COMPLAINANT v GW PHARMACEUTICALS

Arrangements for a meeting, alleged promotion of Epidiolex and unapproved slides

A contactable complainant complained about the provision of inappropriate hospitality and the use of slides about cannabidiol (Epidiolex). Epidiolex was currently unlicensed, although an application for its marketing authorization had been submitted for its use as an adjunctive treatment for seizures associated with Lennox-Gastaut Syndrome and Dravet Syndrome.

The complainant stated that during a customer visit, an employee from a third party organisation engaged by GW Pharmaceuticals took a named health professional to lunch during which topics unrelated to epilepsy were discussed. The health professional did not treat epilepsy or paediatric epilepsy and was therefore according to the complainant not a relevant customer for GW Pharmaceuticals and lunch was provided despite there being no educational content to the meeting.

The complainant further stated that he/she was informed verbally by a doctor that he/she would complain to the PMCPA about the pre-licence promotion of a medicine in relation to a presentation to health professionals the complainant noted that a slide deck was approved by GW Pharmaceuticals but was subsequently amended before the meeting and as it had not been certified a breach was alleged. The complainant also stated that the presentation was solicited by the third party employee upon discussion with the meeting organisers. The complainant alleged that this type of proactive meeting would be considered to be 'promotional' before a market authorisation.

The detailed response from GW Pharmaceuticals is given below.

The Panel noted that the parties' accounts of the meeting differed.

The Panel noted GW Pharmaceuticals' submission that the named health professional was a relevant health professional in the field of epilepsy. The Panel further noted that an email from the third party employee to the health professional to arrange the meeting referred to the chance to catch up and understand his/her perspective on needs and treatments for hard to treat epilepsies and paediatric syndromes. In response, the health professional did not refer to the subject matter of the meeting but stated that it would be a pleasure to meet an old friend. According to GW Pharmaceuticals, matters discussed included the company's ethos in helping patients with complex epilepsies, discussion of a corporate brochure and his/her clinical interactions with paediatric neurologists and the burden of epilepsy in his/her patient population.

The Panel considered both the totality of the evidence in relation to the named health professional's professional interests and the subject matter of the meeting as described above and considered that he/she was a relevant health professional. The company had not failed to maintain high standards in this regard. No breach was ruled.

The complainant was concerned that hospitality had been provided without any educational content. The cost of the meal was £35.35 for three persons. The Panel noted the content of the meeting which lasted for approximately 1 hour according to GW Pharmaceuticals and 20-40 minutes according to the named health professional. The Panel noted that the complainant bore the burden of proof. Despite serious concerns about governance in relation to the meeting, based on the evidence and the very narrow allegation, the Panel did not consider that the complainant had established on the balance of probabilities that there had been no educational content and thus ruled no breaches of the Code including no breach of Clause 2.

The Panel noted that Case AUTH/3024/3/18 and the present case, Case AUTH/3029/4/18 contained similar allegations with regard to a presentation to a group of doctors at a hospital in February 2018 which the complainant alleged promoted a product prior to the grant of its marketing authorisation. The Panel considered that its rulings and comments in Case AUTH/3024/3/18 were relevant here. The Panel noted that there were some differences between Case AUTH/3024/3/18 and the present case.

In Case AUTH/3024/3/18 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 during a meeting in December 2017 between two employees working on behalf of GW Pharmaceuticals and two hospital doctors. The Panel noted that GW Pharmaceuticals provided some evidence in support of its position. The Panel queried whether it could be argued that an email to the hospital doctors 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 2017. That the meeting in question (February 2018) resulted from an unsolicited request was also corroborated by further information provided.

In the previous case, Case AUTH/3024/3/18, 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 taken the decision that the content was appropriate for the small specialized departmental group.

Based on the particular facts of Case AUTH/3029/4/18 and 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 relation to unsolicited requests and the presentation did not promote Epidiolex prior to the grant of its licence. The Panel ruled no breaches of the Code including Clause 2.

The Panel noted that a further allegation in the present case, Case AUTH/3029/4/18, concerned the slides being amended following approval by GW Pharmaceuticals, and that the amended version was not certified. The Panel noted GW Pharmaceuticals' submission that as the slides were non-promotional GW Pharmaceuticals did not consider that they required certification under the Code. The Panel noted its comments above with regard to GW Pharmaceuticals being able to take the benefit of the exemption from the definition of promotion in relation to unsolicited requests which did not require certification and the Panel therefore ruled no breaches of the Code including Clause 2.

A contactable complainant referred to an email from a third party which represented GW Pharmaceuticals. The complainant alleged that the email concerned the provision of inappropriate hospitality and the use of slides about cannabidiol (Epidiolex). Epidiolex was currently unlicensed, although an application for its 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 stated that during a customer visit with a named health professional an employee from a third party engaged by GW Pharmaceuticals, asked the health professional if he/she would like to have lunch at a local café. During the lunch, attended by the complainant, the health professional discussed topics unrelated to epilepsy and stated that he/she did not treat epilepsy or paediatric epilepsy. The complainant maintained that the health professional was not a relevant customer for GW Pharmaceuticals and there was no educational content to the meeting. The employee paid for the lunch even though there was no educational content. The complainant alleged a breach of Clause 22.1.

The complainant further stated that he/she was informed verbally by a doctor that he/she would complain to the PMCPA about the pre-licence promotion of a medicine in relation to a presentation to health professionals at a hospital in February 2018. The complainant noted that a slide deck was approved by GW Pharmaceuticals but was subsequently amended before the meeting. The complainant also stated that the presentation was solicited by the employee upon his/her discussion with the meeting organisers. The complainant alleged that this type of proactive meeting would be considered promotional, before the grant of a market authorisation in breach of Clause 3.1.

Additionally, as the slides were amended they had not been certified and so the complainant also alleged a breach of Clause 14.1.

When writing to GW Pharmaceuticals, the Authority asked it to consider the requirements of Clauses 15.2, 15.9, 9.1 and 2 in addition to Clause 22.1 as cited by the complainant with regards to the meeting and Clauses 3.1, 9.1, 14.1, 15.2 and 15.9 with regard to the slides used at the meeting in February 2018.

RESPONSE

GW Pharmaceuticals understood that to the extent that the meeting in February 2018 was said to be pre-licence promotion of a medicine, that it would be treated as falling under Case AUTH/3024/3/18. GW Pharmaceuticals responded below to each of the remaining points raised by the PMCPA, however, it considered it important to raise certain matters at the outset.

GW Pharmaceuticals wished to make it clear that it took compliance extremely seriously and strove at all times to operate responsibly, ethically and professionally. The company expected and took steps to ensure that all of its employees, and those acting on its behalf, always adhered to the same high standards of ethical conduct imposed by applicable regulatory regimes, including the Code, in line with best practice expected of a responsible corporate undertaking. On being advised of the complaint, GW Pharmaceuticals and its third party immediately launched in-depth investigations. GW Pharmaceuticals appreciated that it could be difficult to investigate and respond to this type of anonymous complaint, but after careful investigation it was comfortable that the complaint had no basis.

As part of its investigations GW Pharmaceuticals had obtained statements including from the employee of the third party and the named health professional.

GW Pharmaceuticals submitted that the third party employee in particular had provided a rigorous and detailed account of what happened at both meetings, backed by robust supporting materials, including a number of records of interactions with health professionals at, and before, the meetings and presentation. Together, these statements and the accounts, and the supporting materials provided with them, provided a clear, comprehensive and credible account of both events and their background.

GW Pharmaceuticals stated that it had taken particular care to re-assess 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 given rise to a representative inappropriately providing hospitality, soliciting, inappropriate amendment of materials, making promotional

statements or presenting promotional material in error. The company had reviewed in the context of the complaint the briefing and training materials. It had also considered the statements and their supporting documents. Further, GW Pharmaceuticals had reviewed the slides which were presented in February, including photographic evidence of the same, along with the detailed account including those provided in response to AUTH/3024/3/18.

The December 2017 lunchtime meeting at a café local to the hospital was attended by three people including the complainant. Full details of the meeting were provided in statements and supporting materials.

In summary, the third party employee knew the health professional as a relevant health professional in the field of epilepsy due to professional interactions while with another company active in the epilepsy field and considered it appropriate to re-introduce himself/herself in his/her new role. The support for this reasoning was provided.

The third party employee emailed the health professional to arrange to catch up and understand his/her perspective on needs and treatment for hard to treat epilepsies and paediatric syndromes. They went to lunch at a nearby café recommended by the health professional. As evidenced by respective accounts, the discussion was largely scientific and about the treatment of patients with complex epilepsies. They also discussed GW Pharmaceuticals and the third party employee responded to unsolicited questions from the health professional on cannabidiol. The interaction was fully documented including in summary reports. The cost of the lunch equated to a spend of roughly £11.80 on the health professional attendee. The meeting lasted around one hour. This summary of events was fully supported by the health professional's account.

GW Pharmaceuticals stated that in response to an unsolicited request and invitation by health professionals, various employees attended the hospital in February 2018 to exchange scientific and medical information about GW Pharmaceuticals' research interests and 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 the third party employee and health professionals at the hospital and contemporaneous notes. The purpose was to present tailored and appropriate data on cannabidiol in response to an unsolicited request. There was no promotional intent. A full list of attendees was provided.

GW Pharmaceuticals noted that the PMCPA had requested a copy of the approved slide deck and of the slide deck amended and used at the meeting. This request raised several issues that needed to be addressed upfront:

(i) **Approval of the slide deck:** as the slides were non-promotional GW Pharmaceuticals did not consider that they required 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'. The employee of the third party who was highly experienced arranged the content of the presentation, and along with another experienced and previous Code signatory who examined the slides. Neither considered, then or now, that there had been any breach of the Code.

(ii) **The slide deck that was used:** The employee of the third party provided a copy of the slide deck that he/she believed was presented, based on his/her recollection of the slides that he/she reviewed before the presentation, and took a contemporaneous photograph of one of the slides during the presentation which was consistent with these slides. Finally, although there was some confusion in the complainant's accounts, these were the slides which the complainant most recently and after some consideration, provided as the slides which were presented.

(iii) **The slide deck:** GW Pharmaceuticals stated that the complainant presented the slides, not the third party employee as shown in a contemporaneous photograph of the presentation. The slides which the complainant provided had his/her name and title on them; they were presented using his/her laptop. The complainant also confirmed that he/she presented the slides and that he/she, or at least he/she in collaboration with the third party employee, added his/her name and title (see below).

(iv) **Amendment of the slide deck by the third party employee:** Although this person amended the slide deck, and ultimately examined and approved it, these amendments were made jointly with the complainant, taking into account any concerns he/she had with the material on the morning of the meeting eg removing a data set with which the complainant was uncomfortable. Although the complainant's accounts were confused, the complainant confirmed that he/she amended the slides, in particular he/she added his/her name and title. These amendments were consistent with the slides which the complainant ultimately provided.

GW Pharmaceuticals stated that it was satisfied that all the circumstances of the meeting in December 2017 were entirely appropriate: the reason for and purpose of the meeting was to discuss with a relevant health professional the scientific and technical information about the treatment of complex epilepsies, the health professional was entirely appropriate and relevant to this aim, there was a short meeting conducive to this aim and, given the time of day, it was appropriate to go to a nearby café for lunch especially in light of the busy schedule and their valuable time. The content of the discussion was appropriate and the hospitality was secondary to the scientific content of the meeting and limited to subsistence only. This account was backed by the account of the health professional.

GW Pharmaceuticals stated that it was also satisfied that the presentation on 7 February 2018 was not

promotional in form or content. The employee of the third party did not solicit the meeting. His/her account was backed by: (i) contemporaneous records of his/her communications with health professionals with whom he/she interacted with as a result of unsolicited requests at another meeting and at the presentation at the meeting in question; (ii) his/her contemporaneous photograph of the February 2018 meeting which showed presentation slides; (iii) the slides themselves; and (iv) briefing materials upon which he/she was well-trained. The various statements etc provided corroborated the accounts. GW Pharmaceuticals considered that the amendments made to the slide deck, including in collaboration with the complainant, and the slides which were presented, were appropriate and did not breach the Code.

GW Pharmaceuticals stated that, in its view, the employee of the third party was highly experienced, had previously been a Code signatory and was fully aware of the Code and his/her responsibilities under it.

Having thoroughly investigated the complaint as set out above, GW Pharmaceuticals considered that the complainant's allegations were unfounded; it denied any wrongdoing or impropriety on the part of the company or its representatives. There were also many factual issues and inconsistencies in the complaint which led GW Pharmaceuticals to suspect that the complaint was unfounded and/or fabricated. GW Pharmaceuticals made a very detailed submission including about the complainant including his/her credibility and what the company considered to be his/her role in relation to the subject matter of the complaint.

Alleged promotion via solicitation

As to solicitation of the meeting in February 2018 which might constitute promotion GW Pharmaceuticals noted that the health professionals requested, unprompted, a 'medical presentation' on the updated clinical data and properties of cannabidiol. This was what was provided at the presentation. The request was corroborated by the email chain between the employee of the third party and the requesting health professionals which stated: 'Thanks for your request to present an update on cannabidiol data and progress'. There was clearly no solicitation.

The basis and nature of the presentation was clear from the above mentioned email chain and the disclaimer on slide 2 which stated 'This slide deck is being presented following an unsolicited request from a healthcare professional' '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.

In relation to the materials which were presented, there was only a slide deck. 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. The information presented was balanced, fair, objective and unambiguous, and was as stated, based on an up-to-date evaluation of the evidence available'. 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 at the hospital agreed and stated that 'the presentation and meeting were of a scientific nature as new scientific data was shared to which he/she had not seen before.

Following the presentation, there followed from the health professionals a series of specific and unsolicited queries concerning the data and properties of cannabidiol. Again, GW Pharmaceuticals was satisfied from this material and accounts of attendees that the discussion/Q&A was non-promotional and there was no element of solicitation.

GW Pharmaceuticals stated that it was satisfied that the presentation and any interactions around it, were part of an appropriate response to an unsolicited request aimed to legitimately exchange medical and scientific information, and not promotional.

Implied allegation by a doctor of promotion

Although GW Pharmaceuticals noted that the allegation about the content of the slide decks would be separately addressed, the complainant stated that a doctor informed him verbally that he/she would complain about the promotion of a medicine before it had a marketing authorization. It was not clear when this interaction took place and very sparse information was provided to assist the investigation, but the complainant stated that this interaction was in reference to the presentation in February. GW Pharmaceuticals did not consider that this was credible.

GW Pharmaceuticals was comfortable from accounts of attendees 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 cannabidiol.

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'. In GW Pharmaceuticals' view, the licensing status could not be more clear. GW Pharmaceuticals understood that the complainant spent quite some time bringing this message to the attention of attendees. Even if the concerned doctor had missed slide 2, the following wording was prominently displayed in clear and large font on 21 out of 33 presentation slides: '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 ('Thanks') slides. The photograph taken of the presentation contemporaneously showed that

the wording was prominent and legible even at a distance. Anyone who attended the presentation at least had the opportunity to see this warning.

Further, GW Pharmaceuticals stated that it had no reason to believe, on the basis of the GW/third party representatives' professional background, experience and training, that they would have orally provided incorrect information on the licensing status or introduced uncertainty. Indeed to do so would have been problematic given the clarity of the wording on the slides; 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 in the previous meeting and again by email. One of the health professionals was apparently in no doubt before and at the presentation that the product was unapproved.

GW Pharmaceuticals rejected any allegation or implication that misleading information as to the status and availability of cannabidiol, or any promotional content, was presented at the meeting on 7 February 2018 which could have caused any attendee to state that they would complain to the PMCPA. GW Pharmaceuticals considered that the interaction was entirely fabricated.

Representatives' high standards and training

GW Pharmaceuticals stated that it was satisfied that it and the third party had discharged their duties to provide appropriate and comprehensive briefing and training to enable its representatives to meet high standards of ethical conduct in compliance with the Code. This also applied to the complainant. However, neither GW Pharmaceuticals nor the third party could, no matter how robust their systems and training, control and prevent individuals from making spurious allegations.

Standard of proof

GW Pharmaceuticals considered that the complaint was unmerited and implausible, if not fraudulent, and that it should be dismissed. However, the company appreciated that the apparent anonymity of the complainant and paucity of evidence in support of what was, in effect, one person's word, presented the Panel with particular difficulties in adjudicating this matter. In that regard, GW Pharmaceuticals noted the appropriate standard when adjudicating complaints involving conflicting claims, namely the 'balance of probabilities'.

GW Pharmaceuticals further noted that the burden of proof in the civil litigation context provided 'the standard to be attained in most cases is that the court must be satisfied "on a balance of probabilities' that what the client had alleged was correct'. In Miller v Minister of Pensions [1947] 2 All E.R. 372, QBD, Denning J. explained this as follows:

> 'If the evidence is such that the tribunal can say "We think it more probable than not", the burden is discharged, but if the probabilities are equal, it is not… In essence, in order to satisfy the judge that one party's version of the events is the version to be accepted, the judge has to be convinced that this version is more likely than not to be true-that the balance of evidence is tilted in the client's favour. If this were to be expressed in simple mathematical terms, at least a 51 per cent probability in favour of the client must be demonstrated, as suggested by Lord Simon in Davies v Taylor [1974] A.C. 207, HL (at p.219). If, on the other hand, the client's version is just as probable as the opponent's version, the client has failed to discharge the burden of proof.'

GW Pharmaceuticals noted that the Appeal Board considered the burden of proof in Case AUTH/2572/1/13 where it stated that where 'it is not always clear how/whether the material supported the complainant's allegation … the Appeal Board [has] to decide how much weight to attach to this evidence'. In that case, the Appeal Board had before it emails and excerpts from published papers which it ruled were insufficient evidence and did not provide a 'fair and balanced reflection of the evidence available at the time'. The Appeal Board also made it clear that where the complainant failed to marshal sufficient evidence to discharge the burden of proof, there should not be a ruling of a breach.

In Case AUTH/2824/2/16 the Panel considered whether there was sufficient evidence to substantiate the allegation that company representatives went to a named location contrary to the terms of a verbal undertaking. The Panel found there was no evidence to substantiate the allegations and therefore no breaches were ruled. The essence of that case demonstrated the difficulty of substantiating an event where there was competing anecdotal or hearsay evidence. Allegations should be substantiated. Such allegations were not substantiated in that case nor were they, in GW Pharmaceuticals' view, substantiated in this case.

That reflected a general and widely-acknowledged strand in the law of evidence that 'the weight of evidence depends on the rules of common sense' (R. v Madhub Chunder (1874) 21 W.R Cr. 13 at 19 (Ind) per Birch J). GW Pharmaceuticals referred, in that regard, to the summary provided in its response to Case AUTH/3014/1/18 on the appropriate standard when adjudicating complaints involving conflicting claims, ie the 'balance of probabilities'.

Considering the points raised above and applicable case law, GW Pharmaceuticals considered that its version of events was clearly more probable than that put forward by 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. The complainant had provided no credible evidence to discharge the burden of proof on the balance of probabilities assessment. Indeed, as set out above, slides provided by the complainant

should be viewed, at best with caution, if not as being fraudulent. Therefore this 'evidence', rather than supporting the complainant's allegations, undermined his/her credibility.

GW Pharmaceuticals concluded that it was impossible on a common sense view to find against GW Pharmaceuticals on the basis of the simple, brief and false allegations put forward by the complainant, given its flaws and the weight of contradictory evidence and material submitted by the company.

GW Pharmaceuticals denied any breach of the Code.

FURTHER INFORMATION FROM GW PHARMACEUTICALS

GW Pharmaceuticals stated that on being advised of Cases AUTH/3014/1/18, AUTH/3024/3/18 and AUTH/3029/4/18, it and its third party immediately investigated the respective circumstances and merits of each complaint. Both GW Pharmaceuticals and the third party companies had serious misgivings about the legitimacy of the complaints, as well as concerns over the inaccuracies and inconsistencies in the complainants' accounts. Further details were supplied.

PANEL RULING

The Panel noted that the parties' accounts differed. The Panel noted the difficulty in dealing with complaints based on one party's word against the other; it was often impossible in such circumstances to determine precisely what had happened. The introduction to the Constitution and Procedure stated that a complainant had the burden of proving their complaint on the balance of probabilities.

The response from GW Pharmaceuticals implied that it was aware of the complainant's identity. The Panel noted that it did not know the identity of the complainant who was nonetheless contactable.

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 Epidiolex was unlicensed, an application for a marketing authorisation was submitted on 29 December 2017 for its use as an adjunctive treatment for seizures associated with Lennox-Gastaut Syndrome and Dravet Syndrome.

The Panel noted the complainant's concern that the meeting between himself/herself the employee from the third party organisation and the health professional at a café was in breach of the Code because the health professional was not a relevant customer as he/she did not treat epilepsy or paediatric epilepsy and he/she was provided with hospitality despite the meeting having no educational content.

The Panel noted GW Pharmaceuticals' submission that the health professional was a relevant health professional in the field of epilepsy. The Panel further noted that an email from the third party employee to arrange the meeting stated that he/she would welcome the chance to catch up with the health professional and understand his/her perspective on needs and treatments for hard to treat epilepsies and paediatric syndromes. In response he/she did not refer to the subject matter of the meeting but stated that it would be a pleasure to meet an old friend. According to a statement, matters discussed included the company's ethos in helping patients with complex epilepsies, discussion of a corporate brochure, discussion of his/her clinical interactions with paediatric neurologists and the burden of epilepsy in his/her patient population. The statement noted that unsolicited questions about cannabidiol were answered. This was supported, in part, by a report written shortly after the meeting in question which noted discussion about the narrow nature of the licence. The Panel queried whether such discussions were truly unsolicited whilst noting that this aspect was not the subject of the complaint.

The Panel noted GW Pharmaceuticals' assertion, that the individual was a relevant health professional and referred to his/her website biography and signature on an epilepsy consensus statement. The Panel also noted that a transcript of a telephone conversation with the health professional, signed by him, stated that the submission that he/she did not treat epilepsy patients was incorrect. Whilst he/she did not treat epilepsy patients under the age of 17 and was not an expert in Dravet Syndrome, many patients survived into adulthood and thus he/she had an interest in and connection to paediatric epilepsy.

The Panel considered both the totality of the evidence in relation to the health professional's professional interests and the subject matter of the meeting as described above and considered that he/she was a relevant health professional. The company had not failed to maintain high standards in this regard. No breach of Clause 9.1 was ruled.

The Panel was very concerned to note that the meeting, at the health professional's request, was held at a local café. The Panel noted the public nature of the venue, the impression given, the lack of a formal agenda and the matters discussed as outlined above and queried whether such a venue was appropriate. The Panel noted however that there was no allegation about these matters including the venue, the complainant was concerned that hospitality had been provided without any educational content. The Panel noted the cost of the meal was £35.35 for three persons. The Panel noted the content of the meeting as described above. The meeting lasted for approximately 1 hour according to the employee of the third party and 20-40 minutes according to the health professional. The Panel noted that the complainant bore the burden of proof. Despite its serious concerns about governance in relation to the meeting as set out above, based on the evidence and the very narrow allegation the Panel did not consider that the complainant had established on the balance of probabilities that there had been no educational content and thus ruled no breach of Clause 22.1. The Panel subsequently ruled no breach of Clauses 15.2, 9.1 and 2.

The Panel noted that the case preparation manager had raised Clause 15.9, which related to briefing material, as potentially being relevant. The Panel did not consider that there was an allegation in this regard and made no ruling.

The Panel noted that Case AUTH/3024/3/18 and the present case, Case AUTH/3029/4/18 contained similar allegations with regard to a presentation to a group of doctors at a hospital in February 2017 which the complainant alleged promoted a product prior to the grant of its marketing authorisation. The Panel considered that its rulings and comments in Case AUTH/3024/3/18 were relevant here. The Panel noted that there were some differences between Case AUTH/3024/3/18 and the present case. In Case AUTH/3024/3/18 the complainant provided photographs, some cropped, of 9 presentation slides. In the present case the complainant provided a printout of 33 slides which were similar to those provided by GW Pharmaceuticals save that they did not include the disclaimer 'Cannabidiol is an investigational product and is not licensed in the EU' at the top of 21 of the 32 slides. According to GW Pharmaceuticals, it appeared that the slides provided by the complainant to the PMCPA had been modified after the meeting at issue.

In the previous case, Case AUTH/3024/3/18, the Panel noted that GW Pharmaceuticals had asserted 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, its 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.

In the previous case, Case AUTH/3024/3/18, the Panel noted that GW Pharmaceuticals had also asserted 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 requests 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.

In Case AUTH/3024/3/18 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 during a meeting with two named doctors from the hospital. The Panel noted that GW Pharmaceuticals provided some evidence in support of its position. The third party employees statement and notes of the meeting 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 dated 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. That the meeting in February resulted from an unsolicited request was also corroborated by various signed documents including one of the health professionals who stated that he/she and a colleague had asked GW Pharmaceuticals to arrange the presentation. 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 was already aware that it was not. The health professional 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.

In Case AUTH/3024/3/18 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 taken the decision that the content was appropriate for the small specialized departmental group.

Whilst the Panel in Case AUTH/3024/3/18 had some concerns about the meeting including the lack of an agenda, 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 health professionals. 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.

Turning to the present case, Case AUTH/3029/4/18, the Panel noted the complainant's allegations and considered that the comments and rulings set out above in Case AUTH/3024/3/18 were relevant.

Based on the particular facts of this case and 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 the presentation did not promote Epidiolex prior to the grant of its licence. The Panel ruled no breach of Clauses 3.1, 15.2, 9.1 and 2.

The Panel noted that as in Case AUTH/3024/3/18, Clause 15.9 had been raised by the case preparation manager. Clause 15.9 required that companies must prepare detailed briefing material that must not advocate, either directly or indirectly, any course of action which would be likely to lead to a breach of the Code. In Case AUTH/3024/3/18 the Panel did not consider that there was an allegation in this regard and therefore made no ruling in relation to this matter. The Panel noted the position was the same in this case, Case AUTH/3029/4/18, and thus made no ruling with regard to Clause 15.9.

The Panel noted that a further allegation in the present case, Case AUTH/3029/4/18, concerned the slides being amended by the employee of the third party agency following approval by GW Pharmaceuticals, and that the amended version was not certified. The Panel noted GW Pharmaceuticals' submission that as the slides were non-promotional GW Pharmaceuticals did not consider that they required certification under the Code. The Panel noted its comments above with regard to GW Pharmaceuticals being able to take the benefit of the exemption from the definition of promotion at Clause 1.2 in relation to unsolicited requests which did not require certification and the Panel therefore ruled no breach of Clause 14.1. The Panel subsequently ruled no breach of Clauses 15.2, 9.1 and 2.

Complaint received **5 April 2018**

Case completed **21 December 2018**