CASE AUTH/3184/4/19

COMPLAINANT/DIRECTOR v GW PHARMACEUTICALS

Website and alleged breach of undertaking

A complainant, who described him/herself as a 'concerned UK health professional', complained about GW Pharmaceuticals' website (gwpharm.co.uk). GW was the marketing authorisation holder of Sativex (delta-9-tetrahydrocannabinol and cannabidiol) used in adults with multiple sclerosis. A marketing authorisation application (MAA) to the European Medicines Agency (EMA) had been made for Epidiolex (cannabidiol) for use in the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) and Dravet syndrome. GW also had a number of other cannabinoid products in development.

As the complaint involved an alleged breach of undertaking, that part of the complaint was taken up by the Director as the Authority was responsible for ensuring compliance with undertakings.

The complainant alleged that a section of the website for patients and carers did not specify what treatment, if any, the patient was on and this was therefore not sufficiently delineated from the general public; there was also not a separate section for the general public on the website.

On the section for health professionals claims were made for Sativex but there was no prescribing information present. The complainant alleged that this was pre-licence promotion.

The complainant noted that GW had already previously been ruled in breach of the Code for pre-licence promotion but did not specify which case he/she was referring to. The case preparation manager asked GW to respond in relation to Case AUTH/3014/1/18. The complainant alleged that this appeared to be a pattern of behaviour and that company processes were clearly inadequate.

The Authority requested that GW respond to the clauses cited by the complainant in relation to the 2016 Code.

The detailed response from GW is given below.

The Panel noted that supplementary information to the 2016 Code stated that unless access to promotional material about prescription only medicines was limited to health professionals and other relevant decision makers, a pharmaceutical company website or a company sponsored website must provide information for the public as well as promotion to health professionals with the sections for each target audience clearly separated and the intended audience identified. This was to avoid the public needing to access material for health professionals unless they chose to. The MHRA Blue Guide stated that the public should not be encouraged to access material which was not intended for them.

The Panel noted GW's submission that its website had a section intended for health professionals and a section intended for non-health professionals titled patients/caregivers, who were, in the company's view, the general public as they were not health professionals or other relevant decision makers. The Panel noted that companies could provide information about a specific medicine to patients for whom the prescribing decision had already been made. Such information should only be accessible to such patients. Publicly accessible information for patients should be suitable for the general public. The Panel further noted GW's submission that before readers could access the health professional part of the website they had to confirm that they were health professionals via a pop-up; if they confirmed that they were health professionals there was a notice at the top of the webpage which stated that the information was intended for European health professionals.

In the Panel's view, the supplementary information to the Code referred to the separation of promotional material intended for health professionals and/or other relevant decision makers from material intended for the public which might include patients, caregivers and/or, *inter alia*, the general public. In the Panel's view, separation of information intended for patients/caregivers from that intended for the general public was not covered by the Code or its supplementary information. The Panel did not consider that the complainant had discharged his/her burden of proof to demonstrate that GW had breached the Code on the narrow ground alleged and no breach was ruled.

The Panel noted that the complainant had raised two clauses in relation to promotion to the public but had not made clear which statements were the subject of his/her concerns nor detailed why in his/her view such statements were in breach of the Code. It was not for the Panel to infer detailed reasons to support the allegation on behalf of the complainant. It was for the complainant to establish his/her case on the balance of probabilities. In the Panel's view, the complainant had not discharged his/her burden of proof and therefore ruled no breach in relation to these matters.

The Panel noted the complainant's allegation that on the health professional section of the website there were claims about Sativex but no prescribing information. The Panel noted GW's submission that although the company manufactured Sativex, the medicine was promoted by Bayer in the UK. The Panel disagreed with GW's submission that as GW did not promote Sativex the information on the GW website was not promotional. The Panel noted that GW was the marketing authorisation holder and therefore, regardless of any agreement with Bayer, if GW provided Sativex material on its website such material was potentially within the scope of the Code.

The Panel noted that on what appeared to be the health professional landing page, it was stated:

> **'GW commercialized the world's first plant-derived cannabinoid prescription drug, Sativex (delta-9-tetrahydrocannibinol and cannabidiol), which is approved for the treatment of spasticity due to multiple sclerosis in numerous countries outside the United States.'**

This webpage further stated, *inter alia*:

'GW is in a unique position to develop and manufacture plant-derived cannabinoid formulations worldwide at sufficient quality, uniformity and scale for the purposes of pharmaceutical development and to meet international regulatory requirements.'

Below this, in what appeared to be a box, the brand name, non-proprietary name and indication for Sativex along with a 'learn more' link was provided

It appeared to the Panel that the 'learn more' link provided further information about Sativex including, *inter alia*, method of administration and that globally the product had received marketing authorisation in over 25 countries for the treatment of spasticity due to multiple sclerosis. It also stated 'GW does not market Sativex directly. All requests for product information and adverse events reporting should be directed through the individual websites for the distributors listed in the HCP section'. Beneath this were links titled 'Prescriber Information' and 'Patient Information'. At the bottom of the webpage was a prominent link titled 'Next: Information on Obtaining Sativex'. In the footer of the webpage, alongside the link to legal privacy terms, was a link to the Sativex SPC on the eMC website.

The Panel noted GW's submission that in addition to the Sativex SPC, the website included a link to the MHRA yellowcard website to report adverse events, redirected the health professional to the Bayer website and provided the Bayer telephone number. The Panel noted that GW had not provided screenshots to illustrate how this information appeared on the website. The Panel further noted that GW did not provide the content when 'Prescriber Information' was selected and further noted GW's submission that as the company did not consider the information on Sativex to be promotional it deliberately did not include the prescribing information on the website.

The Panel noted its comments above including that GW was the marketing authorisation holder of Sativex and the broad definition of promotion in the Code. The material at issue was an integral part of the health professional section of the site. In the Panel's view, the statement that GW had commercialized the world's first plant-derived cannabinoid prescription drug, which is approved for the treatment of spasticity due to multiple sclerosis in numerous countries outside the United States and the reference to Sativex and its indication in the highlighted box were claims for Sativex. The Panel considered that the comments about Sativex could not benefit from an exemption to the definition of promotion. The Panel noted that not all the requirements of the prescribing information required could be fulfilled by the Sativex SPC. The Panel considered that Sativex prescribing information as required by the Code had not been provided nor was there a clear, prominent statement as to where the prescribing information could be found. The Panel ruled breaches of the Code.

The Panel noted that Clause 2 was a sign of particular censure and reserved for such use. The Panel noted its comments and rulings above and considered that as the website included links to the Sativex SPC a breach of Clause 2 of the Code was not warranted.

The Panel noted the complainant's allegation that the pipeline section was 'blatant pre-licence promotion'.

The Panel noted that the pipeline section included a number of statements, a link to press releases, a link to clinicaltrials.gov, and medical information contact details if the reader wanted further information. It also included a list of products in development with their corresponding stage of development and disease area.

The Panel noted that the first sentence of the pipeline section stated:

> **'GW's extensive research into the pharmacology of cannabinoids continues to yield highly promising data and new intellectual property across a range of therapeutic areas.'**

Further information was provided as noted by the complainant including that GW's lead product candidate was a pharmaceutical formulation of purified CBD for severe, early-onset, drug resistant epilepsy syndromes, that Epidiolex was launched in the US and available by prescription for the treatment of seizures associated with LGS or Dravet syndrome and that GW had submitted an marketing authorisation application (MAA) to the European Medicines Agency (EMA).

The Panel noted GW's submission that the information regarding its pipeline was in the health professional section of the company website and that it had received repeated requests from the Department of Health and Social Care to make more information available to health professionals about its unlicensed medical cannabis products. The Panel further noted GW's submission that if the company did not provide such information on its UK website for those health professionals who sought it, it might force these health professionals to seek the information from US websites.

In the Panel's view, it was not necessarily unacceptable for a company to refer in general terms to its pipeline products on its corporate website, however, language, context, location, layout, intended audience and overall impression were important factors. Such references should not constitute promotion of an unlicensed medicine.

The Panel accepted that some health professionals might visit the GW website to seek information about unlicensed cannabinoid medicines. The Panel noted, however, that there was a prominent link to the pipeline section of the website from the health professional landing page, which in the Panel's view was a promotional page, and therefore health professionals who might be looking for information about a licensed product were also invited to follow a link to the company's product development pipeline. The health professional landing page also stated, 'We have a deep pipeline of additional cannabinoid product candidates which include compounds in development for epilepsy, glioma and schizophrenia'.

The Panel noted its comments above, particularly use of the terminology 'highly promising data' as an introductory statement to the detailed information about unlicensed medicines in the pipeline section of the website, which was directed at health professionals. In the Panel's view, the pipeline section was designed to elicit interest in Epidiolex in Europe and the Panel considered that, on balance, the website promoted an unlicensed medicine as alleged and a breach was ruled.

The Panel noted that the supplementary information to Clause 2 listed examples of activities likely to be in breach of Clause 2, which included promotion of a medicine prior to the grant of its marketing authorisation. As noted above, the Panel considered that it was not necessarily unacceptable for a company to refer in general terms to its pipeline products on its website. The Panel had concerns about the layout of the website in question, particularly noting that there was a prominent link to the pipeline section of the website from the health professional landing page which in the Panel's view was a promotional page. However, the Panel noted that health professionals would have to actively click on the link to access the pipeline section of

the website. In the Panel's view, on balance, and in the exceptional circumstances of this case, the information within the pipeline section of the website was not such that GW had brought discredit upon or reduced confidence in the pharmaceutical industry. The Panel therefore ruled no breach of Clause 2.

With regard to the alleged breach of undertaking, the Panel considered that although the previous case (Case AUTH/3014/1/18) and the current case (Case AUTH/3184/4/19) both related to the promotion of Epidiolex prior to the grant of its marketing authorisation, there were differences between the two cases in relation to the material at issue and the intended audience. The Panel noted that in Case AUTH/3014/1/18, GW was found in breach of the Code for an exhibition stand promoting Epidiolex prior to the grant of its marketing authorisation. In the current case the Panel had ruled a breach of the Code in relation to Epidiolex and the pipeline section, a prominent link to which had appeared on a promotional page, within the health professional part of the GW website. The Panel considered that there was a difference between delegates at a learned society meeting visiting an exhibition stand and being presented with material and health professionals visiting the GW website who were likely to be seeking specific information and would have to click on the pipeline link in order to view the information. The Panel also noted that there were differences between the material at issue on the exhibition stand in Case AUTH/3014/1/18 and the content of the pipeline section of the website in the current case.

The particular circumstances of each case were such that, in the Panel's view, and on balance, the ruling of a breach of the Code in Case AUTH/3184/4/19 did not constitute a breach of the undertaking given in Case AUTH/3014/1/18 and the Panel therefore ruled no breaches of the Code including Clause 2.

The Panel noted that the complainant had raised another clause but had made no clear allegation as to what exactly he/she considered was in breach of this clause. In the Panel's view, the complainant had not discharged his/her burden of proof that a breach of the Code had occurred. The Panel therefore ruled no breach.

In the Panel's view, rulings of breaches of the Code did not in itself mean that a company had not met the training requirements as set out in the Code. The Panel noted GW's submission that the company had conducted Code training that year which was mandatory for all staff and attended by the staff who had created the website. The Panel further noted GW's submission that it had trained the whole organisation and its contract sales organisation on the findings of the cases brought against it in 2018. The Panel considered that the complainant had not shown, on the balance of probabilities, that a breach had occurred and no breach was ruled.

A complainant, who described him/herself as a concerned UK health professional, complained about GW Pharmaceuticals' website. GW was the marketing authorisation holder of Sativex (delta-9-tetrahydrocannabinol and cannabidiol) used in adults with multiple sclerosis. A marketing authorisation application (MAA) to the European Medicines Agency (EMA) had been made for Epidiolex (cannabidiol) for use in the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) and Dravet syndrome. GW also had a number of other cannabinoid products in development.

As the complaint involved an alleged breach of undertaking, that part of the complaint was taken up by the Director as the Authority was responsible for ensuring compliance with undertakings.

COMPLAINT

The complainant noted that the first page of the website (gwpharm.co.uk) stated:

> 'GW is now also developing products to treat rare and catastrophic forms of childhood onset epilepsy.'

This continued for the remainder of the website.

The complainant alleged that a section for patients and carers did not specify what treatment, if any, the patient was on and this was therefore not sufficiently delineated from the general public; there was also not a separate section for the general public on the website.

There was a paragraph that stated:

> 'In recent years, GW has focused its efforts on the development of a potential new treatment option for seizures associated with severe, orphan, early-onset, treatment-resistant epilepsy syndromes including Dravet syndrome, Lennox-Gastaut syndrome (LGS) and Tuberous Sclerosis Complex (TSC).'

The next tab, called epilepsy, stated:

> 'GW is committed to helping such patients and is researching new treatment options for conditions including Lennox-Gastaut syndrome, Dravet syndrome and tuberous sclerosis.'

On the section for health professionals there was mention of Sativex as well as claims but there was no prescribing information present.

The section which detailed the pipeline stated:

> 'GW's lead product candidate is a pharmaceutical formulation of purified CBD [cannabidiol] for severe early-onset, drug-resistant epilepsy syndromes. This product is the result of extensive pre-clinical research of CBD in epilepsy which dates back to 2007. In 2013, GW commenced an orphan clinical program in pediatric epilepsy with initial focus on two rare and particularly difficult to treat forms of epilepsy: Dravet syndrome and Lennox-Gastaut syndrome (LGS), both of which have been granted orphan drug designation by the U.S. FDA [Food and Drug Administration].
>
> GW submitted a New Drug Application with the FDA, which was approved by the FDA on June 25th, 2018 for the treatment of seizures associated with LGS or Dravet syndrome. Epidiolex [cannabidiol] was launched in the U.S. and available by prescription on November 1st, 2018. GW had also submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) with an expected decision date in early 2019. To date, GW has received Orphan Drug Designation from the FDA for Dravet syndrome, LGS, TSC and IS. Additionally, GW has received Fast Track Designation from the FDA for the treatment of Dravet syndrome and conditional grant of rare pediatric disease designation by FDA. The Company has also received Orphan Designation from the European Medicines Agency, or EMA, for the treatment of LGS, Dravet syndrome, West syndrome and TSC. GW is currently evaluating additional clinical development programs in other orphan seizure disorders.'

The complainant alleged that this was pretty blatant pre-licence promotion.

The complainant noted that GW had already been ruled in breach of the Code for pre-licence promotion. Yet again, it continued to do so. The complainant did not specify which case he/she was referring to. The case preparation manager asked GW to respond in relation to Case AUTH/3014/1/18. The complainant alleged that this stopped being an oversight and increasingly appeared to be a pattern of behaviour and that the company's processes were clearly inadequate.

The complainant considered that the requirements of Clauses 2, 3.1, 3.2, 4.1, 4.6, 16.1, 26.1, 26.2, 28.1 and 29 should be considered.

The Authority requested that GW respond to the clauses cited by the complainant in relation to the 2016 Code.

RESPONSE

GW submitted that the statement 'GW is now also developing products to treat rare and catastrophic forms of childhood-onset epilepsy' was a simple statement of fact and not a breach of any of the clauses cited by the complainant. In particular, 'catastrophic' was widely used clinically to describe those rare forms of epilepsy, eg Shields (2005) stated 'Although for most children epilepsy is a relatively benign disorder, for some, epilepsy can be designated as "catastrophic" because the seizures are so difficult to control and because they are strongly associated with mental retardation'. GW also referred to an article titled 'Catastrophic Childhood Epilepsy: A Recent Convergence of Basic and Clinical Neuroscience' in the Science Translational Medicines. GW stated that 'catastrophic' was used on its website in a clinical and responsible way to clearly communicate that its research was not in ordinary forms of epilepsy but in very, very serious forms because it did not want to mislead readers who had searched for this information.

GW stated that it did not understand the complainant's comment that the section of the website for patients and carers did not state what treatment, if any, the patient was on. GW stated that it would never be appropriate for a pharmaceutical company to comment on an individual's treatment. The complainant further stated that this was not sufficiently delineated from the general public and there was also not a separate section for the general public on the website. GW stated that its website clearly separated the sections for its audiences: there was a section for health professionals and a section for the general public. The latter section was titled patients/caregivers who were the general public because they were not health professionals or other relevant decision makers. In keeping with good practice recommendations in the supplementary information to Clause 28.5 of the Code, at the top of each of these pages of the company website was a statement identifying the intended audience.

GW further considered that the statement 'In recent years GW has focused its efforts on a potential new treatment option for seizures associated with severe orphan early onset treatment-resistant Epilepsy syndromes including Dravet syndrome, Lennox Gastaut Syndrome (LGS) and Tuberous Sclerosis Complex (TSC)' was again a statement of fact. The statement was not intended to be promotional nor was it promotional; it was valid, objective information for the intended audience. There was no detail on the disease state or the product. There was also no mention of deficiencies in other therapeutic options.

GW noted the complainant's allegation 'there is a mention of Sativex as well as claims but there is no prescribing information present' and stated that in keeping with best practice, before readers accessed

the health professional part of the website there was a pop up which reminded him/her that that section of the website was reserved for health professionals and readers had to confirm 'Yes I am a healthcare professional'. If they clicked on the pop-up and thereby confirmed that they were a health professional there was a notice at the top of the webpage which clearly stated 'information is intended for European Healthcare Professionals'. GW did not promote Sativex, it was the manufacturer. Sativex was promoted in the UK by Bayer. GW submitted that for this reason, the information on Sativex was not promotional and therefore under the Code did not require the prescribing information. The page on the website was purely factual. It told readers what Sativex was and what it was indicated for. It then directed them to the Bayer website and provided the Bayer telephone number. It also reminded health professionals that adverse events should be reported and provided a link to the yellow card page of the MHRA website. This was to comply with the companies' duties to public health which it took very seriously.

GW noted the complainant's comments about the 'pipeline' section of its website and again noted that the statement at issue was a statement of fact which did not correlate to a promotional claim about its product; it merely related to (US) government public policy to provide certain incentives to companies to try to develop treatments for rare disease. Health professionals to whom this communication was intended would clearly understand that.

GW stated that it submitted a New Drug Application with the FDA, which was approved by the FDA on 25 June 2018 for the treatment of seizures associated with LGS or Dravet syndrome. Epidiolex was launched in the US and was available for prescription on 1 November 2018. GW had also submitted a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) with an expected decision date in early 2019. To date, GW had received Orphan Drug Designation from the FDA for Dravet syndrome, LGS, TSC and IS (infantile spasms). Additionally, GW had received Fast Track Designation from the FDA for the treatment of Dravet syndrome and conditional grant of rare paediatric disease designation by FDA. The company had also received Orphan Designation from the EMA for the treatment of LGS, Dravet syndrome, West syndrome and TSC. GW was currently evaluating additional clinical development programs in other orphan seizure disorders.

GW stated that the information was purely factual; it was not a promotional claim about any of its products and was valid objective information for health professionals who had proactively sought it. GW had a duty to provide factual information for health professionals who searched for such information. This information was not prominently displayed on a stand at a congress for passers-by to see; it was on a website which health professionals would have deliberately searched out and in a section reserved for health professionals with the appropriate checks and balances to make sure the readers were health professionals.

GW stated that the duty to provide factual information was particularly important in the context of the huge media attention on cannabidiol (CBD) oil and medical cannabis. There was a lot of misinformation in the public domain both about GW and what it did and about cannabinoids and medical cannabis. Many websites made medical claims about CBD oil which could not be substantiated. Most of these claims were about products which, not only did not have a marketing authorisation, but also had not conducted robust, well designed, randomised controlled clinical trials. Against this backdrop, it was especially important, that for those health professionals who searched for it, there was some factual information about what GW did and the products it had in development.

GW noted that it was a research-based company which, to date, had not commercialised any of its products in Europe. Accordingly, given the context of the huge interest in CBD oils and medical cannabis any health professional who proactively searched the GW website would be looking for

precisely this information. GW considered that it was in a unique and unprecedented position which other pharmaceutical companies had not faced where 'competitor' CBD oil products were being marketed with all sorts of health benefit claims without any clinical trial data to support such claims and without any data upon which to base a marketing authorisation application. In such circumstances, GW had provided limited and factual information to health professional who had deliberately sought it out.

GW submitted that there would be a clear patient safety risk if it did not provide any information to health professionals who had proactively searched for it in an area where there was great interest. There was a high need for factual information to counterbalance the widespread misinformation about unlicensed, untested and unregulated cannabis derived products which were currently available in the UK. In addition, GW considered that if it did not provide information on its UK website for health professionals who sought it, those health professionals might be forced to seek the information from US websites.

GW submitted that since the government changed the law on medical cannabis in October last year, GW had received repeated requests from the Department of Health and Social Care to make more information available to health professionals about its unlicenced medical cannabis products. The Health and Social Care Select Committee which sat in April repeatedly raised the concern that there was not enough information for health professionals in the public domain. GW had tried to fulfil these requests from government and health professionals and also comply with the Code in a responsible way.

All materials on the website were reviewed and approved by appropriately qualified senior members of the medical team.

With regard to Clause 3.1, in addition to the comments above, GW stated that none of the information at issue promoted a medicine prior to the grant of its marketing authorisation. All of the information was factual and there were no product or promotional claims.

Clause 3.1 of the Code was designed to prohibit the promotion of medicines prior to the grant of a marketing authorisation. Clause 3.2 was designed to prohibit off-label promotion after the grant of a marketing authorisation. It followed logically that GW could not be in breach of Clause 3.2 for any pipeline products because it did not have a marketing authorisation or SPC with which to be inconsistent. GW was also not in breach of this clause for Sativex because the information on the GW website was not promotional and merely stated the indication for which it was licenced which was wholly consistent with the marketing authorisation and SPC.

With regard to Clause 4.1, as stated above, GW submitted that it did not promote Sativex and therefore the information on the GW website was not promotional and redirected the health professional to Bayer's website as the promoter of Sativex. Accordingly, it did not need to provide the prescribing information.

With regard to Clause 4.6, again, GW submitted that the information about Sativex on GW's website was not promotional and therefore the company deliberately did not include the prescribing information. It did, however, include the SPC and a link to the MHRA yellow card website to report adverse events.

GW noted that the complainant did not submit any evidence of a breach of Clause 16.1, ie 'All relevant personnel including representatives and members of staff, and others retained by way of contract, concerned in any way with the preparation or approval of material or activities covered by the Code must be fully conversant with the Code and the relevant laws and regulations'. GW submitted that it

took Code compliance and training very seriously and had carried out three mandatory Code training sessions this year. One was a general session for all staff, one was a signatory training session which was also attended by a number of those who created materials, including those staff members who created the website and the third session was for the International Leadership Team. These training sessions were followed by a test to ensure understanding. In addition, the findings of the cases brought against the company last year were trained to the whole organisation. Further, the company had required its contract sales organisation to carry out Code training and it had trained out the findings of the previous cases to the same. Finally, the company had provided training on certain hot topics including, *inter alia*, advisory boards (training records provided).

With regard to Clause 26.1, GW reiterated that it did not promote Sativex and the information on the website about that product was not promotional. With regard to the company's pipeline product candidates, it did not have a licence for these products therefore they were not prescription only medicines and this clause could not apply. GW noted that the PMCPA had agreed with this position in Case AUTH/3037/4/18.

With regard to Clause 26.2, GW submitted that the only information made available to the public about Sativex was the generic name of the product and the indication for which it was licensed. The website then advised the patient 'Please consult your doctor if you would like more information'. The SPC was available on the website. Accordingly, there was no breach of this clause.

GW submitted that there was no information available to the public about pipeline products; any information on such products was within the health professional section of the website which, as noted above, was behind a pop-up which required readers to confirm that they were health professionals. However, in addition to this, as the pipeline products did not have a marketing authorisation, *de facto*, they could not be prescription only medicines and therefore for both these reasons there was no breach of this clause.

With regard to Clause 28.1, GW submitted that there was no promotional material about Sativex on the website and although there was also no promotional material about any pipeline products on the website, this clause did not apply to the pipeline section of the website because they were not prescription only medicines.

With regard to Clause 29, GW submitted that it gave an undertaking in relation to Case AUTH/3014/1/18. The fact of that undertaking was widely trained out to GW staff and its contract sales organisation. GW submitted that it undertook not to use the exhibition stand again; which it had not. GW withdrew all materials which had been on the stand and re-reviewed them. GW noted that the particulars of the case were that the Panel held, on the balance of probabilities, that the cumulative effect of the materials was likely to induce health professionals passing by at the congress to ask about GW's product. GW had not reused these materials since and in particular had trained its staff not to use these or other similar types of materials together again. The information on the website was entirely different; the information was not prominently displayed and could only be obtained by someone who proactively searched for it; it did not give any information on the disease states for which an indication had been applied for, it merely stated the fact that these applications had been made to the EMA and it also did not highlight that current therapeutic options were inadequate. Accordingly, this previous case could be wholly distinguished from the factual information on the website and as such no breach of undertaking had occurred.

With regard to Clause 2, GW submitted that the material on its website was not, and was not intended to be, promotional and therefore was not 'associated with promotion'. A ruling of a breach of Clause 2

was a sign of particular censure and given that GW had been careful not to make promotional claims and not make statements which were not factual, accurate, balanced and capable of substantiation, GW denied a breach of that clause. In particular, GW highlighted the very difficult external environment which it had to navigate in the wake of the intense media focus on medical cannabis and the plethora of untested and unlicensed products being promoted in the UK. Against this backdrop GW had reinforced the importance of regulatory approved products for patient safety and therefore had certainly not brought discredit upon, or reduced confidence in, the pharmaceutical industry but rather endorsed a greater confidence in the industry to provide regulatory approved medicines rather than unregulated products.

Finally, GW submitted that it expected a decision on the marketing authorisation for its cannabidiol oral solution to be made in the middle of 2019.

PANEL RULING

The Panel noted the complainant's allegation that a section of the website for patients and carers did not specify which treatment, if any, the patient was on and this was therefore not sufficiently delineated from the general public; there was no separate section for the general public on the website.

The Panel noted that the supplementary information to Clause 28.1 of the 2016 Code stated that unless access to promotional material about prescription only medicines was limited to health professionals and other relevant decision makers, a pharmaceutical company website or a company sponsored website must provide information for the public as well as promotion to health professionals with the sections for each target audience clearly separated and the intended audience identified. This was to avoid the public needing to access material for health professionals unless they chose to. The MHRA Blue Guide stated that the public should not be encouraged to access material which was not intended for them.

The Panel noted GW's submission that its website had a section intended for health professionals and a section intended for non-health professionals titled patients/caregivers, who were, in the company's view, the general public as they were not health professionals or other relevant decision makers. The Panel noted that companies could provide information about a specific medicine to patients for whom the prescribing decision had already been made. Such information should only be accessible to such patients. Publicly accessible information for patients should be suitable for the general public. The Panel further noted GW's submission that before readers could access the health professional part of the website they had to confirm that they were a health professional via a pop-up; if readers confirmed that they were health professionals there was a notice at the top of the webpage which stated that the information was intended for European health professionals.

In the Panel's view, the supplementary information to Clause 28.1 was referring to the separation of promotional material intended for health professionals and/or other relevant decision makers from material intended for the public which might include patients, caregivers and/or other types of members of the public such as the general public. In the Panel's view, separation of information intended for patients/caregivers to that intended for the general public was not covered by Clause 28.1 or its supplementary information. The Panel did not consider that the complainant had discharged his/her burden of proof to demonstrate that GW had breached Clause 28.1 on the narrow ground alleged and no breach of Clause 28.1 was ruled.

The Panel noted that the complainant had raised Clauses 26.1 and 26.2 but had not made clear which statements were the subject matter of his/her concerns under Clause 26 nor detailed why in his/her

view such statements were in breach of the Code. It was not for the Panel to infer detailed reasons to support the allegation on behalf of the complainant. It was for the complainant to establish his/her case on the balance of probabilities. In the Panel's view, the complainant had not discharged his/her burden of proof that a breach of Clauses 26.1 or 26.2 had occurred. The Panel therefore ruled no breach of Clauses 26.1 and 26.2.

The Panel noted the complainant's allegation that in the health professional section of the website there were claims about Sativex but no prescribing information. The Panel noted GW's submission that although the company manufactured Sativex, the medicine was promoted by Bayer in the UK. The Panel did not have a copy of the agreement with Bayer. The Panel disagreed with GW's submission that as GW did not promote Sativex the information on the GW website was not promotional. The Panel noted that GW was the marketing authorisation holder for Sativex and therefore, regardless of any agreement with Bayer, if GW provided Sativex material on its website such material was potentially within the scope of the Code. In the Panel's view, to decide otherwise would allow a marketing authorisation holder to provide detailed comments to the public and health professionals about a specific medicine whilst circumventing accountability under the Code.

The Panel noted that on what appeared to be the health professional landing page, it was stated:

> 'GW commercialized the world's first plant-derived cannabinoid prescription drug, Sativex (delta-9-tetrahydrocannibinol and cannabidiol), which is approved for the treatment of spasticity due to multiple sclerosis in numerous countries outside the United States.'

This webpage further stated, *inter alia*:

> 'GW is in a unique position to develop and manufacture plant-derived cannabinoid formulations worldwide at sufficient quality, uniformity and scale for the purposes of pharmaceutical development and to meet international regulatory requirements.'

Below this, in what appeared to be a box, the brand name, non-proprietary name and indication for Sativex along with a 'learn more' link was provided.

It appeared to the Panel that the 'learn more' link provided further information about Sativex including, *inter alia*, method of administration and that globally the product had received marketing authorisation in over 25 countries for the treatment of spasticity due to multiple sclerosis. It also stated 'GW does not market Sativex directly. All requests for product information and adverse events reporting should be directed through the individual websites for the distributors listed in the HCP section'. Beneath this were links titled 'Prescriber Information' and 'Patient Information'. At the bottom of the webpage was a prominent link titled 'Next: Information on Obtaining Sativex'. In the footer of the webpage, alongside the link to legal privacy terms, was a link to the Sativex SPC on the eMC website.

The Panel noted GW's submission that in addition to the Sativex SPC, the website included: a link to the MHRA yellowcard website to report adverse events, redirected the health professional to the Bayer website and provided the Bayer telephone number. The Panel noted that GW had not provided screenshots to illustrate how this information appeared on the website. The Panel further noted that GW did not provide the content when 'Prescriber Information' was selected and further noted GW's submission that as the company did not consider the information on Sativex to be promotional it deliberately did not include the prescribing information on the website.

The Panel noted its comments above including that GW was the marketing authorisation holder of Sativex and the broad definition of promotion in Clause 1.2 of the Code. The material at issue was an integral part of the health professional section of the site. In the Panel's view, the statement 'GW commercialized the world's first plant-derived cannabinoid prescription drug, Sativex (delta-9-tetrahydrocannibinol and cannabidiol), which is approved for the treatment of spasticity due to multiple sclerosis in numerous countries outside the United States' and the reference to Sativex and its indication in the highlighted box were claims for Sativex. The Panel considered that the comments about Sativex could not benefit from an exemption to the definition of promotion. The Panel noted that Clause 4.1 stated that the prescribing information listed in Clause 4.2 must be provided in a clear and legible manner in all promotional material. Failure to provide the required information in Clause 4.2 would be a breach of Clause 4.1. The Panel noted that not all the requirements of Clause 4.2 could be fulfilled by the Sativex SPC. The Panel considered that Sativex prescribing information as required by the Code had not been provided and the Panel therefore ruled a breach of Clause 4.1.

The Panel noted that Clause 4.6 stated that in the case of promotional material included on the Internet, there must be a clear, prominent statement as to where the prescribing information can be found. The Panel noted its comments and ruling of a breach of Clause 4.1 above and ruled a breach of Clause 4.6.

The Panel noted that Clause 2 was a sign of particular censure and reserved for such use. The Panel noted its comments and rulings above and considered that as the website included links to the Sativex SPC a breach of Clause 2 of the Code was not warranted in this regard and the Panel ruled no breach accordingly.

The Panel noted the complainant's allegation that the pipeline section was 'blatant pre-licence promotion'.

The Panel noted that the pipeline section included a number of statements, a link to press releases, a link to clinicaltrials.gov, and medical information contact details if the reader wanted further information. It also included a list of products in development with their corresponding stage of development and disease area.

The Panel noted that the first sentence of the pipeline section stated:

> 'GW's extensive research into the pharmacology of cannabinoids continues to yield highly promising data and new intellectual property across a range of therapeutic areas.'

Further information was provided as noted by the complainant including that GW's lead product candidate was a pharmaceutical formulation of purified CBD for severe, early-onset, drug resistant epilepsy syndromes, that Epidiolex was launched in the US and available by prescription for the treatment of seizures associated with LGS or Dravet syndrome and that GW had submitted an MAA to the EMA.

The Panel noted GW's submission that the information regarding its pipeline was in the health professional section of the company website and that it had received repeated requests from the Department of Health and Social Care to make more information available to health professionals about its unlicensed medical cannabis products. The Panel further noted GW's submission that if the company did not provide such information on its UK website for those health professionals who sought it, it might force these health professionals to seek the information from US websites.

In the Panel's view, it was not necessarily unacceptable for a company to refer in general terms to its pipeline products on its corporate website, however, language, context, location, layout, intended audience and overall impression were important factors. Such references should not constitute promotion of an unlicensed medicine.

The Panel accepted that some health professionals might visit the GW website to seek information about unlicensed cannabinoid medicines. The Panel noted, however, that there was a prominent link to the pipeline section of the website from the health professional landing page, which in the Panel's view was a promotional page, and therefore health professionals who might be looking for information about a licensed product were also invited to follow a link to the company's product development pipeline. The health professional landing page also stated, 'We have a deep pipeline of additional cannabinoid product candidates which include compounds in development for epilepsy, glioma and schizophrenia'.

The Panel noted its comments above, particularly use of the terminology 'highly promising data' as an introductory statement to the detailed information about unlicensed medicines in the pipeline section of the website, which was directed at health professionals. In the Panel's view, the pipeline section was designed to elicit interest in Epidiolex in Europe and the Panel considered that, on balance, the website promoted an unlicensed medicine as alleged. A breach of Clause 3.1 was ruled.

The Panel noted that the supplementary information to Clause 2 listed examples of activities likely to be in breach of Clause 2, which included promotion of a medicine prior to the grant of its marketing authorisation. As noted above, the Panel considered that it was not necessarily unacceptable for a company to refer in general terms to its pipeline products on its website. The Panel had concerns about the layout of the website in question, particularly noting that there was a prominent link to the pipeline section of the website from the health professional landing page which in the Panel's view was a promotional page. However, the Panel noted that health professionals would have to actively click on the link to access the pipeline section of the website. In the Panel's view, on balance, and in the exceptional circumstances of this case, the information within the pipeline section of the website was not such that GW had brought discredit upon or reduced confidence in the pharmaceutical industry. The Panel therefore ruled no breach of Clause 2.

With regard to the alleged breach of undertaking, the Panel considered that although the previous case (Case AUTH/3014/1/18) and the current case (Case AUTH/3184/4/19) both related to the promotion of Epidiolex prior to the grant of its marketing authorisation, there were differences between the two cases in relation to the material at issue and the intended audience. The Panel noted that in Case AUTH/3014/1/18, GW was found in breach of Clause 3.1 for an exhibition stand promoting Epidiolex prior to the grant of its marketing authorisation. In the current case the Panel had ruled a breach of Clause 3.1 in relation to Epidiolex and the pipeline section, a prominent link to which had appeared on a promotional page, within the health professional part of the GW website. The Panel considered that there was a difference between delegates at a learned society meeting visiting an exhibition stand and being presented with material and health professionals visiting the GW website who were likely to be seeking specific information and would have to click on the pipeline link in order to view the information. The Panel also noted that there were differences between the material at issue on the exhibition stand in Case AUTH/3014/1/18 and the content of the pipeline section of the website in the current case. The material at issue in Case AUTH/3014/1/18 included infographics which highlighted that current therapeutic options in certain epilepsy syndromes were inadequate. These infographics which were described in Case AUTH/3014/1/18 as 'striking and very prominently placed and thus highly visible to delegates visiting the stand' did not appear in the pipeline section of GW's website in the current case, nor did the webpages in question contain a closely similar visual representation. There were some

similarities between the materials at issue in Case AUTH/3014/1/18 and in the current case including that both materials referred to GW's 'lead' cannabinoid, which the Panel considered was a reference to Epidiolex.

The Panel noted its comments above and considered that there were differences between the materials at issue and how they were presented/accessed in Cases AUTH/3014/1/18 and AUTH/3184/4/19. The particular circumstances of each case were such that, in the Panel's view, and on balance, the ruling of a breach of Clause 3.1 in Case AUTH/3184/4/19 did not constitute a breach of the undertaking given in Case AUTH/3014/1/18 and the Panel therefore ruled no breach of Clause 29 and consequently no breach of Clause 2 in this regard.

The Panel noted that the complainant had raised Clause 3.2 but had made no clear allegation as to what exactly he/she considered was in breach of this Clause. In the Panel's view, the complainant had not discharged his/her burden of proof that a breach of Clause 3.2 had occurred. The Panel therefore ruled no breach of Clause 3.2.

The Panel noted that the complainant raised Clause 16.1. In the Panel's view, rulings of breaches of the Code did not in itself mean that a company had not met the training requirements set out in Clause 16.1. The Panel noted GW's submission that the company had conducted Code training that year which was mandatory for all staff and attended by the staff who had created the website. The Panel further noted GW's submission that it had trained the whole organisation and its contract sales organisation on the findings of the cases brought against it in 2018. The Panel considered that the complainant had not shown, on the balance of probabilities, that a breach of Clause 16.1 had occurred, and no breach was ruled.

Complaint received **24 April 2019**

Case completed **18 November 2019**