CASE AUTH/3449/1/21

COMPLAINANT v SMALL PHARMA

Small Pharma is not a member company of the ABPI. On being notified of the complaint it agreed to comply with the Code and accept the jurisdiction of the PMPCA and the complaint was processed and considered by the Code of Practice Panel. Following notification of the Panel ruling, Small Pharma did not appeal the Panel's rulings nor provide the requisite undertaking and assurance. It withdrew its agreement to comply with the ABPI Code and accept the jurisdiction of the PMCPA. As the complaint was also copied by the complainant to the Medicines and Healthcare products Regulatory Agency (MHRA), the complainant and the MHRA were informed of the position.

Post publication note: Following publication of this case report, Small Pharma subsequently requested to re-join the list of non-member companies that agreed to comply with the Code and accept the jurisdiction of the PMPCA. As a condition of re-joining the list, Small Pharma was required to provide the requisite undertaking and assurance in this case. Small Pharma provided the undertaking and assurance as required.

Alleged misleading press statement

An anonymous contactable complainant complained about an article which appeared in the Guardian entitled 'Psychedelic drug DMT [dimethyltryptamine] to be trialled in UK to treat depression'. The article, published in December 2020 included quotations attributed to a senior employee at Small Pharma, the company running the trial in collaboration with a named university.

The complainant alleged that Small Pharma appeared to be misrepresenting a medicine it was developing for use in mental health indications. The complainant referred to misleading statements attributed to the senior Small Pharma employee and noted that he/she had stated that dimethyltryptamine 'breaks up all of the ruminative thought processes in your brain – it literally undoes what has been done by either the stress you've been through or the depressive thoughts you have – and hugely increases the making of new connections'. The complainant alleged that there was no evidence to support that claim. The complainant noted that Small Pharma had a financial incentive in representing that type of (unproven) efficacy.

The complainant subsequently submitted that some of the most compelling evidence for this assertion came from the fact that, in some cases, DMT had been reported to induce psychosis. The complainant referred to an extract from a peer-reviewed article discussing DMT-induced psychosis.

The complainant submitted that, furthermore, press coverage of Small Pharma's recent approval to conduct clinical studies evidenced a major flaw in the employee's assertion that '[DMT] literally undoes what has been done by either the stress you've been through or the depressive thoughts you have,' in response to announcements that Small Pharma was prepared to conduct the first trials that would test the efficacy of DMT for depression.

The complainant submitted that the assertions about how/why DMT affected depression *prior* to conducting the 'world's first patient clinical trial using the psychedelic drug N,N-dimethyltryptamine (DMT) to treat depression' begged significant questions as to how the employee could make assertions about the efficacy of the medicine for unstudied applications, and what evidence he/she was using to make those assertions.
Given that this was the world's first clinical trial examining the efficacy of DMT for depression, and given that there was such little understanding as to the mechanisms and mental effects of DMT on the human psyche, the Small Pharma employee's claims that '[DMT] literally undoes what has been done by either the stress you've been through or the depressive thoughts you have' appeared to be unsupported by scientific evidence. There were no studies in the peer-reviewed literature that offered evidence for the assertion that '[DMT] breaks up all of the ruminative thought processes in your brain – it literally undoes what has been done by either the stress you've been through or the depressive thoughts you have – and hugely increases the making of new connections', and quite a bit of evidence to the contrary.

A glance through anecdotal 'trip reports' of DMT users evidenced a wide range of experiences, ranging from the ineffably beautiful to agonizingly hellish (including instances in which extreme DMT experiences appeared to contribute to psychotic breaks).

The complainant alleged that the above provided sufficient evidence as to the degree to which the Small Pharma employee's comments should be understood as irresponsible and inappropriate, particularly given his/her company's financial stake in promoting the efficacy of DMT for understudied psychiatric indications.

The detailed response from Small Pharma is given below.

The Panel noted that the complainant referred to an article in the Guardian and alleged that Small Pharma appeared to be misrepresenting N,N-dimethyltryptamine (DMT) which it was developing for use in mental health indications. The complainant referred to a quote from a senior employee of Small Pharma within the article that dimethyltryptamine 'breaks up all of the ruminative thought processes in your brain – it literally undoes what has been done by either the stress you've been through or the depressive thoughts you have – and hugely increases the making of new connections' and alleged that this misrepresented the medicine and could not be substantiated.

The Panel noted that, in addition to sharing a press release with the Guardian after the approval of its Phase I/IIa clinical trial evaluating the effects of N,N-dimethyltryptamine (DMT)-assisted therapy in psychedelic naïve healthy volunteers and it's efficacy in patients suffering with major depressive disorder, the Small Pharma employee spoke with the Guardian for an introductory briefing about the company ahead of the clinical trial approval. The Panel noted Small Pharma's subsequent submission that the Guardian article was based on a broader interview with the employee which was wide ranging and covered different aspects of Small Pharma's business. In the specific quote, the employee was talking to the hypothesis behind DMT-assisted therapy treatment based on accumulating evidence to date. The Panel noted that there was no evidence before it of what was said during this interview.

The Panel noted that the quotation at issue did not appear in the press release shared with the Guardian by Small Pharma, although Small Pharma appeared to accept that the quotation at issue had been made by its employee and the Panel's ruling was made on this basis.

The Panel noted Small Pharma's initial submission that the quotation was based on unpublished and published research conducted by the Centre for Psychedelic Research at Imperial College London and reported in various papers in the literature including Timmermann *et al,* 2019. The Panel had to make a judgement based on the evidence provided.

The Panel noted that Timmermann *et al* presented results from the first ever placebo-controlled investigation of the effects of DMT on spontaneous human brain activity in thirteen healthy volunteers. The Panel noted that the primary aim of the study was to determine how a bolus intravenous injection of DMT affected the power spectrum and signal diversity of EEG recorded brain activity. Further, that the study analysed the subjective effects of DMT.

The Panel noted that the EEG results showed that compared with placebo, DMT markedly reduced oscillatory power in the *alpha* and *beta* bands and robustly increased spontaneous signal diversity. The Panel also noted that the emergence of oscillatory activity within the *delta* and *theta* frequency bands was found to correlate with the peak of the experience.

The Panel noted that Timmermann *et al* concluded that the present results might shed light on the mechanisms underpinning the antidepressant potential of DMT and DMT-related compounds. Increased *alpha* power and decreased *delta* power had been found in populations of depressed individuals and associations had been observed between signal diversity and fluctuations in mood including depressive states. Timmermann *et al* stated that it was reasonable to consider that the massive effects observed here under DMT might have implications for modelling, and perhaps treating, psychopathology.

The Panel noted the positive data in healthy volunteers presented in Timmermann *et al,* particularly in relation to the change in *alpha* and *delta* power. The Panel also noted the study's qualified reference to antidepressant potential.

The Panel further noted Small Pharma's submission that in the specific quote at issue, the employee was talking to the hypothesis behind DMT-assisted therapy treatment based on accumulating evidence to date.

The Panel considered, however, that the quotation at issue was strong and unqualified. It was not qualified by other quotations in the article which were not the subject of the complaint but were, nonetheless, relevant and referred to the treatment of a number of depressive disorders besides major depression. The Panel noted that when providing quotations to the press, the ultimate audience should be borne in mind; the Panel noted the audience was the general public rather than the medical press and thus the weight to be attached to the evidence should have been made especially clear. In this regard, the Panel noted that although the press release did not contain the quotation at issue, it, nonetheless, referred to DMT as a 'potentially revolutionary treatment'.

The Panel considered that the quotation in the lay press that 'DMT broke up all of the ruminative thought processes in your brain, literally undoing what had been done by either the stress one had been through or the depressive thoughts one had and hugely increased the making of new connections' implied a clear and unequivocal clinical benefit in relation to the treatment of stress and depression and that the evidence provided was insufficient to substantiate that implication. The Panel, noting its comments above, considered that on the evidence before it, the unqualified quotation was incapable of substantiation and thereby misleading. Breaches of the Code were ruled.

An anonymous contactable complainant complained about an article which appeared in the Guardian entitled 'Psychedelic drug DMT [dimethyltryptamine] to be trialled in UK to treat depression'. The article, published in December 2020, included quotations attributed to a senior employee at Small Pharma, the company running the trial in collaboration with a named university.

COMPLAINT

The complainant alleged that Small Pharma appeared to be misrepresenting a medicine it was developing for use in mental health indications. In that regard, he/she referred to misleading statements attributed to the named Small Pharma senior employee and noted that he/she had stated that dimethyltryptamine 'breaks up all of the ruminative thought processes in your brain – it literally undoes what has been done by either the stress you've been through or the depressive thoughts you have – and hugely increases the making of new connections'. The complainant alleged that there was no evidence to support that claim. The complainant noted that Small Pharma had a financial incentive in representing that type of (unproven) efficacy.

The complainant subsequently submitted that some of the most compelling evidence for this assertion came from the fact that, in some cases, DMT had been reported to induce psychosis. The complainant referred to, and included, an extract from a peer-reviewed article discussing DMT-induced psychosis:

N,N-Dimethyltryptamine-Induced Psychosis

> **Background:** N,N-dimethyltryptamine (DMT) is a 5-hydroxytryptamine 2A and 1A receptor agonist that exhibits potent psychoactive properties in humans. Recreational use of this drug has increased precipitously and is likely to result in an increase in patients presenting with substance-induced psychoses. The present case provides an early example of substance-induced psychosis attributable to repeated use of DMT.
>
> **Case:** A 42-year-old white man, with no significant past psychiatric history, was brought to the emergency department by the police and was found to exhibit disinhibited behavior, elevated affect, disorganized thought process, and delusions of reference. Laboratory studies revealed elevated creatinine kinase level indicative of rhabdomyolysis. The patient endorsed recent and repeated use of DMT, as well as long-term Cannabis (marijuana) use. Over the course of the next 3 weeks, the patient was successfully treated with quetiapine for psychosis, divalproex sodium (Depakote) for impulsivity, gabapentin for anxiety, and hydroxyzine for sleep, which resulted in the resolution of his symptoms and development of reasonable insight and judgment. Approximately 6 months

> after discharge, the patient remained treatment compliant, as well as drug and symptom free.
>
> **Conclusions:** This case report illustrates an important example of substance-induced psychosis that resolved with antipsychotic treatment in a 42-year-old white man with no past psychiatric history likely attributable to the use of DMT. Given the increasing use of this substance, the emergency department, primary care, and inpatient services are likely to see a significant increase in similar cases.

The complainant submitted that, furthermore, press coverage of Small Pharma's recent approval to conduct clinical studies evidenced a major flaw in the employee's assertions that '[DMT] literally undoes what has been done by either the stress you've been through or the depressive thoughts you have,' in response to announcements that his/her company was prepared to conduct the first trials that would test the efficacy of DMT for depression (links to examples provided).

The complainant submitted that the fact that he/she was making assertions about how/why DMT affected depression *prior* to conducting the 'world's first patient clinical trial using the psychedelic drug N,N-dimethyltryptamine (DMT) to treat depression' begged significant questions as to how he/she could make assertions about the efficacy of the medicine for unstudied applications, and what evidence was used to make those assertions.

Given the fact that this was the world's first clinical trial examining the efficacy of DMT for depression, and given that there was such little understanding as to the mechanisms and mental effects of DMT on the human psyche, the employee's claims that '[DMT] literally undoes what has been done by either the stress you've been through or the depressive thoughts you have' appeared to be unsupported by scientific evidence. There were no studies in the peer-reviewed literature that offered evidence for his/her assertion that '[DMT] breaks up all of the ruminative thought processes in your brain – it literally undoes what has been done by either the stress you've been through or the depressive thoughts you have – and hugely increases the making of new connections', and quite a bit of evidence to the contrary.

A mere glance through anecdotal 'trip reports' of DMT users evidenced a wide range of experiences, ranging from the ineffably beautiful to agonizingly hellish (including instances in which extreme DMT experiences appeared to contribute to psychotic breaks, as discussed above).

The complainant considered that the above provided sufficient evidence as to the degree to which the Small Pharma employee's comments should be understood as irresponsible and inappropriate, particularly given his/her company's financial stake in promoting the efficacy of DMT for understudied psychiatric indications.

When writing to Small Pharma, the Authority asked it to consider the requirements of Clauses 7.2 and 7.4 of the Code.

RESPONSE

Small Pharma submitted that no statements made to the Guardian or any other newspaper with respect to the experimental medicine referred to in the article in question were intended to make definitive claims about that medicine which was still preclinical and untested. Small Pharma did

not consider that its statements needed modification, but it was happy to receive guidance from the Panel.

The basis for the specific statements referred to in the complaint were from unpublished and published research conducted by the Centre for Psychedelic Research at Imperial College London and were reported in various papers in the literature, eg Timmermann *et al* 2019. In response to a request for clarification as to whether the company made statements to the Guardian, Small Pharma explained that a press release (copy provided) was shared with the Guardian after the clinical trial had been approved and that the named senior Small Pharma employee had provided the Guardian with an introductory briefing about the company ahead of the clinical trial being approved.

In response to a request for further information from the Panel, a Small Pharma's third party reiterated that the quotation in the Guardian article was based on unpublished and published research conducted by the Centre for Psychedelic Research at Imperial College London and were reported in various papers in the literature, eg Timmermann *et al*, 2019.

The third party explained that the employee's initial conversation with the Guardian ahead of the clinical trial approval was a simple and brief introduction to Small Pharma the company. The press release was then subsequently shared with the Guardian providing details regarding the trial approval. It was confirmed that neither the third party nor Small Pharma were given sight of the article or the opportunity to comment before the article was published.

In response to the further information submitted by the complainant, Small Pharma set out its background and position as a neuropharma company carrying out clinical trials exploring DMT-assisted psychotherapy.

Small Pharma submitted that it was developing SPL026 (DMT fumarate; manufactured to Good Manufacturing Practise (GMP) quality) which was a new chemical entity (NCE) being trialled in-clinic with therapy (DMT-assisted therapy) as a treatment for patients with major depressive disorders. The trial, taking place in collaboration with Imperial College London, had been approved by the UK Regulatory Authorities; the Medicines and Healthcare products Regulatory Agency (MHRA) and by a regional ethics committee. Small Pharma submitted that it was progressing well and provided a link to updates from the Q1 results.

Small Pharma submitted that whilst it was committed to safely trialling the potential benefits of DMT-assisted psychotherapy as a treatment for depressive disorders, **it did not advocate and did not condone** the taking of DMT outside the safe, controlled environment of a clinical trial where experts were present to administer the process end to end; Small Pharma understood its responsibility to make that clear to those whom it sought to educate and inform about the potential of psychedelic-assisted psychotherapy.

With regard to the allegation of a misleading press statement, Small Pharma stated that it would never want to mislead anyone about its clinical trials and/or the potential benefits of DMT and assisted psychotherapy. Small Pharma had a responsibility to accurately reflect scientific evidence in its company communications, and it took that responsibility extremely seriously.

The Guardian article at issue was based on a broader interview with the senior Small Pharma employee. The interview was wide ranging and covered different aspects of Small Pharma's business. In the specific quote at issue, the employee was talking to the hypothesis behind

DMT-assisted therapy treatment based on accumulating evidence to date. Small Pharma provided further details.

Small Pharma stated that its interest in developing DMT-assisted therapy for the treatment of depressive disorders evolved from the existing preclinical and clinical scientific data outlined below. In addition, the significant unmet medical need in depressive disorders, which was not fully addressed by current antidepressants, added significant impetus to Small Pharma's intent and inspired the Small Pharma team to take this molecule into clinical development.

Small Pharma explained that DMT was an indole alkaloid found in various plant species, as well as animals including rats (Barker *et al,* 2013, Dean *et al,* 2019) and humans (Barker *et al*, 2012); it had a long history of use within Mesoamerican and South American culture, with archaeological evidence for its use via smoking dating back to c.2130 BC (Torres 1995).

Small Pharma submitted that DMT was the principal hallucinogen within the psychedelic brew ayahuasca, and whilst Small Pharma did not condone the use of ayahuasca, its therapeutic potential had been tested in the conventional clinical trial setting, with studies revealing a significant reduction in depressive symptoms following a single dose (Osorio Fde *et al,* 2015, Palhano-Fontes *et al,* 2019). Small Pharma submitted that given ayahuasca contained other active ingredients, it was difficult to ascertain that the antidepressant effects were due entirely to DMT, but given it was the principal ingredient of ayahuasca, this was certainly supportive.

Small Pharma submitted that, in addition, the Centre for Psychedelic Research at Imperial College London had also completed multiple studies on the mechanism of action of different psychedelics including DMT. Through their use of magnetoencephalography (MEG), electroencephalography (EEG) and functional magnetic resonance imaging (fMRI), they had demonstrated that the psychedelic state induced by DMT (Timmermann *et al*, 2019), psilocybin (Muthukumaraswamy *et al,* 2013, Schartner *et al,* 2017) and lysergic acid diethylamide (LSD; (Carhart-Harris *et al,* 2016a, Schartner *et al,* 2017) was associated with a decrease in oscillatory power across a range of frequency bands (indicative of a suppressive of the Default Mode Network), and increasing spontaneous signal diversity and global integration of brain networks. Small Pharma submitted that networks, including the Default Mode Network, were overactive in depression and this was thought to cause the ingrained patterns of thinking; Psychedelics supressed this network, hence the decrease in oscillatory power noted above, to allow greater flexibility of such neuronal networks. In addition, DMT had been shown to increase plasticity (Ly *et al*, 2018), and together this was proposed to allow the increase in interconnectedness in the brain as measured in humans using the above methodologies. The work of researchers at the Centre for Psychedelic Research at Imperial College supported this hypothesis. Together, this work had been compiled into the entropic brain hypothesis (Carhart-Harris 2018, Carhart-Harris *et al,* 2014) which might explain the antidepressant effects of psilocybin recently reported by the group ((Carhart-Harris *et al,* 2018a, Carhart-Harris *et al*, 2016b) for which a recent review was done Carhart-Harris 2019. Small Pharma submitted that as DMT caused similar changes in brain activity as psilocybin, it might have a comparable antidepressant potential. In addition, the psychedelic experience elicited by psilocybin was predictive of longer-term therapeutic outcome with psilocybin across a range of indications (Bogenschutz *et al, 2015*, Griffiths *et al,* 2016, Roseman *et al,* 2017). As the DMT experience scored comparably (Timmermann *et al*, 2018), or higher (Griffiths *et al,* 2019) than psilocybin on such scales, it was anticipated to have therapeutic benefit in MDD, and additionally provide enhanced clinical flexibility over psilocybin given the short-duration of the psychedelic experience along with the predicted long-term therapeutic benefit.

Additional information provided by Small Pharma:

Non clinical

Safety:
Potential abuse liability: Previous drug discrimination testing of DMT in rats plus additional data from the use of DMT in academic research trials demonstrated that this psychedelic had a low abuse potential, was not observed to be addictive and administration to humans did not appear to lead to physical dependence. These findings supported the view that classical psychedelic drugs were very unlikely to be addictive and did not pose an abuse risk (Nichols 2016).

Efficacy:

Small Pharma submitted that there have been a number of nonclinical and clinical studies investigating the efficacy and pharmacology of pure forms of DMT. Non-clinical assessment of DMT using the forced swim test (FST), a commonly used screen for antidepressant medications, revealed that DMT significantly reduced immobility time, signalling a reduction in behavioural despair (Porsolt *et al*, 1977; Cameron *et al*, 2018). In addition, DMT was shown to have positive effects in the fear conditioning model in rats (Cameron *et al,* 2019) corroborating the potential benefits of such compounds in patients with post-traumatic stress disorder (PTSD. In addition, a number of studies showed that DMT induced synaptic plasticity and this might be linked to behavioural effects of this drug (Ly *et al*, 2018).

Small Pharma stated that not all of the interview was published in the final article – and therefore some context could be lost. While the employee would always speak in line with the scientific evidence, it was at the journalist's discretion to decide exactly what quote they wanted to use.

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Small Pharma were sorry to hear about the gentleman the complainant referenced and reiterated that it **'did not advocate and did not condone the taking of DMT outside the safe, controlled environment of a clinical trial where experts were present to administer the process end to end'**. Small Pharma submitted that in the absence of any detailed evidence, it was unable to comment as to whether DMT was the likely cause.

Small Pharma's trial and existing evidence on DMT

Small Pharma submitted that whilst its trial was the world's first patient clinical trial using N,N-dimethyltryptamine (DMT), there had been a number of non-clinical and clinical studies investigating the efficacy and pharmacology of pure forms of DMT.

Non-clinical assessment of DMT using the forced swim test (FST), a commonly used screen for antidepressant medications, revealed that DMT significantly reduces immobility time, signalling a reduction in behavioural despair (Porsolt *et al*, 1977; Cameron *et al*, 2018). In addition, DMT was shown to have positive effects in the fear conditioning model in rats (Cameron *et al,* 2019) corroborating the potential benefits of such compounds in patients with post-traumatic stress disorder (PTSD). In addition, a number of studies show that DMT induces synaptic plasticity

and this may be linked to behavioural effects of this drug (Ly *et al*, 2018). This page on Small Pharma's website provided further detail on DMT and its history.

Small Pharma added that in January 2021 the MHRA and Ethics committee approved Small Pharma's Phase I/IIa clinical trial study based on the following criteria:

- **Safety** – this was of paramount importance to the MHRA and they approved this study based on prior preclinical and clinical safety data obtained from studies evaluating the effects of DMT.
- **Preclinical and clinical data** – supporting the mechanism of action of DMT fumarate and supporting the potential therapeutic utility of DMT-assisted therapy.
- **The study design –** used to evaluate DMT in healthy subjects and patients with depressive disorders in a safe, tolerable and scientifically rationale way.

Small Pharma submitted that as it continued to explore the potential of DMT-assisted psychotherapy, it would always uphold the greatest levels of openness, transparency, and academic rigour – while ensuring that its owned communications remained accurate, fair and balanced at all times.

PANEL RULING

The Panel noted that the complainant referred to an article in the Guardian and alleged that Small Pharma appeared to be misrepresenting N,N-dimethyltryptamine (DMT) which it was developing for use in mental health indications. In that regard, he/she referred specifically to a quote from a senior employee of Small Pharma within the article that dimethyltryptamine 'breaks up all of the ruminative thought processes in your brain – it literally undoes what has been done by either the stress you've been through or the depressive thoughts you have – and hugely increases the making of new connections' and alleged that this misrepresented the medicine and could not be substantiated.

The Panel noted that, in addition to sharing a press release with the Guardian after the approval of its Phase I/IIa clinical trial evaluating the effects of N,N-dimethyltryptamine (DMT)-assisted therapy in psychedelic naïve healthy volunteers and it's efficacy in patients suffering with major depressive disorder, Small Pharma's employee spoke with the Guardian for an introductory briefing about the company ahead of the clinical trial approval. The Panel noted Small Pharma's subsequent submission that the Guardian article was based on a broader interview with the senior employee at Small Pharma which was wide ranging and covered different aspects of Small Pharma's business. In the specific quote, the employee was talking to the hypothesis behind DMT-assisted therapy treatment based on accumulating evidence to date. The Panel noted that there was no evidence before it of what was said during this interview.

The Panel noted that the quotation at issue did not appear in the press release shared with the Guardian by Small Pharma, although Small Pharma appeared to accept that the quotation at issue had been made by its employee and the Panel's ruling was made on this basis.

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The Panel noted that the EEG results showed that compared with placebo, DMT markedly reduced oscillatory power in the *alpha* and *beta* bands and robustly increased spontaneous signal diversity. The Panel also noted that the emergence of oscillatory activity within the *delta* and *theta* frequency bands was found to correlate with the peak of the experience.

The Panel noted that Timmermann *et al* concluded that the present results might shed light on the mechanisms underpinning the antidepressant potential of DMT and DMT-related compounds. Increased *alpha* power and decreased *delta* power had been found in populations of depressed individuals and associations had been observed between signal diversity and fluctuations in mood including depressive states. Timmermann *et al* stated that it was reasonable to consider that the massive effects observed here under DMT might have implications for modelling, and perhaps treating, psychopathology.

The Panel noted the positive data in healthy volunteers presented in Timmermann *et al,* particularly in relation to the change in *alpha* and *delta* power. The Panel also noted the study's qualified reference to antidepressant potential.

The Panel further noted Small Pharma's submission that in the specific quote at issue,its employee was talking to the hypothesis behind DMT-assisted therapy treatment based on accumulating evidence to date.

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The Panel considered that the quotation in the lay press that 'DMT broke up all of the ruminative thought processes in your brain, literally undoing what had been done by either the stress one had been through or the depressive thoughts one had and hugely increased the making of new connections' implied a clear and unequivocal clinical benefit in relation to the treatment of stress and depression and that the evidence provided was insufficient to substantiate that implication. The Panel, noting its comments above, considered that on the evidence before it, the unqualified quotation was incapable of substantiation and thereby misleading. Breaches of Clauses 7.2 and 7.4 were ruled.

* * * * * * *

Small Pharma is not a member company of the ABPI. On being notified of the complaint it agreed to comply with the Code and accept the jurisdiction of the PMPCA and the complaint

was processed and considered by the Code of Practice Panel. Following notification of the Panel ruling, Small Pharma did not appeal the Panel's rulings nor provide the requisite undertaking and assurance. It withdrew its agreement to comply with the ABPI Code and accept the jurisdiction of the PMCPA. As the complaint was also copied by the complainant to the Medicines and Healthcare products Regulatory Agency (MHRA), the complainant and the MHRA were informed of the position.

Post publication note: Following publication of this case report, Small Pharma subsequently requested to re-join the list of non-member companies that agreed to comply with the Code and accept the jurisdiction of the PMPCA. As a condition of re-joining the list, Small Pharma was required to provide the requisite undertaking and assurance in this case. Small Pharma provided the undertaking and assurance as required.

Complaint received	**5 January 2021**
Small Pharma withdrew its agreement to comply with the Code and accept the jurisdiction of the PMCPA	**17 September 2021**
Case report published	**4 November 2021**
Undertaking provided	**26 January 2022**