergent adverse events. In my view, the information presented was balanced, fair, objective and unambiguous, and was as stated, based on an up-to-date evaluation of the evidence available'. GW Pharmaceuticals stated that in its view the slides comprised scientific and medical information, genuine non-promotional information about GW Pharmaceuticals and its research interests and disease awareness information. One of the health professionals also agreed and stated that in his/her opinion 'The presentation and meeting were of a scientific nature as new scientific data was shared which he/she had not seen before'.

Following the presentation, manager A's contemporaneous notes from the meeting showed that there followed, from the health professionals, a series of specific and unsolicited queries about the data and properties of cannabidiol. GW Pharmaceuticals was satisfied from this material and accounts of attendees that the discussion/Q&A was non-promotional and that the presentation and any interactions around it were part of an entirely appropriate response to an unsolicited request aimed to legitimately exchange medical and scientific information.

GW Pharmaceuticals noted that although it was not expressed the complainant implied that he/she only became aware that Epidiolex was not licensed after the presentation. Although not stating exactly when he/she received the correct information, the complainant implied that during the presentation, and perhaps for some time after, he/she understood that cannabidiol was available to prescribe and licensed in the UK and Europe. GW Pharmaceuticals assumed either that the complainant alleged that he/she misunderstood the presentation and/or was misled by it.

GW Pharmaceuticals noted that manager A addressed this issue in depth in his/her statement. The company was comfortable from his/her and other attendees' accounts, and its review of supporting material, that it was simply implausible that anyone who had attended the presentation, even if only part of it, could have misunderstood, or worse, been misled, as to the licensing status of Epidiolex.

GW Pharmaceuticals noted that on slide 2 there was a large and prominent disclaimer which stated 'Cannabidiol is an investigational product and is not FDA or EMA approved, for any indication'; the licensing status could thus not be clearer. GW Pharmaceuticals understood that a third employee who presented the data spent quite some time bringing this message to the attention of attendees. Even if the complainant had arrived late and missed this slide, 21 out of 33 of the slides prominently displayed in clear and large font: 'Cannabidiol is an investigational product and is not licensed in the EU'. This warning was featured throughout the slides including on the first and concluding slides. The contemporaneous photograph which manager A took of the presentation showed that the wording was prominent and legible even at a distance. Thus, anyone who attended the presentation at least had the opportunity to see this warning.

GW Pharmaceuticals submitted that it had no reason to believe, on the basis of the employees' professional background, experience and training, that they would have orally provided incorrect information on the licensing status or introduced uncertainty. Indeed, it would have been problematic to introduce such uncertainty given the clarity of the words on the slides, and it would have required significant departure and contradiction which would have prompted queries from the attendees, especially as at least two of the health professionals had been expressly informed of the licensing status and availability at the meeting in December 2017 and again by email. From his/her signed statement, one of the health professionals was apparently in no doubt before and at the presentation that the product was not approved. GW Pharmaceuticals thus rejected entirely that misleading information about the status and availability of cannabidiol was presented at the meeting in February.

GW Pharmaceuticals stated that it was satisfied that it and its third party had discharged their duties to provide appropriate and comprehensive briefing and training in order to enable managers A and B and the speaker to represent GW Pharmaceuticals in their respective roles to high standards of ethical conduct fully in compliance with the Code.

Finally, GW Pharmaceuticals submitted that it had significant concerns with aspects of the complaint itself, which it considered went to its credibility.

GW Pharmaceuticals noted that the complainant's allegation that GW Pharmaceuticals or its representatives hosted the meeting, was inaccurate. From the statements and supporting information, and in particular the email exchange leading up to the meeting, it was clear that:

- the presentation was in response to an unsolicited request from two health professionals;
- the two health professionals invited the GW Pharmaceuticals representatives and not the other way around;
- the health professionals invited GW Pharmaceuticals to their premises, and no GW Pharmaceuticals or any other premises arranged by GW Pharmaceuticals or its representatives were offered and
- the health professionals provided the facilities whereas the representatives only took an electronic copy of the slide deck on their devices.

GW Pharmaceuticals further noted that although the complainant alleged that GW Pharmaceuticals hosted a presentation on Epidiolex, that brand name was not used in the presentation or contemporaneous notes; these all referred to cannabidiol or CBD only by its non-proprietary name. That was reflected in the company's briefing and training materials.

For the reasons stated above, GW Pharmaceuticals considered that it was implausible that the complainant, if he/she attended the presentation, could have been confused as to the licensing status of Epidiolex or informed of the correct status only after the event.

GW Pharmaceuticals alleged that the complainant was either not at the presentation or had made fraudulent allegations, because:

- The slide deck presented contained a licensing warning/header on most of the slides. However, the photographs of the slides which were attached to the complaint did not contain that wording. Although a number of the slides had been cropped, if these were true contemporaneous photographs of the presented deck, at least five were extended enough to have shown this wording (namely photographs of slides 3, 4, 6, 21 and 27) but they did not.
- In addition, the presenter's name and role were clearly located below the title on slide 1 of what was presented but were obviously missing from the photograph which purported to be of this slide.
- The photographs therefore could not be contemporaneous.
- The selective nature of the photographs both in terms of excluding the disclaimer slide and by possibly doctoring the slides to remove the warning, undermined the credibility of the complaint and the complainant.
- GW Pharmaceuticals stated that neither it nor its third party had found a slide deck which matched the photographs. The company understood that the slides were not provided in electronic or hard copy to attendees in advance, during or at the presentation. There was no evidence that the slides or any related decks were shared beyond GW Pharmaceuticals and its third party. GW Pharmaceuticals stated that it was still investigating but could state at this stage that the photographs were not of the slides which were presented and must have been obtained and/or doctored improperly, if not illegally.
- The photographs were poor quality and contained the type of glare which would normally appear when taking photographs of an electronic device such as tablet or laptop screen at close range, and not a large presentation screen. In that regard, GW Pharmaceuticals compared managers A's contemporaneous photograph and statement. Also the usual tablet/laptop black surround could be seen in a number of the photographs whereas

the presentation surround was clearly grey/white and irrespective of the quality of the images, it was highly unlikely that there would be such a stark change or that such contrast difference would not have caused the slides to also be blacked out. As well as further supporting the company's submission that the photographs were not of the presented slides, GW Pharmaceuticals stated that these factors also caused it to believe that the photographs were taken of a set of slides on a laptop or tablet device and not at the presentation.

GW Pharmaceuticals stated that, in its view, the only conclusion must be that the complainant did not attend the presentation, and/or had improperly or illegally obtained copies of the slides or created or doctored them to appear like those presented, and/or had fraudulently presented these as contemporaneous or true copies of the slides which were presented. GW Pharmaceuticals did not currently know the motivation for this series of illicit acts but was deeply troubled by them.

GW Pharmaceuticals stated that in its view the complaint was without merit and implausible, if not fraudulent, and that it should be dismissed by the Panel. However, it also appreciated that the anonymity of the complainant and paucity of evidence in support of what was in effect one person's word, presented the Panel particular difficulties in adjudicating this matter. With this in mind, GW Pharmaceuticals referred the Panel to the summary provided in its response to Case AUTH/3014/1/18 on the appropriate standard when adjudicating complaints involving conflicting claims, namely the 'balance of probabilities'.

Considering the points raised in this summary and applicable case law, GW Pharmaceuticals submitted that its version of events was more probable than that of the complainant. GW Pharmaceuticals had provided substantial evidence and careful assessment of the materials at issue and relevant events. Conversely, the complainant's allegations and account of events were simply not plausible. GW Pharmaceuticals stated that to its knowledge the complainant had provided no credible evidence to discharge the burden of proof on the balance of probabilities assessment. Indeed, for the reasons set out above, GW Pharmaceuticals considered that the material attached to the complaint should be viewed at best with caution, if not as misrepresentative or even fraudulent. Therefore this 'evidence', rather than supporting the complainant's allegations, entirely undermined his/her credibility.

To conclude, GW Pharmaceuticals submitted that it was impossible on a common sense view to find against the company on the basis of the simple, brief complaint, given its flaws and the weight of contradictory evidence submitted by GW Pharmaceuticals. GW Pharmaceuticals thus denied any breach of the Code, including Clauses 3.1, 9.1 and 2 and also 15.2 and 15.9 if these are considered by the Panel.

GW Pharmaceuticals noted that the Authority had asked for certificates approving the material in question but as it was non-promotional it did not require certification under the Code. The supplementary information to Clause 14.3 required that 'other material…which is not promotional *per se*, such as corporate advertising…should be examined to ensure that it does not contravene the Code or the relevant statutory requirements'. GW Pharmaceuticals confirmed that it and/or its third party had examined all applicable materials at issue and found them to be compliant. In particular, manager A, who was a highly experienced medical affairs professional and qualified Code signatory, arranged the content of the presentation, examined the presentation material, supervised the presentation, and participated in post-presentation discussions, and did not consider there had been any breach of the Code.

GW Pharmaceuticals stated that a marketing authorization application for Epidiolex was submitted on 29 December 2017 and as and until the European Commission issued its marketing authorization, it remained unlicensed in the EU.

FURTHER INFORMATION FROM GW PHARMACEUTICALS

GW Pharmaceuticals stated that when first advised of Case AUTH/3014/1/18, it and its third party immediately investigated the circumstances and merits of the complaint; both companies had serious misgivings about the legitimacy of the complaint, as well as concerns over the inaccuracies and inconsistencies in the complainant's brief account. GW Pharmaceuticals had continued to investigate the matter beyond the submission date of the response set for Case AUTH/3014/1/18. When GW Pharmaceuticals was advised of the second complaint, (Case AUTH/3024/3/18) it again immediately investigated the matter, independently of the ongoing investigation in Case AUTH/3014/1/18. Although investigations were still ongoing, GW Pharmaceuticals provided its outline finding below.

GW Pharmaceuticals submitted that rather than two unrelated incidents, leading to separate complaints by individual and unrelated complainants, the complaints were entirely fabricated by the same individual. GW Pharmaceuticals suspected, but was investigating, the position of the complainant and details were provided including that the complaints were made anonymously and without the possibility for follow-up because they were disingenuous. The complaints were also each entirely implausible for the reasons set out above and were made some time after the alleged events.

In relation to this case, GW Pharmaceuticals was especially concerned that the photographs provided by the complainant were not of the slides presented in February 2018, as he/she claimed. In particular, the slides provided by the complainant did not match any slide deck found so far and so must have been doctored without consent, possibly on a personal device. GW Pharmaceuticals considered that the omission of the licensing status of cannabidiol from all of the slides and the selective presentation were intended to present a particularly egregious impression of the company and its representatives.

With this in mind, GW Pharmaceuticals had hoped to be able to provide the Panel with a signed statement from the person who presented the slides. That person prepared a statement (copy enclosed) in March 2018 and indicated that he/she was happy to sign it; he/she also provided a copy of the slides presented. However, he/she then declined to sign it or any statement or to attest to the authenticity of the slide deck which he/she stated he/she presented in February 2018. Manager A stated, to the best of his/her knowledge and belief, that the slide deck provided by GW Pharmaceuticals was the slide deck which was presented. GW Pharmaceuticals stated that it did not yet know with certainty why the presenter appeared troubled when confronted by inconsistencies between the slides presented and those in the complaint, but the Panel could draw whatever inferences it wished.

GW Pharmaceuticals noted that Case AUTH/3029/4/18 had the same troubling inconsistencies in the slide deck as seen in Case AUTH/3024/3/18. GW Pharmaceuticals referred to its response to Case AUTH/3029/4/18 and noted that the Panel should be aware that the complainant was aware that the slides which he/she attached to an email in February 2018 were not those presented and were in fact created by the complainant in February 2018.

Bearing in mind the above, and from the company's knowledge of the circumstances and individuals involved, GW Pharmaceuticals was satisfied that the three complaints were without merit and were fraudulent.

PANEL RULING

The Panel noted that the complainant was anonymous and non-contactable and that, as set out in the introduction to the Constitution and Procedure, complainants had the burden of proving their complaint on the balance of probabilities. Anonymous complaints were accepted and, like all complaints, judged on the evidence provided by the parties. The Panel noted that as the complainant was non-contactable it was not possible to ask him/her for further information.

The Panel noted that the company's response implied that it was aware of the complainant's identity. The Panel noted that from the PMCPA's perspective, the complainant was anonymous and non-contactable.

The Panel noted a third party organisation employed manager A and B to represent GW Pharmaceuticals. The Panel noted that it was an established principle under the Code that companies were responsible for the acts/omissions of third parties acting on their behalf.

The Panel noted the complainant's allegation that Epidiolex was promoted prior to the grant of its marketing authorization at a hospital meeting on 7 February 2018. The Panel noted that an application for a marketing authorization was submitted to the European Medicines Agency (EMA) on the 29 December 2017; its proposed indications were as adjunctive treatment for seizures associated with Lennox-Gastaut Syndrome and Dravet Syndrome, each forms of child onset epilepsy.

The Panel noted that the content of the slides provided by the parties in relation to the meeting on 7 February differed. The complainant provided photographs of nine slides, some of which had been cropped such that the full slide could not be seen, whilst GW Pharmaceuticals provided thirty-two slides (ref VV-MED-01262). The Panel noted GW Pharmaceuticals' detailed submission about the slides provided by the complainant including that they were not those used at the meeting in question. It was difficult in such circumstances to establish which set of slides was used. The complainant could not be contacted for more information. The Panel noted its comments above about the burden of proof. The complainant had not provided any additional evidence on this point. The Panel however noted that a photograph taken by GW Pharmaceuticals at the meeting in question of a particular slide appeared to be consistent with slide 10 in the presentation provided by GW Pharmaceuticals as part of its response; both appeared to contain the header 'Cannabidiol is an investigational product and is not licensed in the EU'. The Panel noted the company's submission that the employee who presented the material at issue had prepared but ultimately declined to sign a statement.

The Panel examined the slides provided by both parties. The Panel noted that the second slide of the presentation 'GW Pharmaceuticals and Cannabidiol Oral Solution' provided by GW Pharmaceuticals stated that 'Cannabidiol was an investigational product and was not FDA or EMA approved, for any indication. All labelling language was subject to change'. This slide was not included in those provided by the complainant. The Panel noted that the header referred to above 'Cannabidiol is an investigational product and is not licensed in the EU' appeared on 21 of the 32 slides provided by GW Pharmaceuticals. However, those provided by the complainant did not contain such wording including five slides which showed that part of the slide where the header appeared in the equivalent GW Pharmaceuticals' version. The Panel noted that the slides provided by GW Pharmaceuticals discussed cannabidiol, Phase III trial data including Dravet Syndrome and Lennox-Gastaut Syndrome and GW Pharmaceuticals' cannabidiol pharmaceutical production.

The Panel noted that GW Pharmaceuticals submitted that the meeting in question in February 2018 was the legitimate exchange of medical and scientific information in response to an unsolicited enquiry about the development of cannabidiol. The Panel noted that Clause 3.1 prohibited the promotion of a medicine prior to the grant of its marketing authorization; supplementary information stated that the legitimate exchange of medical and scientific information during the development of a medicine was not prohibited provided that this did not constitute promotion which was prohibited by Clause 3 or any other clause. The Panel queried whether a product subject to Phase III trials and for which a licence had been applied for in the US and Europe would be considered an investigational

molecule or otherwise in development. The Panel noted that the GW Pharmaceuticals' version of the slides presented included the proposed indications, usage and dosage. In the Panel's view and given the content of the presentations provided by each party, health professionals were likely to view Epidiolex as a pre-licence product. The Panel considered that its view was supported by the list of questions asked by those present which included questions about cost, shelf life, storage and others relevant to the product's use. There did not, on the information before the Panel, appear to be an exchange of medical and scientific information about the development of the product. In the Panel's view the presentation could not take the benefit of the supplementary information to Clause 3.1.

The Panel noted that GW Pharmaceuticals also submitted that the presentation was provided in response to an unsolicited enquiry. The Panel noted that Clause 1.2 provided an exemption to the definition of promotion stating that replies made in response to individual enquiries from members of the health professions or other relevant decision makers or in response to specific communications from them whether of enquiry or comment, were excluded from the definition of promotion, but only if they related solely to the subject matter of the letter or enquiry, were accurate and did not mislead and were not promotional in nature. The Panel noted that the exemption only applied to unsolicited enquiries, an enquiry made without any prompting from the company. If an enquirer subsequently requested further information this could be provided and would be exempt from the Code provided the additional information met the requirements of this exemption. The Panel noted that when relying on this limited exemption in relation to a meeting about an unlicensed product, documentation was very important.

The Panel noted GW Pharmaceuticals' submission that the presentation was provided in response to an unsolicited verbal request from health professionals for a medical presentation on updated clinical data and properties of cannabidiol in December 2017 during a meeting between managers A and B and two doctors from the hospital. The Panel noted that GW Pharmaceuticals provided some evidence in support of its position. Manager A's statement and his/her notes of the meeting in December 2017 indicated that the health professionals had requested that GW Pharmaceuticals present at the departmental multi-disciplinary meeting on cannabidiol and clinical data. A follow-up email from manager A to the two doctors referred to their request to present an update on cannabidiol data and progress at the weekly department meeting and asked for specific questions around cannabidiol to ensure that the company presented the most pertinent information. The Panel queried whether it could be argued that this email was soliciting enquiries, however it did not appear that either doctor responded with any specific topics to be covered. The general points covered in the presentation provided by GW Pharmaceuticals appeared to be consistent with the points raised by the health professionals at the earlier meeting in December. That the meeting in February resulted from an unsolicited request was also corroborated by a signed statement from manager B who attended the meetings in December 2017 and in February 2018. In addition, a signed transcript of a telephone conversation with one of the health professionals confirmed, in response to a question about whether GW Pharmaceuticals had suggested the meeting or whether it had been requested by him/herself and the other doctor, that he/she and the other doctor had asked GW Pharmaceuticals to arrange the presentation. One of the doctors noted that whilst he/she did not remember whether or not the presentation included any disclaimers that the product was not yet licensed, that would not be something he/she would have paid special attention to as he/she already knew that it was not. When asked if the presentation was scientific or promotional in nature, the doctor stated that it was scientific in nature, as new scientific data which he/she had not seen before was shared. The doctor stated that he/she was particularly interested to hear more about study results, safety information, side-effects, efficacy and also to get an update on recent trial data, when market approval might be expected and whether prescriptions on a named patient basis might be a possibility.

The Panel noted the list of 12 attendees. From the evidence before the Panel, it appeared that in requesting the meeting the two health professionals, rather than GW Pharmaceuticals, had decided that the content was appropriate for the small specialized departmental group.

Whilst the Panel had some concerns about the meeting, including the lack of formal documentation, it noted that based on the company's account there was no evidence that the meeting went beyond the original information requested by the two doctors. The Panel noted that the complainant bore the burden of proof and had not established that the meeting was promotional and not in response to an unsolicited request. On the evidence before it, the Panel considered that, on balance, GW Pharmaceuticals could take the benefit of the exemption of the definition of promotion at Clause 1.2 in relation to unsolicited requests and therefore did not consider on the particular facts of this case, that the meeting promoted Epidiolex prior to the grant of its license as alleged. The Panel therefore ruled no breach of Clause 3.1 and subsequently no breach of Clauses 15.2, 9.1 and 2.

The Panel noted that the case preparation manager had raised Clause 15.9. The Panel did not consider that the complainant's allegation raised a Clause 15.9 matter and therefore ruled no breach of Clause 15.9.

Complaint received **12 March 2018**

Case completed **18 October 2018**