CASE AUTH/3669/6/22

COMPLAINANT v SMALL PHARMA

Information about pipeline products on the Small Pharma website

CASE SUMMARY

This case was in relation to information about Small Pharma's pipeline products on its website.

The Panel ruled a breach of the following Clause of the 2021 Code as it considered, noting the language used in relation to the pipeline products was strong and unqualified and the sensitive subject matter which was likely to be of interest to a wide audience including members of the public, in not making the intended audience clear, Small Pharma had failed to maintain high standards.

Breach of Clause 5.1	**Failing to maintain high standards**

The Panel ruled no breach of the following Clauses of the 2021 Code on the basis that:

- **Clause 16.1 applied solely to prescription only medicines and therefore did not apply to the website**
- **the complainant had not established that provision of a link inviting viewers to 'Stay up to date with our breakthrough R & D programs' promoted a medicine prior to the grant of its marketing authorisation**
- **the complainant had not established their case in relation to the 'DMT Training' and therapy sections of the website**
- **in the particular circumstances of this case the ruling of a breach adequately covered the matter raised and an additional ruling of a breach of Clause 2 would be disproportionate.**

No Breach of Clause 2	**Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**
No Breach of Clause 3.1	**Requirement that a medicine must not be promoted prior to the grant of its marketing authorisation**
No Breach of Clause 5.1	**Requirement to maintain high standards**
No Breach of Clause 11.1	**Requirement that a medicine must not be promoted prior to the grant of its marketing authorisation**
No Breach of Clause 16.1	**Requirement that promotional material about prescription only medicines directed to a UK audience which is provided on the internet must comply with all relevant requirements of the Code**

This summary is not intended to be read in isolation.
For full details, please see the full case report below.

FULL CASE REPORT

An anonymous contactable complainant who described themselves as a health professional complained about the Small Pharma website.

COMPLAINT

The complainant alleged that the website, small pharma.com, was completely open to the general public and had no clear delineation for what was for the general public, health professionals or the media.

The website section of interest, smallpharma.com/research-and-trials/, had all products in the pipeline visible in a graphic and there were claims about the pipeline products in a section of the research and trials webpage sub-titled 'Pipeline programmes'. Beneath this was a section sub-titled 'DMT therapist training' which the complainant noted offered [N,N- dimethyltryptamine (DMT) therapist] training.

Below on the same page there was an invitation to 'Stay up to date with our breakthrough R & D programs' and a click through link to register interest. The complainant stated that this appeared to be proactively asking health professionals – or even worse, members of the general public (there was nothing to delineate the two, after all), to sign up for their 'Breakthrough' programmes. The complainant alleged that this was clearly promoting to health professionals before a licence was granted.

A different page, smallpharma.com/resources/therapy/, had many links to further information that mentioned the pipeline products that were available.

The complainant stated that they did not have the time to list every issue that was present with this website, but concluded the lack of any attempt to delineate what was appropriate for health professionals, members of the public and the press demonstrated a company that appeared to have little understanding of how pharmaceutical companies were required to act in the UK – which was even more surprising given its recent Code case.

When writing to Small Pharma, the Authority asked it to consider the requirements of Clauses 2, 3.1, 5.1, 11.1 and 16.1 of the Code.

RESPONSE

Small Pharma acknowledged the complaint and stated that it would address each aspect of the complaint, share an overview of its website processes and the steps it had taken, and continued to take, to comply with the ABPI Code.

Small Pharma explained that it was a small biotechnology company set up in 2015 focused on early-stage research and development, with no marketed medicines in its current portfolio which included one clinical stage asset at Phase IIa and a pipeline of candidates in preclinical development. It operated as a private UK-limited company until May 2021, at which time it became a Canadian publicly listed company.

As a company, it valued the importance of being responsible and aimed to uphold its responsibility to not mislead the public or misrepresent its research. In addition, it operated

under core values of being evidence-based, patient focused and transparent. These values, it believed, which mirrored the key principles that underpinned the ABPI Code, were important for it to uphold in its external communication.

With respect to addressing this complaint, Small Pharma submitted that it had maintained a website for simple informational purposes intended for an investor audience. As a company in the early stages of medicine development, one of its major priorities was to continue to raise funds to support its clinical trials and, as such, investors were its core audience.

Small Pharma submitted that it had undertaken a rigorous process to develop and launch its website. Prior to initiating the development of the website, it conducted a review of numerous UK and global biotech companies operating in neuropsychiatry, as well as direct competitors within the psychedelic medicine sector, to align itself to the typical standard of biotech companies at a similar stage of development. An overview of the process its team had undertaken outlined the rigorous approach taken, which included multiple review stages by internal medical and scientific employees, as well as external legal counsel, to ensure that content and language was clinically, scientifically and legally correct. The website copy was generated in-house by two individuals with extensive experience marketing regulated health products. In addition, Small Pharma highlighted that at the time the website launched (October 2021), it had not agreed to comply with the ABPI Code and, as such, no approval certificate (in the context of Clause 8 of the Code) existed for the website.

Small Pharma addressed the clauses outlined by the PMCPA as follows: regarding Clause 2, it believed it had taken a rigorous approach to its website development and external communications, overall, which had been closely supported by its experienced technical team who, collectively, had decades of experience in the pharmaceutical and medical industries. Small Pharma was aware that the ABPI Code highlighted the need to maintain high standards (Clause 5.1) and imposed certain restrictions regarding promotional materials, including medicines prior to market authorisation (Clause 3.1 and 11.1). Clause 3.1 also highlighted that companies could provide information regarding assets in development, provided that the information was not promotional in nature. The Small Pharma website was designed for informational purposes, targeted at an investor audience. Finally, Small Pharma appreciated that the Code highlighted that information regarding the website architecture required clear delineation between target audiences, as highlighted for prescription-only medicines in Clause 16.1. However, Small Pharma did not currently have any commercially-marketed medicines, and thus it believed this requirement was less relevant for its current stage of development.

Responding to the complaint

Small Pharma responded to the following points addressed in the complaint:

‘1 The Small Pharma website was completely open to the general public and had no clear delineation for what is for the general public, health professionals or the media.
2 The Research and Trials section had all products in the pipeline visible.
3 There were claims made about pipeline products and therapist training offered.
4 The phrase “Stay up to date with our breakthrough R&D programs - Register Interest” appeared to proactively entice health professionals or members of the public to sign up for its breakthrough programs, promoting to health professionals before a licence had been granted.’

Small Pharma submitted that regarding complaint point one above, and with respect to Clause 16.1, the website did not provide promotional material regarding prescription-only medicines. As such, given its sole purpose was to provide information regarding its early-stage development programs and the nature of the information provided, it had not felt that, at this point, a distinct delineation was required for the various target audiences mentioned. However, it did maintain such distinction, as discussed below, with respect to inbound communication.

Regarding complaint points two and three above, Small Pharma submitted that it had no commercially-marketed products and, as such, a summary of product characteristics (SPC) was not relevant for its stage of development. The information regarding its pipeline and DMT therapist training on its website was outlined for simple informational purposes aimed at investors, and was not felt or intended to be promotional in nature. The information provided regarding its pipeline programs focused on describing its investigational medicinal candidates and made no reference or claims on intended patient outcomes. Details provided regarding its therapist training program stated that it purely related to the process of training therapists to support the company's clinical trial only. This information was not directed for the recruitment of health professionals for commercial use. Information regarding eligibility for its trials immediately took a user to an external site, clinicaltrials.gov, where they could learn about the trial details.

Regarding complaint point four above, there were two points to address. Firstly, the word 'breakthrough' within the phrase 'Stay up to date with our breakthrough R&D programs' related to the 'ILAP' Innovation Passport designation Small Pharma had been awarded with by the Medicines and Healthcare products Regulatory Agency (MHRA) in 2021. As defined by the MHRA the Innovative Licensing and Access Pathway 'was a new way of bringing *breakthrough* medicines to patients more quickly'.

Secondly, the intention behind 'Stay up to date with our breakthrough R&D programs - Register interest' was for investors to stay up-to-date on the progress of its clinical trials. To evidence this point, Small Pharma included an overview of the user journey once a user clicked on 'Register Interest'. This demonstrated how a user, automatically upon submitting a form, received a default '*You're on the list*' email outlining that they would receive 'occasional updates' regarding future company developments. Further evidence was provided in two emails sent during July to a new subscriber (redacted); the first was a welcome message relevant to investors and the second the announcement of Small Pharma's change in CEO, which was also relevant to investors.

With respect to the interpretation of this phrase, Small Pharma had updated it on its website to state 'Stay up to date with our company progress' in order to avoid any potential misinterpretation or confusion.

<u>Process steps taken since January 2022, when Small Pharma agreed to comply with the ABPI Code as a non-member</u>

Since January 2022, Small Pharma had taken a number of steps to ensure it was in compliance with the ABPI Code. It had:

1 Reviewed the Small Pharma website to remove all articles and content containing language related to the previous complaint Case AUTH/3449/1/2.
2 Notified the journalist associated with the complaint to make them aware and request they do not use similar language in future.

3 Established a communications and PR sign-off process to ensure a robust review process of all external communications.
4 Hired a new UK PR agency trained in the ABPI Code and changed agencies to one which also had healthcare and pharma experts and the full team trained on the ABPI Code.
5 Hired a lead for all compliance matters who was experienced in the biotech and pharmaceutical industry.

In addition, Small Pharma would build upon the processes and policies that had been implemented to date to optimise compliance with respect to marketing and communications, and establish further internal protocols that align with Small Pharma's duties to uphold the Code, as well as ensure the team remained trained and up-to-date with the elements of the Code.

Next steps

In consideration of the complaint made, Small Pharma was taking additional steps to ensure compliance with the Code. Firstly, it had undertaken a review of its website. Despite having no marketed medicines, it had added additional clarity regarding the intended audiences for the website and had updated any language that could be the subject of misinterpretation. Secondly, it had accelerated training for the team on the APBI Code. It had received proposals from two external consultancies and was in the selection process. Thirdly, it was in the process of engaging an external registered medical practitioner as an Authorised Signatory. Additionally, the selected ABPI Code consultancy would work with the compliance lead to implement the necessary standard operating procedures (SOPs) and protocols to ensure compliance with both the ABPI Code and Small Pharma's other obligations as its pipeline progressed through clinical trials towards commercialisation. Small Pharma provided additional details on its compliance plan.

PANEL RULING

The Panel noted that the allegations made by the complainant about the Small Pharma website were general and related to a lack of delineation of information including pipeline information suitable for public, media and health professional audiences; and alleged promotion of pipeline products to health professionals prior to the grant of a licence.

The Panel noted that at the time the website was launched in October 2021, Small Pharma was not a member company of the ABPI and was not included on the list of non-members who had agreed to comply with the Code and accept the jurisdiction of the PMCPA. The Panel noted that, nonetheless, Small Pharma would have had to comply with UK law. Small Pharma joined the list of non-member companies that comply with the Code in January 2022. In such circumstances, the Panel noted that it was not unusual for the subject matter of the complaint to have occurred/been launched before the company joined the list of non-member companies that complied with the Code. Whether such cases fell to be considered was decided on a case-by-case basis. The Panel also bore in mind the long-established principle that if the subject matter of the complaint could very broadly be described as potentially a matter covered by legal requirements, such as the prohibition on promoting prior to the grant of a licence, then the whole complaint would be considered in the usual way.

The Panel noted that Small Pharma was focussed on early-stage research and did not have any marketed products; its area of interest was in the development of medicinal uses for psychedelic

substances, an area very likely to be of interest to a broad audience including the general public and the media. In the Panel's view, given the potentially broad interest in the development of psychedelic medicines, the company had a particular responsibility to ensure that relevant information on the open-access website was presented cautiously and otherwise complied with the Code.

The Panel noted that the complainant had provided links to the website and four screenshots of sections of it. The Panel also had screenshots downloaded by the case preparation manager from the links provided by the complainant. The first link appeared to be the homepage of the website while the second was to the webpage titled 'Research and Trials' which could also be accessed from a link on the homepage. This webpage contained information about the company's medicine development programs in DMT-based therapy and its development molecules. It also included the images submitted by the complainant of the company's pipeline showing four molecules and a description of their formulations and what they were, details of two clinical trials, a section titled DMT Therapist training and a banner stating 'Stay up to date with our breakthrough R & D programs' with a link to register interest.

The Panel noted Small Pharma's submission that the website in question was aimed at investors and that it was intended to raise funds to support Small Pharma's clinical trials. The Panel noted that, in this regard, it differed from the broader content associated with a pharmaceutical company corporate website. The Panel noted that there was a tab labelled 'Investors' in the menu at the top of the website, and on what appeared to be the homepage, there was a banner that referred to, and had a link to, an investor deck. The Panel noted that investors were, of course, a legitimate audience but noted its comments above about the potentially broad interest in the subject matter of the website. In this regard, the Panel noted that the 'Research and Trials' page invited readers to apply for a 'Part B, phase IIA trial' that was recruiting in London and Liverpool; the contact form drop-down menu included enquiries about 'Media Communications', 'Recruitment', 'Clinical Trials' and 'General' in addition to 'Investor Relations'. In the Panel's view, whilst it was clear that investors were an important audience, it was also clear that the website content was aimed beyond investors including at health professionals, the media and others.

In relation to the complainant's allegation that the website small pharma.com/ was completely open to the general public, and had no clear delineation for what was for the general public, health professionals or the media, the Panel noted the supplementary information to Clause 16.1 of the Code, 'Website Access' 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 Panel noted that other than a webpage menu tab for investors, there were no separate labelled sections for different target audiences on the webpages in question, as alleged by the complainant and acknowledged by Small Pharma. The Panel did not have a copy of the webpages that appeared under the Investor tab. The Panel noted its comments above about the website's purpose, potential audience and content.

The Panel noted that, in addition to financial and investor-related information, the website contained a lot of general information about psychedelics and also referred to their potential use in major depression. The Panel was concerned that it included strong statements such as

‘Open your mind to psychedelics’, ‘People deserve mental health therapies that are safe, work quickly and have long lasting effects, tackling the root causes rather than numbing the symptoms’ and claims such as ‘Mental health medicines made better’, ‘DMT based treatments may have incredible potential as fast acting antidepressants’ and ‘They also have multiple benefits over existing treatments’ but noted that these claims were not the subject of complaint.

The Panel did not doubt that the website’s objective was to provide information about the company, its pipeline and development work in the area of DMT-assisted psychedelic therapy but considered that the sensitive nature of the company’s research interests would be of interest to a broad population including members of the public and health professionals as well as investors. In the Panel’s view, it was, therefore, important to be clear and unambiguous about the intended audience.

The Panel noted that Clause 16.1 applied solely to prescription-only medicines. Therefore, in the Panel’s view, it did not apply to the website in question as Small Pharma’s portfolio was limited to one Phase IIa asset and a pipeline of candidates in preclinical development. Accordingly, the Panel ruled **no breach of Clause 16.1**.

The Panel noted its comment above about the general nature of the allegations. The Panel noted the complainant’s references to pipeline products in relation to both their visibility and claims and what appeared to be a broad allegation that such references were inappropriate in the absence of clear delineation for the public, health professionals and the media. In the Panel’s view, the screenshots of the pipeline and pipeline programmes from the ‘Research and Trials’ webpage had been provided in support of this narrow allegation. The Panel noted its comments above in relation to the importance of being clear and unambiguous about the intended audience.

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 when deciding whether such references were acceptable. Such references should not otherwise constitute promotion of an unlicensed medicine.

The Panel noted that the first screenshot provided by the complainant was a graphical representation of the research programme showing the stage of development of each compound. The Panel noted that, in isolation, the graphical representation appeared to be low key. Little information was provided other than the stage of development.

The Panel noted that the second screenshot of the ‘Pipeline programs’ section in the ‘Research & Trials’ webpage stated:

> ‘We are developing a pipeline of tryptamine based psychedelic drug candidates.
>
> Our pipeline offers alternative drug formulations and drug profiles, providing options that could potentially suit different patient preferences and better target alternative health indications.
>
> Using our proprietary deuterium enriching technology (replacing hydrogen atoms with heavier hydrogen atoms) we are able to alter the pharmacokinetic profile (how a drug travels through the body) of tryptamine drugs. By re-engineering tryptamine-based compounds, we are able to develop a drug pipeline that potentially offers the ability to:

- Vary the duration of a psychedelic experience
- Establish alternative formulations.'

The Panel noted that the complainant had not identified any specific content within this section.

The Panel noted that the complainant had also provided a link to what appeared to be the homepage in relation to their concerns about delineation of the audience which, in the Panel's view, featured claims about the products in development including potential benefits over existing treatments.

The Panel considered that the website, as a whole, had been designed to broadly elicit interest in the company's development programs and Phase IIA unlicensed product and went beyond merely providing material for investors. In its view, the language used in relation to the pipeline products was strong and unqualified, particularly on the homepage that introduced the website as a whole and noting the sensitive subject matter, which was likely to be of interest to a wide audience including members of the public, the Panel considered that Small Pharma, in not making the intended audience clear, had failed to maintain high standards. Accordingly, the Panel ruled **a breach of Clause 5.1**.

The Panel noted that the complainant had referred to delineation but had not commented on the appropriateness of the content for any specific audience such as the general public and thus the Panel made no ruling in that regard.

In relation to the allegation that there was promotion to health professionals prior to the grant of a licence, the Panel noted the screenshot submitted by the complainant of a blue banner stating 'Stay up to date with our breakthrough R & D programs' with a link for viewers to register interest, which the complainant alleged appeared to be proactively asking health professionals or, even worse, members of the general public to sign up for their Breakthrough programmes. This, the complainant alleged, was clearly promoting to health professionals before a licence was granted.

The Panel noted that Clauses 3.1 and 11.1 prohibited the promotion of a medicine prior to the grant of its marketing authorisation and that the supplementary information to Clause 3.1 Marketing Authorisation stated:

> 'The legitimate exchange of medical and scientific information during the development of a medicine is not prohibited, provided that any such information or activity does not constitute promotion which is prohibited under this or any other clause.'

The Panel did not consider that the supplementary information was relevant to the particular circumstances of this case. The Panel noted that Clauses 3.1 and 11.1 were identical other than the supplementary information and treated the allegation on this point as one matter.

The Panel noted Small Pharma's submission that clicking the link to register interest in staying up-to-date with its breakthrough R&D programs took the viewer to the 'Contact Us' page and an enquiry form inviting users to leave contact details, a message and specify the nature of their enquiry from a drop-down menu of options including 'Investor Relations', 'Clinical Trials', 'Media Communications', 'General', 'Recruitment' and 'Other'. Having submitted a completed form, the user was directed to the 'Thank You' page which included information about receiving updates

on developments at Small Pharma, how to unsubscribe as well as a link to a video titled 'Open Your Mind to Psychedelics'. The Panel did not have the video content before it and noted that the complainant had not made an allegation about the video, nor had the complainant explained why signing up for updates on Small Pharma's breakthrough R&D programmes constituted pre-licence promotion. The Panel was concerned that 'breakthrough' was a strong term and queried its acceptability whilst noting that it was used to describe the R&D programs. The Panel noted that Small Pharma was no longer using the term.

The Panel noted that the complainant had the burden of proving his/her complaint on the balance of probabilities. All complaints were judged on the evidence provided by the parties. In the Panel's view, on balance, the complainant had not established that by providing a link inviting viewers to 'Stay up to date with our breakthrough R & D programs' Small Pharma had promoted unlicensed medicines and consequently **no breach of Clauses 3.1 and Clause 11.1** was ruled.

The Panel noted that the complainant had not made any specific allegation in respect of the 'DMT Therapist Training' section which consisted of expandable sections titled 'Overview', 'Designed by experts', 'Multi-method approach' and 'Recruitment process'. The Panel noted Small Pharma's submission that the details provided, regarding its therapist training program, related to the process of training therapists to support the company's clinical trial only.

The Panel similarly noted that the complainant had also provided a third link to the therapy section within the resources page of the website. This page contained a number of links to articles and press releases issued by Small Pharma but the complainant had not made any specific allegations in respect of this material other than that it contained information which mentioned the pipeline.

The Panel noted that the Constitution and Procedure stated that the complainant had the burden of proving his/her complaint on the balance of probabilities. All complaints were judged on the evidence provided by the parties. It was not for the Panel to infer detailed reasons to support the allegation on behalf of the complainant. The complainant had not established their case in relation to either the 'DMT Training' screenshot or the therapy section and ruled **no breach of Clause 5.1** in relation to each matter.

The Panel noted that Clause 2 was used as a sign of particular censure and reserved for such use. The Panel considered that in the circumstances in this particular case the ruling of a breach above adequately covered this matter and an additional ruling of a breach of Clause 2 was disproportionate. The Panel, on balance, ruled **no breach of Clause 2**.

Complaint received **29 June 2022**

Case completed **24 July 2023**