

CASE AUTH/3574/11/21

HEALTH PROFESSIONAL v GW PHARMACEUTICALS

Alleged promotion to the public

An anonymous non-contactable complainant who described him/herself as a hospital consultant treating patients with neurological conditions complained about the alleged promotion of medicines to the public by GW Pharmaceuticals.

The complainant stated that he/she had serious concerns following the 7th Global Symposium on Medical Ketogenic Dietary Therapies meeting where conference delegates included patients and their carers in addition to health professionals, including members of the public aged 10 and under with their parents.

The complainant stated that GW pharmaceuticals had a stand at the meeting which was in full view of everyone at the conference and on which representatives were having discussions about the company's medicines in full view and ear shot of the non-medical delegates. The complainant alleged that there was promotion to the public by having a stand at the conference which was in full view of everyone and he/she saw patients reading the banner which included the company's pipeline of medicines.

The detailed response from Jazz Pharmaceuticals, which GW Pharmaceuticals was now a part of, is detailed below.

The Panel noted Jazz's submission that the conference was usually split into two days, one day for health professionals, which it sponsored and attended, and one day for patients which the company had never attended and which it understood had not gone ahead in 2021. The Panel further noted that the conference exhibition and sponsorship programme described the participants as approximately 500+ health care professionals; there was no mention of the attendance of patients or any members of the public.

The Panel noted Jazz's submission that the two medical team members on the non promotional stand reported that during the congress they spoke with five health professional delegates and an ex-GW Pharmaceuticals employee and that no conversations took place that mentioned any medicine.

The Panel noted Jazz's submissions that the only material present on the stand was a banner headed 'GW Cannabinoid Pipeline' which illustrated the development pipeline of four molecules. Each of the molecules on the banner was an investigational product which was sometime away from potential licensing and most were pre phase three investigational products except one product which was about to start recruiting for patients for the phase three trial. There was no other material or branding nor was there mention of any prescription only medicine on the stand.

In the Panel's view, the complainant's allegation was in relation to promotion to members of the public; there was no allegation in relation to health professionals and therefore it ruled no breach of the Code in this regard.

In relation to the overall allegations of promotion to the public, the Panel did not consider that there was any evidence that there were any members of the public

present at the meeting that would view the stand nor that any discussions about medicines had occurred within the ear shot of members of the public. The Panel further noted that each of the molecules listed on the banner did not yet have a licence and therefore were not at the time considered prescription only medicines.

The Panel, noting its comments above, did not consider that the complainant had established that GW Pharmaceuticals had promoted its pre-licence pipeline products to members of the public as alleged.

Nor did the Panel consider that the complainant had established, on the balance of probabilities, that prescription only medicines had been promoted to the public as alleged and based on the evidence before it, ruled no breaches of the Code.

The Panel consequently ruled no breaches of the Code including no breach of Clause 2 overall.

An anonymous non-contactable complainant who described him/herself as a hospital consultant treating patients with neurological conditions complained about the promotion of medicines to the public by GW Pharmaceuticals.

COMPLAINT

The complainant stated that he/she had serious concerns following the 7th Global Symposium on Medical Ketogenic Dietary Therapies meeting he/she attended in Brighton from 19 to 22 October 2021 with a nurse and dietitian colleague.

The complainant stated that the conference delegates included patients and their carers in addition to health professionals. For example, on 21 October there were members of the public aged 10 and under with their parents.

The complainant stated that GW pharmaceuticals had a stand at the meeting and was the only pharmaceutical company with a stand that he/she noticed. There were three representatives on the stand who were having discussions about the company's medicines in full view and ear shot of the non-medical delegates. They were also promoting with a banner their pipeline of medicines. The complainant alleged that GW Pharmaceuticals was promoting to the public by having a stand at the conference. The stand was in full view of everyone at the conference and the complainant saw patients reading the banner that GW Pharmaceuticals displayed.

The complainant had no problem with any pharmaceutical company having stands at conferences, however this should not be allowed when there were patients at the conference. The complainant stated that GW Pharmaceuticals should have noted that there were patients at the conference as it was evident from the registration process. The registration process asked if you were a health professional or a patient/carer.

The complainant was concerned that because GW Pharmaceuticals had promoted its pipeline and its product, that patients would put undue pressure on their healthcare team to prescribe those products. The discussions on the GW Pharmaceuticals stand were not in any way concealed from the public. He/she overheard a discussion about the company's current medication and where it was available in ear shot of a carer. What made this worse was that not all centres had access to GW Pharmaceuticals' medicines.

The complainant was disappointed that pharmaceutical companies did not take more care and alleged that GW Pharmaceuticals had promoted to the public and should not do this in the future.

When writing to GW Pharmaceuticals, the Authority asked it to consider the requirements of Clauses 2, 5.1, 11.1, 26.1 and 26.2 of the 2021 Code.

RESPONSE

As GW Pharmaceuticals was now part of Jazz Pharmaceuticals, Jazz Pharmaceuticals responded to the complaint.

Jazz Pharmaceuticals stated that it took its responsibilities to the principles and letter of the Code extremely seriously at GW Pharmaceuticals (legacy) and Jazz Pharmaceuticals. Whilst progressing through the integration of the two organisations the company's commitment to healthcare compliance had been maintained with emphasis on continuity of adherence to high standards and codes of practice for each organization, clarity on accountability and implementation of a comprehensive integration plan for processes, systems, and team structure.

The company attendees on the stand were two medical employees. Also present at the congress sessions was an account manager.

Jazz Pharmaceuticals stated that the complainant presented themselves as a health professional who attended the 7th Global Symposium on Medical Ketogenic Dietary Therapies conference in Brighton from 19-22 October 2021, also in attendance with him/her were a nurse and dietician from his/her hospital medical team. The complainant indicated that they had chosen to travel and attend this global annual meeting taking place in Brighton, due to the relevance of the scientific content in treating patients with neurological conditions.

Jazz Pharmaceuticals noted that the complainant wrote that in addition to health professionals being in attendance as conference delegates, members of the public and their children were observed by them on 21 October. Usually, this congress was split into two days; the health professional day which Jazz Pharmaceuticals sponsored and attended and a separate patient day which Jazz Pharmaceuticals had never attended. Jazz Pharmaceuticals understood that the patient day did not go ahead in the end this year. The conference brochure indicated the established scientific credibility of the congress and described the core target audience as health professionals and allied health professionals. Page 3 of the brochure describing the participants as 'approximately 500+ healthcare professionals' and the invitation from the Chair, an expert in childhood epilepsies, included: 'I have pleasure in presenting our Sponsorship Opportunities information for the meeting and would welcome your company in joining us in providing a memorable event; providing invaluable learning and sharing as well as the fantastic opportunity for you to connect with health professionals working in this field.'

Jazz Pharmaceuticals noted that the complainant wrote that the representatives were having discussions about the company's medicines in full view and earshot of those individuals he/she believed to be members of the public.

In advance of the congress a briefing session had been attended by the three GW congress attendees, where detailed congress briefing (Pre-congress briefing slides) was provided about their roles and conduct for the congress. The two medical team members were responsible for hosting the GW Pharmaceuticals sponsored stand. As this was a non-promotional stand the experienced medical attendees had been briefed to not proactively make any reference to medicines.

Each of the GW Pharmaceuticals attendees had been individually asked to recall their experiences and recollection of the congress. Any delegate who approached the stand was

asked for an introduction by name and role prior to any discussion. The GW Pharmaceuticals medical attendees reported that during the congress they spoke with five delegates, all of whom presented themselves as health professionals and also an ex-GW Pharmaceuticals employee who was in attendance as an employee of another pharmaceutical company. The GW Pharmaceuticals attendees separately reported that none of their conversations made any reference to a GW Pharmaceuticals medicine. Further, each of the GW Pharmaceuticals attendees had reported that at no point was the commercial representative on the medical non-promotional stand.

Jazz Pharmaceuticals stated that each of the GW Pharmaceuticals attendees reported that the pre-congress briefing guidance was followed throughout. The allegation that patients/members of the public, who might have been in attendance, could have been inadvertently promoted to by Jazz Pharmaceuticals, as a consequence of being in earshot of conversations taking place on the stand was refuted by Jazz Pharmaceuticals, since no conversations took place that mentioned any medicine, neither on the stand nor at any time during the congress. Therefore, Jazz Pharmaceuticals believed there had been no breaches of Clauses 26.1 or 26.2 in this regard.

GW Pharmaceuticals had taken up the invitation to attend the congress as a Bronze sponsor and therefore had a space for a six-foot table, two chairs and a pull up banner. There was no other material or branding on the stand. The stand was planned as a non-promotional GW Pharmaceuticals stand, as was evident in the congress briefing slides, and the certified banner (the only material ever present on the stand) was a non-promotional banner, on which no reference to any GW medicines were made. The banner provided a factual representation of the ongoing GW Pharmaceuticals research projects in early phase trials for several molecules in a range of disease areas. None of this content was prohibited from being shared with members of the public. There was no mention of any prescription only medicine nor any claims. Each of the molecules on the banner was an investigational product which was sometime away from potential licensing, in fact most of the products mentioned were pre phase three investigational products except one product which was about to start recruiting for patients for the phase three trial. Jazz Pharmaceuticals therefore submitted, and with reference to case precedent Case AUTH/3442/12/20, that there had been no breaches of Clauses 11.1, 26.1 and 26.2.

Jazz Pharmaceuticals submitted that having demonstrated the nature of the stand, its content and the detailed briefing, along with the accounts provided by the GW Pharmaceuticals representatives at the congress, high standards had been maintained throughout and there had been no breaches of Clauses of 5.1 or 2.

PANEL RULING

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

The Panel noted the complainant's concern that GW Pharmaceuticals was promoting its medicines including its pipeline to members of the public.

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. Clauses 26.1 and 26.2 only applied to prescription only medicines.

The Panel noted Jazz's submission that the conference was usually split into two days, one day for health professionals, which it sponsored and attended, and one day for patients which the company had never attended and which it understood had not gone ahead in 2021. The Panel further noted that the 2021 conference exhibition and sponsorship programme described the participants as approximately 500+ health care professionals; there was no mention of the attendance of patients or any members of the public.

The Panel noted Jazz's submission that GW Pharmaceuticals had taken up the invitation to attend the congress as a Bronze sponsor and was given a stand which was planned as a non-promotional GW Pharmaceuticals stand. The Panel further noted Jazz's submission that the two medical team members on the medical stand reported that during the congress they spoke with five delegates, all of whom presented themselves as health professionals, and also an ex-GW Pharmaceuticals employee who was in attendance as an employee of another pharmaceutical company and no conversations took place that mentioned any medicine.

The Panel noted Jazz's submission that the only material present on the stand was a banner headed 'GW Cannabinoid Pipeline' which illustrated the development pipeline of four molecules (GWP42003-P OS, GWP42003-P IV solution, GWP42006 and GW-1000-02) including each molecule's proposed indication and stage of development and included the disclaimer 'None of the above products are licensed for use in the listed indications. Content herein is for background information only'. The Panel noted Jazz's submission that each of the molecules on the banner was an investigational product which was sometime away from potential licensing; most were pre phase three investigational products except one product which was about to start recruiting for patients for the phase three trial.

The Panel noted Jazz's submission that there was no other material or branding nor was there mention of any prescription only medicine on the stand.

The Panel noted that Clause 11.1 prohibited the promotion of a medicine to health professionals and other relevant decision makers prior to the grant of its marketing authorisation which permits its sale or supply. In the Panel's view, the complainant's allegation was in relation to promotion to members of the public; there was no allegation in relation to health professionals and therefore it ruled no breach of Clause 11.1.

The Panel considered that the more relevant clause in relation to the allegation that GW Pharmaceuticals was promoting its pipeline of medicines to members of the public was Clause 3.1 which was not raised by the case preparation manager. The Panel therefore decided to consider this allegation under Clause 5.1.

In relation to the overall allegations of promotion to the public, the Panel did not consider that there was any evidence that there were any members of the public present at the meeting that would view the stand nor that discussions about GW Pharmaceuticals medicines had occurred within ear shot of members of the public. The Panel further noted that each of the molecules listed on the banner did not yet have a licence and therefore were not at the time considered prescription only medicines.

The Panel, noting its comments above, did not consider that the complainant had established that GW Pharmaceuticals had promoted its pre-licence pipeline products to members of the public as alleged, and no breach of Clause 5.1 was ruled in this regard.

Nor did the Panel consider, noting its comments above, that the complainant had established, on the balance of probabilities, that prescription only medicines had been promoted to the public as alleged. Based on the evidence before it, no breach of Clauses 26.1 and 26.2 were ruled.

The Panel noted its comments and rulings above and consequently ruled no breach of Clauses 5.1 and 2 overall.

Complaint received 4 November 2021

Case completed 29 July 2022