

CASE AUTH/3404/10/20

INDIVIOR v CAMURUS

Promotion of Buvidal

Indivior complained about the promotion of Buvidal (buprenorphine, prolonged-release solution for injection) by Camurus. The materials at issue were a booklet, 'Clinical guidelines for the use of depot buprenorphine (Buvidal) in the treatment of opioid dependence' and related webinars issued by a registration body and network for addiction professionals.

Buvidal was indicated for the treatment of opioid dependence within a framework of medical, social and psychological treatment and was intended for use in adults and adolescents aged 16 years or over.

Guidelines

Indivior noted that the registration body and network for addiction professionals clinical guidelines for the use of Buvidal in the treatment of opioid dependence were initially described by Camurus as an output of an arm's length grant, but the company commissioned the guidelines and was responsible for them. Indivior alleged that the contract with the registration body and network for addiction professionals made it very clear that the commissioned guidelines would be, in effect, promotional material for Buvidal and they did not comply with the Code. Prescribing information was not included, the most prominent mention of Buvidal on the first page of the guidelines did not include its non-proprietary name and the adverse event reporting statement was missing from the guidelines.

Indivior noted the declaration on the guidelines stated 'This guideline was funded by Camurus Ltd. The funding enabled the [registration body and network for addiction professionals] to provide clinical, managerial, editorial and administrative input. Representatives from Camurus (manufacturers of Buvidal) have had the opportunity to provide comment on the draft guidelines, however, all decisions have been made by the authors and endorsed by the consultation working group'. Indivior submitted that the declaration implied an arm's length arrangement, which was reinforced because other aspects of the guidelines did not comply with the Code (eg lack of prescribing information). Indivior submitted that the declaration should have been clear that the guidelines had been commissioned by Camurus.

Indivior alleged that, given the above, readers would not have appreciated they were reading promotional material and promotion was disguised.

Indivior submitted that as the disclaimer on the guidelines appeared to suggest they were written independently of Camurus, the lack of a clear statement that some/all of the authors were affiliated to Camurus was therefore misleading which was acknowledged by Camurus during inter-company dialogue and was only raised by Indivior in support of

its allegation that Camurus had failed to maintain high standards and brought discredit to, or reduced confidence in, the pharmaceutical industry .

In Indivior's view, the failure to adhere to basic Code requirements and include obligatory information on promotional material as well as certify such material, amounted to a lack of high standards.

Indivior considered that Camurus had a poor understanding of Code requirements and alleged that Camurus omitted important safety information (prescribing information and adverse events reporting statement) from guidelines it commissioned to promote the prescription of Buvidal. Indivior submitted the activity brought discredit upon the industry.

The detailed response from Camurus is given below.

In the Panel's view, the Guidelines in question had been paid for by Camurus and according to the agreement with the registration body and network for addiction professionals that, whilst all decisions were made by the authors and endorsed by the consultation working group, Camurus had the opportunity to provide comment on the draft guidelines and Camurus would retain the right to review the guidelines ahead of publication for correction of any factual inaccuracies and to ensure compliance with requirements under the Code.

The Panel considered that Camurus was responsible for the content of the guidelines. In the Panel's view, Camurus was closely linked to the production of the Guidelines such that there was no arm's length arrangement between the provision of funds and the adaptation of the Guidelines. It did not appear that the original request was wholly unsolicited as submitted by Camurus; the email dated October 2019 referred to a previous conversation at which 'ball park' figures were discussed. Irrespective of whether the original request was solicited or unsolicited, the Panel noted that the work was undertaken by the registration body and network for addiction professionals under the framework of the signed consultancy agreement described above which, in the Panel's view, made it clear that the registration body and network for addiction professionals was working on behalf of Camurus and that Camurus considered the final guideline to be its promotional material requiring prescribing information. The Panel noted that Camurus acknowledged that under the agreement it retained responsibility for ensuring that the final guidance complied with the Code.

The Panel also noted that it was clear at the outset from the registration body and network for addiction professionals' proposal that the Guidelines would support Buvidal and that it appeared that the proposal would only go ahead with the involvement of Camurus. The Guidelines were, in effect, promotional material for Buvidal.

The Panel noted Camurus' submission that aspects of the agreement were not fully executed as prescribing information an adverse event reporting statement and the non-proprietary name as required by the Code were not included in the guideline. The Panel therefore ruled breaches of the Code as acknowledged by Camurus.

The Panel noted that the guidelines were not certified for issue in their final form and a breach of the Code was ruled as acknowledged by Camurus.

The Panel noted that the Code stated, *inter alia*, that material relating to medicines and their uses, whether promotional or not, which is sponsored by a pharmaceutical company must clearly indicate that it has been sponsored by that company. In the Panel's view, given its comments above, the Guidelines were, in effect, Camurus' commissioned promotional material rather than Camurus' sponsored material and thus no breach of the Code was therefore ruled.

The Panel noted that the second page of the guideline, below the list of authors, other acknowledgements and reference to the NSW Ministry of Health Guidelines from which these guidelines had been adapted was a statement of Camurus' involvement as set out above. The Panel noted its finding above that the Guidelines were, in effect, Camurus' promotional material for Buvidal, and considered that this was not sufficiently clear: only the registration body and network for addiction professionals in logo format was mentioned prominently at the outset on the front page; the declaration about Camurus' involvement on page 2 was not satisfactory: its location and format was such that it could easily be overlooked and thus pharmaceutical company involvement was not immediately apparent to readers and its content was, in any event, inadequate given the Panel's finding that the guidelines were promotional material. The misleading implication was compounded by the phrase '[registration body and network for addiction professionals] Clinical Guidelines for the use of prolonged release buprenorphine (Buvidal) in the treatment of opioid dependence' at the bottom of each page. The Panel considered that it would thus not be sufficiently clear to readers that the guidelines were Camurus' promotional material and it was therefore disguised in this regard. A breach of the Code was ruled.

The Panel considered that Camurus had failed to maintain high standards and ruled a breach of the Code.

The Panel noted its comments and rulings above and considered that Camurus appeared to have a poor understanding of the Code. The Panel noted that an adverse event reporting statement was a safety requirement and given that Buvidal was an opioid, it was particularly important. In the Panel's view, Camurus had brought discredit upon, and reduced confidence in, the industry and a breach of Clause 2 was ruled.

Webinars

Indivior submitted that the registration body and network for addiction professionals conducted two webinars in May 2020 about Buvidal and the guidelines which were inextricably linked to Camurus.

Indivior alleged that the cumulative impression of both the webinars' promotional content and the use of certain wording in the evaluation form conveyed, from the outset, that Camurus intended the webinars to be promotional.

Indivior submitted that as the webinar content was solely about Buvidal and the promotional guidelines, the intent was promotional, and the arrangements were not arm's length. Indivior alleged that the webinars failed to include the prescribing information, the non-proprietary name next to the first mention of the brand name and the adverse event reporting statement.

Indivior further stated that the webinars appeared to be conducted at arm's length from Camurus, which was not so as the disclaimer stated, 'These guidelines and webinars were funded by Camurus Ltd'. Indivior alleged that attendees were misled by the unacceptable declaration of involvement and that the webinars were not conducted at arm's length and they were under the full control of Camurus which failed to certify their content beforehand.

Indivior further submitted that the promotional webinars were made available to the public because there was a lack of a robust registration process which allowed non-health professionals to register and webinar 1 was available on YouTube without any log-in or access restriction. Indivior noted that Camurus had acknowledged that point and the registration body and network for addiction professionals had taken the webinars down from access via its YouTube channel. Indivior submitted that that reinforced the fact that Camurus had control over the webinars and should have cancelled webinar 2 when alerted by Indivior as to its non-compliance. The content of the webinar promoted Buvidal, a prescription-only medicine, to members of the public and encouraged them to ask their doctor to prescribe a specific medicine.

Indivior submitted that the promotional webinars were made available to the public when access should have been restricted to health professionals only. In addition, Indivior noted that the webinar 1 was still accessible via a Google search for 'Buvidal webinar', '[the registration body and network for addiction professionals] Buvidal' or 'Camurus webinar' without any acknowledgement or clarity that viewers should be health professionals.

Indivior alleged that not clearly recognising that a request to support a promotional activity in itself constituted promotion was poor standards.

Indivior alleged that Camurus had a poor understanding of Code requirements – for example, the request from the registration body and network for addiction professionals stated that the webinars would discuss the (promotional) guidelines and Camurus failed to appreciate its liability under the Code to include important safety information (such as the prescribing information and adverse events reporting statement) from webinars which appeared to be independently conducted. Indivior alleged that the whole activity brought discredit upon the industry and unfortunately these webinars were hosted by the registration body and network for addiction professionals and, on the balance of probabilities, likely to have been accessed by patients and the public.

The detailed response from Camurus is given below.

The Panel noted that in April 2020 the registration body and network for addiction professionals emailed Camurus with a preliminary proposal for a series of webinars on the use of Buvidal. It spoke positively about the demand for, and use of, Buvidal and described three webinars including one webinar discussing the overall theme of treatment options, moving into the basics of Buvidal – what it is, how it works, things to consider when bringing it in to services and another providing more detail on Buvidal prescribing including case discussions – the grey areas, and clinical decisions. The email then stated that there may be 'widescale take up of Buvidal in Wales in community and prison settings fairly soon and it would be great to provide support to clinicians/services....'. It referred to the guidelines stating 'this could hopefully form part of their launch as well'. It also referred to the likelihood that Buvidal will be prescribed in

at least one English prison. This preliminary request was followed by a formal request for an educational grant. This formal request stated 'In response to the Covid-19 pandemic the Welsh government has recently endorsed the use of Buvidal to support safety in both community and prison settings. Clinicians in Scotland are also advocating the use of Buvidal as a response to the pandemic. However, there is lack of understanding regarding its distinctive features and how to prescribe the medication in the drug treatment field'. The training content would be based upon new guidance 'Clinical guidelines for use of depot buprenorphine (Buvidal) in the treatment of opioid dependence' currently being developed by the registration body and network for addiction professionals, and other current UK clinical guidance. It further stated that the registration body and network for addiction professionals would evaluate the course materials with Camurus and that all delivered training would be evaluated by course participants and would be shared with Camurus during the project and an evaluation report would be shared with Camurus at the end of the project. It appeared from the inter-company dialogue that Camurus clarified that this related to a factual accuracy check in relation to the company product being discussed and it did not take up this offer and no presentation materials were shared with it in advance of the webinars.

The Panel noted Camurus' submission that given the product-related activity could not be supported as a grant, the event sponsorship form was forwarded to the registration body and network for addiction professionals for completion and execution.

The Panel noted that the final title of the two webinars at issue were: 'Buvidal-introduction to first available prolonged release Buprenorphine in the UK' and 'Buvidal in a range of challenging community scenario's - including a pandemic'.

The Panel noted that the final slide of the webinars included an evaluation form which asked, *inter alia*, if there were issues attendees would like to have covered in future webinars in the series on Buvidal and asked attendees if they were happy for Camurus to contact them by email with promotional [information] about its products and services.

The Panel considered that it was abundantly clear from the outset that the proposed webinars would encourage and support the use of Buvidal within an environment of particular demand in Wales. In the Panel's view, given this and the content and links to the promotional Guidelines above, the webinars were, in effect, promotional material for Buvidal for which Camurus was responsible.

The Panel noted that prescribing information, an adverse event reporting statement, and the non-proprietary name as required by the Code were not included in the two webinars at issue. The Panel therefore ruled breaches of the Code.

The Panel noted Camurus' submission that the webinars had not been certified for use and a breach of the Code was ruled.

The Panel noted that the declaration for the webinars, as highlighted by Indivior, stated 'These webinars have been sponsored by Camurus Ltd. The funding enabled the registration body and network for addiction professionals to provide clinical and digital designer time, hosting and advertising'. The Panel considered that the declarations of sponsorship did not fairly reflect Camurus' role and responsibility in relation to the activity and a breach of the Code was ruled.

The Panel noted Camurus' submission that the sponsorship agreement between it and the registration body and network for addiction professionals clearly confirmed the intended audience as health professionals and other relevant decision makers. Despite this, the Panel noted that the material in relation to the first webinar had been accessible to the public. The Panel noted that when so advised by Indivior, Camurus took steps with the registration body and network for addiction professionals to remedy matters and that, before the second webinar took place, health professional self-certification was incorporated into the registration process.

The Panel noted that it was unclear how the hosting webinar page subsequently became accessible to the public without self-certification; it was not anticipated that by entering '[the registration body and network for addiction professionals]' and 'Buvidal webinar' an internet search could bypass the self-certification system and arrive directly at the webinar page. However, Camurus anticipated that very few (if any) members of the public would have accessed the webinars in that way due to the obscure nature of the search, although it accepted that it would have been possible for them to do so.

The Panel noted that in relation to the first live webinar, it appeared that there was no self-certification of health professional status at that time and thus it was not restricted to health professionals and other relevant decision makers.

The Panel further considered that it was unfortunate that despite only intending to be available to health professionals, the webinars could still be accessed on a public YouTube page via a Google search using foreseeable and standard search terms which by-passed the self-certification requirements that had been imposed after the first webinar. The Panel noted that the YouTube page provided as a screenshot by Indivior invited the public to subscribe to the registration body and network for addiction professionals channel stating that 'This webinar provides information regarding treatment selection of prolonged-release formulations including basic pharmacology and issues regarding introducing Buvidal into service provision'. There was no mention on the YouTube page in question that the material was for health professionals.

The Panel noted its comments above and considered that a prescription only medicine had been promoted to the public, breaches of the Code were ruled.

The Panel noted that Camurus had since also amended its corporate sponsorship forms to ensure that measures taken by third-parties to ensure that online content was restricted to intended audiences were documented for review prior to approval of the funding request. The Panel noted its comments and rulings above and considered that, overall, Camurus had failed to maintain high standards and a breach of the Code was ruled.

The Panel considered that Camurus appeared to have a poor understanding of the Code, including the distinction between promotional and non-promotional material. The Panel noted that an adverse event reporting statement was an important safety requirement and given that Buvidal was an opioid, it was particularly important. In the Panel's view, Camurus had brought discredit upon, and reduced confidence in, the industry and a breach of Clause 2 was ruled.

Indivior UK Limited complained about the promotion of Buvidal (buprenorphine, prolonged-release solution for injection) by Camurus UK. The materials at issue were a 54-page booklet,

'Clinical guidelines for the use of depot buprenorphine (Buvidal) in the treatment of opioid dependence' and related webinars issued by the registration body and network for addiction professionals.

Buvidal was indicated for the treatment of opioid dependence within a framework of medical, social and psychological treatment and was intended for use in adults and adolescents aged 16 years or over.

Inter-company dialogue had not resolved matters.

Background provided by Indivior

Indivior noted that a number of webinars and documents that appeared to be linked to Camurus appeared on the registration body and network for addiction professionals website:

- Webinar 1 (7 May 2020) 'Buvidal: An introduction to first available prolonged- release buprenorphine in the UK'.
- Webinar 2 (14 May 2020) 'Buvidal in a range of challenging community scenarios including a pandemic'.
- Webinar 3 (28 May 2020): 'Depot buprenorphine in criminal justice settings'.
- Document 'Clinical guidelines for use of depot buprenorphine (Buvidal) in the treatment of opioid dependence'.

The declaration associated with these activities implied that Camurus had provided financial support only. However, Indivior was concerned that the activities were not conducted at arm's length, as stated by Camurus during inter-company dialogue, and focused on the Camurus prescription-only medicine Buvidal and were promotional in that regard. Indivior provided further details about the inter-company dialogue.

Background provided by Camurus

Camurus noted that the guidelines and webinars at issue were separate materials/activities governed by different arrangements. Both were based on unsolicited requests for support received from the registration body and network for addiction professionals at different times. The request to support the guideline development was received in October 2019 and the request to support the webinar series was received in April 2020. Camurus had not circulated the guidelines or any of the webinars. Camurus further explained that the registration body and network for addiction professionals was a professional network that offered training, education and expert support to individuals involved in the treatment of addictions and its website and its resources were accordingly aimed towards such health professionals.

1 Guidelines

COMPLAINT

Indivior submitted that the registration body and network for addiction professionals clinical guidelines for the use of [prolonged release] buprenorphine (Buvidal) in the treatment of opioid dependence were initially described by Camurus as an output of an arm's length grant, but the company commissioned the guidelines under an agreement with the registration body and network for addiction professionals, was liable for them and they did not comply with the Code.

Although Camurus acknowledged that ‘aspects of the agreement were not fully executed’, it was entirely unsatisfactory that, during inter-company dialogue, the company refused to provide a commitment to cease to inappropriately support similar guidelines.

Indivior stated that its specific concerns about the guidelines related to the fact that Camurus was inextricably linked to their content, the material was therefore promotional for Buvidal and did not comply with the Code. Camurus had initially stated that it was ‘approached by the registration body and network for addiction professionals in October 2019 with a request to support an adaptation of the New South Wales Ministry of Health Guidelines on long-acting buprenorphine for UK clinicians’ – thus implying an arm’s length relationship between the company and the registration body and network for addiction professionals. However, after further questioning, Camurus confirmed that it had commissioned the guidelines:

- the registration body and network for addiction professionals was commissioned by Camurus to adapt the New South Wales guidelines on long-acting buprenorphine.
- External clinicians would be paid by Camurus to write the guidelines.
- the registration body and network for addiction professionals would be paid to produce a final version to be hosted on its website.
- Camurus retained the right to approve the guidelines to ensure compliance with the Code.

Indivior alleged, however, that the guidelines breached the following clauses of the Code:

- Clause 4.1: The contract with the registration body and network for addiction professionals made it very clear that the commissioned guidelines would be, in effect, promotional material for Buvidal. Prescribing information was not included. In addition, as the guidelines were available on the registration body and network for addiction professionals website to download for an unknown amount of time (and Camurus persisted with the webinars even after concerns were raised by Indivior), an ‘acknowledgement’ of this ‘issue’ from Camurus was insufficient.
- Clause 4.3: The most prominent mention of Buvidal on the first page of the guidelines did not include its non-proprietary name.
- Clause 4.9: The adverse event reporting statement was missing from the guidelines.
- Clause 9.10: The declaration on the guidelines stated:

‘This guideline was funded by Camurus Ltd. The funding enabled [the registration body and network for addiction professionals] to provide clinical, managerial, editorial and administrative input. Representatives from Camurus (manufacturers of Buvidal) have had the opportunity to provide comment on the draft guidelines, however all decisions have been made by the authors and endorsed by the consultation working group.’

Indivior submitted that the declaration implied an arm’s length arrangement, which was reinforced because other aspects of the guidelines did not comply with the Code (eg lack of prescribing information). The declaration should have been clear that the guidelines had been commissioned by Camurus. Whilst Camurus acknowledged that point, the guidelines were available on the website to download for an unknown amount of time and Camurus persisted

with webinar 2 promoting the guidelines even after concerns were raised. Therefore, Indivior did not consider this matter resolved, as an 'acknowledgement' was insufficient.

- Clause 12.1: Given the lack of clear declaration of involvement on the guidelines and the lack of obligatory information such as Buvidal prescribing information amongst other issues, readers would not have appreciated they were reading promotional material and promotion would have been disguised.
- Clause 14.1: Camurus implied during inter-company dialogue (copy provided) that the materials were not certified but did not accept that breach specifically, even though it was cited in Indivior's letter of 23 June 2020.

Indivior submitted that as the disclaimer on the guidelines appeared to suggest they were written independently of Camurus, the lack of a clear statement that some/all of the authors were affiliated to Camurus was therefore misleading and not in line with Clause 23.1. Indivior noted that it was not alleging a breach of this clause as Camurus had already acknowledged that point in its letter of 8 July 2020 (copy provided); Indivior stated that it noted the matter to support its alleged breaches of Clause 9.1 and 2.

- Clause 9.1: In Indivior's view, the failure to adhere to basic Code requirements and include obligatory information on promotional material as well as certify such material, amounted to a lack of high standards.
- Clause 2: Indivior considered that Camurus had a poor understanding of Code requirements – for example the contract with the registration body and network for addiction professionals (copy provided) suggested that off-licence indications should not be the focus but could be mentioned. In addition, Camurus omitted important safety information (such as that in the prescribing information and adverse events reporting statement) from guidelines it commissioned to promote the prescription of Buvidal, but which appeared to be independently written. The activity brought discredit upon the industry and unfortunately the guidelines were further used by the registration body and network for addiction professionals and other organisations (some for patients and the public).

RESPONSE

Camurus stated that it had never described the guidelines as 'output of an arm's length grant'. As stated to Indivior during inter-company dialogue, in responses dated 10 June and 8 July 2020, a preliminary request for support for two projects was received from the registration body and network for addiction professionals by email on 18 October 2019. One of the projects related to the adaptation of the New South Wales Ministry of Health Guidelines on long-acting buprenorphine for UK clinicians. Camurus determined that as the request related to specific medicines, including a company product, it could not be processed as a grant and it was recommended that the project be enacted under a consultancy agreement. The intention behind the consultancy agreement was not to influence the content of the guidance but to provide a mechanism of support for the development of the guidance and ensure that it adhered to the relevant standards and requirements of the Code. The standard Camurus template for non-health professional consultancy services was used to execute the agreement with a description of the project outlined as set out below:

‘Adapting Clinical guidelines for use of depot buprenorphine (Buvidal and Sublocade) in the treatment of opioid dependence

[The registration body and network for addiction professionals] will adapt the above NSW Ministry of Health guidelines on long-acting buprenorphine for a UK health professional audience. The adapted guidelines will focus on Buvidal as it is the only depot buprenorphine product currently approved in the UK. This would involve adapting both the longer version, and also the brief guidance. A small group of clinicians, overseen by [the registration body and network for addiction professionals Clinical Director] will review the above guidance, identifying areas that require adaptation for the UK market. Clinicians will then re-write sections as required, and the registration body and network for addiction professionals team will edit and provide a final version. The adapted guidance will be advertised and hosted on the [registration body and network for addiction professionals] website, adhering to the relevant standards and requirements of the Code including, but not limited to provision of the relevant prescribing information and acknowledgement of Camurus involvement (see Exhibit B). Camurus will retain the right to review the guidelines ahead of publication for correction of any factual inaccuracies and to ensure compliance with requirements under the Code.’

Camurus noted that while the use of the template set up a fee-for-service arrangement, this did not reflect the intention behind the agreement and Camurus therefore refuted the assertion that Camurus commissioned the registration body and network for addiction professionals to adapt the guidelines. The intention was to support the independent adaptation of the guidelines instigated by the registration body and network for addiction professionals, with Camurus’ involvement limited to a factual accuracy check, and this was how the project was executed. All meetings related to the project were organised and managed by the registration body and network for addiction professionals. Nevertheless, Camurus acknowledged that under this agreement it retained responsibility for ensuring that the final guidance complied with the Code.

During inter-company dialogue, Camurus acknowledged that these aspects of the agreement were not fully executed, in that prescribing information and other obligatory information were not attached, and the guidelines were not approved and certified for issue in their final form. Camurus confirmed that it had not used the guidelines proactively or reactively but acknowledged the need to take immediate corrective action with respect to their use by the registration body and network for addiction professionals. Camurus therefore asked the registration body and network for addiction professionals to remove the guidelines from its website which was confirmed by the registration body and network for addiction professionals on 9 July 2020. During inter-company dialogue, Camurus did not agree to Indivior’s request to provide an inter-company commitment to ‘cease to support similar promotional guidelines or webinars under the guise of non-promotional “arm’s length arrangements”’ as it implied that there had been disguised promotion, which Camurus refuted and so it was unwilling to make such a broad and undefined commitment.

Camurus accepted that there had been breaches of Clauses of 4.1, 4.3, 4.9 and 14.1 with respect to the guidelines. However, the company considered that the declaration on page 1 of the guidelines ‘This guideline was funded by Camurus Ltd. The funding enabled the registration body and network for addiction professionals to provide clinical, managerial, editorial and administrative input. Representatives from Camurus (manufacturers of Buvidal) have had the opportunity to provide comment on the draft guidelines, however, all decisions have been made by the authors and endorsed by the consultation working group’ accurately reflected the nature of the company’s involvement and was not misleading. Camurus therefore denied a breach of

Clause 9.10. Given that the declaration was accurate and the entire document related to use of depot buprenorphine (Buvidal) in the treatment of opioid dependence, as stated on the cover, Camurus refuted the allegation of disguised promotion and therefore denied a breach of Clause 12.1.

Camurus noted that whilst not alleging a breach of Clause 23.1, Indivior had referred to that clause in support of the alleged breaches of Clauses 9.1 and 2. Camurus submitted that the requirement of Clause 23, that companies include provisions regarding the obligation of consultants to declare that they had been a consultant to the company, was met in all relevant consultancy agreements. However, in line with procedural shortcomings leading to the above acknowledged breaches, Camurus agreed that there had been a failure to maintain high standards and accepted a breach of Clause 9.1. However, given that the guidelines were independently written by clinical experts in line with the declaration, contained important prescribing and safety information consistent with the SPC and were not circulated by Camurus, the company did not consider that any of its actions had brought discredit upon, or reduced confidence in, the pharmaceutical industry and therefore it did not accept that there had been a breach of Clause 2.

PANEL RULING

The Panel noted that an email from the registration body and network for addiction professionals to Camurus on 18 October 2019 regarding 'proposals' for educational grants referred to the adaptation of the New South Wales Ministry of Health Guidelines on depot buprenorphine (Buvidal and Sublocade) for UK clinicians and stated that the registration body and network for addiction professionals would be 'happy to draw up more detailed proposals/discuss detail if Camurus was interested in taking the projects further'. The email also referred to a previous telephone conversation about the proposals. The Panel noted Camurus' submission that as the request related to specific medicines, including a company product, it could not be processed as a grant and it was recommended that the project be enacted under a consultancy agreement. The Panel noted Camurus' submission that whilst the use of the standard Camurus template for non-health professional consultancy services was used to execute the agreement as a fee-for-service arrangement, it did not reflect the intention behind the agreement and Camurus denied that it had commissioned the registration body and network for addiction professionals to adapt the guidelines. According to Camurus, the intention was to support the independent adaptation of the guidelines instigated by the registration body and network for addiction professionals, with Camurus' involvement limited to a factual accuracy check, and that was how the project was executed.

The Panel noted that under the agreement dated 5 November 2019 Camurus had contracted the registration body and network for addiction professionals to adapt the Guidelines. The Panel noted that the agreement included a description of the project which stated, *inter alia*, that '[the registration body and network for addiction professionals] will adapt the above NSW Ministry of Health guidelines on long-acting buprenorphine for a UK health professional audience. The adapted guidelines will focus on Buvidal as it is the only depot buprenorphine product currently approved in the UK. The adapted guidance will be advertised and hosted on the registration body and network for addiction professionals website, adhering to the relevant standards and requirements of the Code including, but not limited to provision of the relevant prescribing information and acknowledgement of Camurus' involvement'. The agreement also referred to providing regular reports to Camurus and involving it in the project as required throughout its duration. In the Panel's view, the Guidelines in question had been paid for by Camurus and according to the agreement that whilst all decisions were made by the authors

and endorsed by the consultation working group, representatives from Camurus had the opportunity to provide comment on the draft guidelines and Camurus would retain the right to review the guidelines ahead of publication for correction of any factual inaccuracies and to ensure compliance with requirements under the Code.

The Panel noted that it was possible for a company to sponsor material which mentioned its own products and not be liable under the Code for its contents, but only if it had been a strictly arm's length arrangement with no input by the company and no use of the material by the company.

It had previously been decided, in relation to material aimed at health professionals, that the content would be subject to the Code if it was promotional in nature or if the company had used the material for a promotional purpose. Even if neither of these applied, the company would be liable if it had been able to influence the content of the material in a manner favourable to its own interests.

The Panel considered that Camurus was responsible for the content of the guidelines. In the Panel's view, Camurus was closely linked to the production of the Guidelines such that there was no arm's length arrangement between the provision of funds and the adaptation of the Guidelines. It did not appear that the original request was wholly unsolicited as submitted by Camurus; the email dated 18 October 2019 referred to a previous conversation at which 'ball park' figures were discussed. Irrespective of whether the original request was solicited or unsolicited, the Panel noted that the work was undertaken by the registration body and network for addiction professionals under the framework of the signed consultancy agreement described above which, in the Panel's view, made it clear that the registration body and network for addiction professionals was working on behalf of Camurus and that Camurus considered the final guideline to be its promotional material requiring prescribing information. The Panel noted that Camurus acknowledged that under the agreement it retained responsibility for ensuring that the final guidance complied with the Code.

The Panel also noted that it was clear at the outset from the registration body and network for addiction professionals' proposal that the Guidelines would support Buvidal and that it appeared that the proposal would only go ahead with the involvement of Camurus. The Guidelines, entitled 'Clinical Guidelines for use of depot buprenorphine (Buvidal) in the treatment of opioid dependence' contained several positive mentions of Buvidal and given its content, the Guidelines were, in effect, promotional material for Buvidal.

The Panel noted Camurus' submission that aspects of the agreement were not fully executed, as prescribing information and other obligatory information were not attached. Exhibit A to the agreement referred to the inclusion of prescribing information. The Panel noted that prescribing information, an adverse event reporting statement and the non-proprietary name as required by Clause 4.3 were not included in the guideline. The Panel therefore ruled breaches of Clauses 4.1, 4.3 and 4.9 as acknowledged by Camurus.

The Panel noted that the guidelines were not certified for issue in their final form and a breach of Clause 14.1 was ruled as acknowledged by Camurus.

The Panel noted that Clause 9.10 stated, *inter alia*, that material relating to medicines and their uses, whether promotional or not which is sponsored by a pharmaceutical company must clearly indicate that it has been sponsored by that company. In the Panel's view, given its comments above, the Guidelines were, in effect, Camurus' commissioned promotional material rather than

Camurus' sponsored material and Clause 9.10 was thus not relevant: no breach of Clause 9.10 was therefore ruled.

The Panel noted that the second page of the guideline, below the list of authors, other acknowledgements and reference to the NSW Ministry of Health Guidelines from which these guidelines had been adapted it stated 'This guideline was funded by Camurus Ltd. The funding enabled the registration body and network for addiction professionals to provide clinical, managerial, editorial and administrative input. Representatives from Camurus (manufacturers of Buprenorphine) have had the opportunity to provide comment on the draft guidelines, however all decisions have been made by the authors and endorsed by the consultation working group'. The Panel noted its finding above that the Guidelines were, in effect, Camurus' promotional material for Buprenorphine, and considered that this was not sufficiently clear: only the registration body and network for addiction professionals in logo format was mentioned prominently at the outset on the front page; the declaration about Camurus' involvement on page 2 was not satisfactory: its location and format was such that it could easily be overlooked and thus pharmaceutical company involvement was not immediately apparent to readers and its content was, in any event, inadequate given the Panel's finding that the guidelines were promotional material. The misleading implication was compounded by the phrase '[the registration body and network for addiction professionals] Clinical Guidelines for the use of prolonged release buprenorphine (Buprenorphine) in the treatment of opioid dependence' at the bottom of each page. The Panel considered that it would thus not be sufficiently clear to readers that the guidelines were Camurus' promotional material and it was therefore disguised in this regard. A breach of Clause 12.1 was ruled.

The Panel noted its comments and rulings above and considered that Camurus had failed to maintain high standards and a breach of Clause 9.1 was ruled as acknowledged by the company.

The Panel noted its comments and rulings above including breaches of Clauses 4.1 and 4.9 and considered that Camurus appeared to have a poor understanding of the Code. The Panel noted that an adverse event reporting statement was a safety requirement and given that Buprenorphine was an opioid, it was particularly important. In the Panel's view, Camurus had brought discredit upon, and reduced confidence in, the industry and a breach of Clause 2 was ruled.

2 Webinars

COMPLAINT

Indivior submitted that the registration body and network for addiction professionals conducted webinars about Buprenorphine and the guidelines on 7 and 14 May 2020 which were inextricably linked to Camurus. On 13 May and 10 June 2020, Camurus suggested that the webinars were outside of its control and described them definitively as being held at arm's length, but Camurus later admitted that it processed the registration body and network for addiction professionals' request for support as event sponsorship. It was not clear why the company was not full and frank at the outset of inter-company dialogue.

Indivior stated that Camurus did not provide detail behind its reasoning that a 'grant was not an appropriate mechanism of support' but presumably this was because the webinar content was clearly promotional and the intent was to promote the Buprenorphine guidelines and 'how to prescribe the medication in the drug treatment field'. In addition, Indivior did not accept Camurus' assertion that 'it was possible for companies to provide sponsorship for third-party events that

included product-related educational content without assuming responsibility for the content'. If this was the case, then companies could easily bypass the requirements of the Code when it came to ensuring promotional activities and materials complied with the Code.

Indivior noted that the registration body and network for addiction professionals evaluation form provided in full at the end of the webinar and again via a link in the 'Thank You' email sent to delegates afterwards, asked delegates to answer 'Yes' or 'No' to the question 'I am happy for Camurus to contact me by email with promotional [sic] about its products and services...'. Indivior accepted that this wording did not immediately render an activity as promotional. However, the cumulative impression of both the promotional content and the use of such wording conveyed, from the outset, that Camurus intended the webinars to be promotional. Apart from the value of promotion, Camurus would also receive a contact list of targets to whom it could further promote its medicine. In that regard, Indivior noted that access to the webinars was not limited to health professionals.

Indivior stated that according to Camurus' response, it provided the registration body and network for addiction professionals with its privacy notice to be shared with attendees who selected to receive promotional information. However, this notice was made available to all (irrespective of whether such person elected to receive promotional materials). Indivior was thus concerned as to the precise extent of the list of parties whom Camurus could later contact for promotional purposes. This further reinforced the commercial value of the webinars and implied that Camurus prioritised commercial objectives over compliance concerns.

Indivior was concerned that Camurus likened the option of choosing to 'opt-in to promotion' to choosing 'to visit a company stand during the course of attending a non-virtual meeting'. Indivior stated that Camurus had not appreciated that the 'opt-in' on the registration body and network for addiction professionals evaluation form or via the 'Thank You' email, and/or the presence of the Camurus privacy notice, allowed attendees to subsequently receive promotional emails/materials from Camurus following the event, conveying a promotional intent from the outset. Indivior reiterated that the webinars were open to all and not just health professionals.

Indivior submitted that as the webinar content was solely about Buvidal and the promotional guidelines, the intent was promotional, and the arrangements were not arm's length. Indivior alleged that the webinars breached the following clauses of the Code:

- Clause 4.1: The webinars failed to include the prescribing information (either as a link or embedded in the content).
- Clause 4.3: The webinars failed to include the non-proprietary name next to the first mention of the brand name.
- Clause 4.9: The adverse event reporting statement was missing.
- Clause 9.10: The webinars appeared to be conducted at arm's length from Camurus, which was not so as the disclaimer stated, 'These guidelines and webinars were funded by Camurus Ltd'. Attendees were misled by the unacceptable declaration of involvement.
- Clause 14.1: The webinars were not conducted at arm's length and they were under the full control of Camurus which failed to certify their content beforehand.

- Clauses 26.1 and 26.2: The promotional webinars were made available to the public because there was a lack of a robust registration process which allowed non-health professionals to register and webinar 1 was available on YouTube without any log-in or access restriction. Indivior noted that Camurus had acknowledged that point and the registration body and network for addiction professionals had taken the webinars down from access via its YouTube channel. Indivior submitted that that reinforced the fact that Camurus had control over the webinars and should have cancelled webinar 2 when alerted by Indivior as to its non-compliance. The content of the webinar promoted Buprenorphine, a prescription-only medicine, to members of the public and encouraged them to ask their doctor to prescribe a specific medicine.
- Clause 28.1: The promotional webinars were made available to the public when access should have been restricted to health professionals only. Indivior noted that Camurus acknowledged that point and the registration body and network for addiction professionals changed its registration process on 15 May. This again reinforced the fact that Camurus had control over the webinars and should have cancelled webinar 2 when alerted by Indivior as to its non-compliance. In addition, Indivior noted that the webinar 1 was still accessible via a Google search for 'Buprenorphine webinar', '[the registration body and network for addiction professionals] Buprenorphine' or 'Camurus webinar' without any acknowledgement or clarity that viewers should be health professionals.
- Clause 9.1: Indivior submitted that not clearly recognising that a request to support a promotional activity in itself constituted promotion was poor standards.
- Clause 2: Indivior alleged that Camurus had a poor understanding of Code requirements – for example, the request from the registration body and network for addiction professionals stated that the webinars would discuss the (promotional) guidelines and Camurus failed to appreciate its liability under the Code to include important safety information (such as that in the prescribing information and adverse events reporting statement) from webinars which appeared to be independently conducted. Indivior alleged that the whole activity brought discredit upon the industry and unfortunately these webinars were hosted by the registration body and network for addiction professionals and on the balance of probabilities, likely to have been accessed by patients and the public.

RESPONSE

Camurus stated that on 23 April 2020, the registration body and network for addiction professionals emailed the company with a preliminary proposal for a series of educational webinars on the use of long-acting buprenorphine, instigated by a physician from Wales (copy provided). The context for this request was recent guidance issued by the Scottish and Welsh Governments recommending use of long-acting buprenorphine in prison settings due to its potential to support reduced treatment episodes and physical distancing in the context of the Covid-19 pandemic. As indicated in the email, other topics had been discussed previously that were unrelated to the proposed webinars. This context was provided to clarify that the webinars themselves had not been a prior topic of discussion and were not instigated by Camurus, but by the clinical community in response to a perceived educational need. It was for this reason that they focussed on a single medicine which was the only approved long-acting formulation of

buprenorphine licensed and available in the UK, and not an intention on the part of Camurus to promote its medicine. The preliminary request was followed up with a formal emailed request for an educational grant received on 27 April 2020. Given that this product-related activity could not be supported as a grant, the event sponsorship form was forwarded to the registration body and network for addiction professionals for completion and full execution.

Camurus stated that the sponsorship agreement confirmed that its involvement would be declared on all materials related to the series with the statement 'Camurus has supported this webinar series and e-learning by providing funds for clinician and digital designer time, advertising and hosting'. Camurus was not involved in the initiation of the webinars, or the concept, nor was it involved in the development of the content or scope of the webinar materials and it did not have any influence over the list of attendees. In the initial inter-company call between Indivior and Camurus on 13 May 2020, after the first webinar that took place on 7 May 2020, Indivior raised some areas of concern in relation to Camurus' activities and requested confirmation of an 'arm's length relationship'. Camurus confirmed during that call, and subsequently in its written responses of 10 June 2020 and 8 July 2020, that whilst it had provided financial support for the webinars, in line with the declaration above, it had no involvement in the concept, preparation, delivery or advertising of them. It was not clear why Indivior considered that this was not full and frank disclosure from the outset.

Camurus stated that with respect to Indivior's concerns regarding the possibility for attendees to 'opt-in' to receive product-related information from Camurus, the company noted that Clause 22 did not preclude commercial arrangements in association with company sponsorship of meetings and events, such as brand visibility, stand space, conference bag inserts etc and such arrangements frequently existed in association with sponsored third-party meetings or events. Additionally, that was not requested by Camurus but offered by the registration body and network for addiction professionals. The 'opt-in' afforded Camurus the opportunity to obtain consent from attendees to subsequently receive product-related information by email and the privacy notice was provided to all attendees to inform them of how their information would be processed should they 'opt-in'.

The idea for the webinars was not initiated by Camurus, and Camurus was neither responsible for, nor involved in the development of the content or scope, review or approval of the webinar materials nor had it any influence over the list of attendees. Camurus did not invite any delegates and did not have a presence at the webinar. As a result, there was no means by which Camurus could influence or control the content of the webinars. Additionally, Camurus had not used the sponsored webinar content for any promotional purpose, and it had not directed any individuals to the live or recorded versions. Camurus stated that it therefore refuted the alleged breaches of Clauses 4.1, 4.3, 4.9 and 14.1. Given that the nature of Camurus' involvement was accurately reflected in the declaration statement 'These webinars have been sponsored by Camurus Ltd. The funding enabled the registration body and network for addiction professionals to provide clinical and digital designer time, hosting and advertising', Camurus also refuted the assertion that attendees were misled by an unacceptable declaration of involvement and did not accept any breaches of Clause 9.10 or 12.1.

Camurus stated that with respect to the alleged breaches of Clauses 26.1, 26.2 and 28.1, the sponsorship agreement between it and the registration body and network for addiction professionals clearly confirmed the intended audience as health professionals and other relevant decision makers. For clarity, Camurus noted that keyworkers and social workers were health professionals in the context of substance use management as they would be involved in the administration and/or recommendation of medicines. As a network for substance use health

professionals, there was a reasonable expectation that individuals registering for the webinars via the registration body and network for addiction professionals website would be health professionals. However, Camurus took Indivior's concerns raised in the initial telephone call on 13 May 2020, following the first webinar on 7 May 2020, related to the possibility of members of the public being able to access both the live sponsored the registration body and network for addiction professionals webinar events and subsequent recordings, very seriously and immediately contacted the registration body and network for addiction professionals to request that they be addressed. This was enacted immediately, before the second webinar took place on 14 May 2020 in that health professional self-certification was incorporated into the registration process as confirmed by Indivior in one of the enclosures it provided. It was unclear how the hosting page subsequently became accessible without self-certification as submitted by Indivior, however this was again immediately raised with the registration body and network for addiction professionals. The registration body and network for addiction professionals had since investigated and confirmed that it had originally created a tick box on its website that individuals had to tick confirming they were health professionals before they could access the webinars from the website and believed that this would limit access to the webinars only to health professionals. However, it was not anticipated that an internet search could bypass that system and by entering '[the registration body and network for addiction professionals]' and 'Buvidal webinar' people could land directly at the webinar page without having to confirm their professional status. However, Camurus anticipated that very few (if any) members of the public would have accessed the webinars in that way due to the obscure nature of the search, although it accepted that it would have been possible for them to do so.

Camurus stated that it took the issue of members of the public potentially being able to access material intended only for health professionals very seriously and had since also amended its corporate sponsorship forms to ensure that measures taken by third-parties to ensure that online content was restricted to intended audiences were documented for review prior to approval of the funding request. However, as Camurus was not involved in the registration process or distribution of meeting material, the company did not accept breaches of Clauses 26.1, 26.2 and 28.1. As previously communicated to Indivior during inter-company dialogue, under Clause 22, companies might sponsor a wide range of meetings and events including third-party events in which company or other medicines were discussed, provided there was a clear educational content and the meeting arrangements complied with the Code, without assuming responsibility for the content. Camurus stated that it therefore disagreed with the allegation that sponsorship of the meeting in itself constituted 'poor standards' and refuted the alleged breach of Clause 9.1.

Camurus stated that it had sought to ensure full transparency with respect to its involvement in the webinars and addressed issues arising in the conduct of the webinars that were not consistent with the agreement between Camurus and the third-party. While Camurus conceded that greater oversight of third-party processes would be required to avoid such issues arising in the future, it did not consider that any of its actions in relation to this activity had brought discredit upon, or reduced confidence in, the pharmaceutical industry. Camurus therefore did not accept the alleged breach of Clause 2.

PANEL RULING

The Panel noted that on 23 April 2020, the registration body and network for addiction professionals emailed the company with a preliminary proposal for a series of webinars on the use of Buvidal. The email stated 'I have just spoken to [named health professional] who is very enthusiastic about the prospect of webinars on Buvidal'. It spoke positively about the demand

for and use of Buvidal in Wales and described three webinars; a webinar on 7 May discussing the overall theme of treatment options, moving into the basics of Buvidal – what it is, how it works, things to consider when bringing it in to services; a webinar on 14 May providing more detail on Buvidal prescribing including case discussions—the grey areas, clinical decisions; and a webinar the following week, to discuss issues for prisons. It then stated that there may be ‘widescale take up of Buvidal in Wales in community and prison settings fairly soon and it would be great to provide support to clinicians/services....’. It referred to the guidelines stating ‘this could hopefully form part of their launch as well’. It also referred to the likelihood that Buvidal will be prescribed in at least one English prison. This preliminary request was followed by a formal request for an educational grant on 27 April 2020. This formal request stated ‘In response to the Covid-19 pandemic the Welsh government has recently endorsed the use of Buvidal to support safety in both community and prison settings. Clinicians in Scotland are also advocating the use of Buvidal as a response to the pandemic. However, there is lack of understanding regarding its distinctive features and how to prescribe the medication in the drug treatment field’. The training content would be based upon new guidance ‘Clinical guidelines for use of depot buprenorphine (Buvidal) in the treatment of opioid dependence’ currently being developed by the registration body and network for addiction professionals, and other current UK clinical guidance. It further stated that the registration body and network for addiction professionals would evaluate the course materials with Camurus. All delivered training would be evaluated by course participants and would be shared with Camurus during the project. An evaluation report would be shared with Camurus at the end of the project. It appeared from the inter-company dialogue that Camurus clarified that this related to a factual accuracy check in relation to the company product being discussed and it did not take up this offer and no presentation materials were shared with it in advance of the webinars.

The Panel noted Camurus’ submission that given the product-related activity could not be supported as a grant, the event sponsorship form was forwarded to the registration body and network for addiction professionals for completion and execution.

The Panel noted that Appendix A to the signed Event Sponsorship Proposal Form described the 3 webinars and referred to online e-learning on Buvidal, including a certificate when passed. The training content would be based, *inter alia*, on the new guidelines at issue above. Brand visibility (company/product logo) was part of the agreement.

The Panel noted that the final title of the two webinars at issue were: ‘Buvidal- introduction to first available prolonged release Buprenorphine in the UK’ and ‘Buvidal in a range of challenging community scenario’s - including a pandemic’.

The Panel noted that the final slide of the webinars included an evaluation form which asked, *inter alia*, if there were issues attendees would like to have covered in future webinars in the series on Buvidal and asked attendees if they were happy for Camurus to contact them by email with promotional [information] about its products and services.

The Panel noted that it was possible for a company to sponsor activities in which its own products were mentioned and not be liable under the Code for its contents, but only if it had been a strictly arm’s length arrangement with no input by the company and no use by the company. It had previously been decided, in relation to material/activities aimed at health professionals, that the content would be subject to the Code if it was promotional in nature or if the company had used the material for a promotional purpose. Even if neither of these applied, the company would be liable if it had been able to influence the content of the material in a manner favourable to its own interests.

It appeared that the proposal would only go ahead with the involvement of Camurus.

Noting its comments above, the Panel considered that it was abundantly clear from the outset that the proposed webinars would encourage and support the use of Buvidal within an environment of particular demand in Wales. In the Panel's view, given this and the content and links to the promotional Guidelines above the webinars were, in effect, promotional material for Buvidal for which Camurus was responsible.

The Panel noted that prescribing information, an adverse event reporting statement, and the non-proprietary name as required by Clause 4.3 were not included in the webinars held on 7 and 14 May. The Panel therefore ruled breaches of Clauses 4.1, 4.3 and 4.9.

The Panel noted Camurus' submission that the webinars had not been certified for use and a breach of Clause 14.1 was ruled.

The Panel noted that Clause 9.10 stated, *inter alia*, that material relating to medicines and their uses, whether promotional or not which is sponsored by a pharmaceutical company must clearly indicate that it has been sponsored by that company. The Panel noted the requirements of Clause 9.10 and its supplementary information including that the declaration of sponsorship must be sufficiently prominent to ensure that readers of sponsored material were aware of it at the outset. The wording of the declaration must be unambiguous so that readers would immediately understand the extent of the company's involvement and influence over the material. The supplementary information included that this was particularly important when companies were involved in the production of material which was circulated by an otherwise wholly independent party. The Panel noted that the declaration for the webinars, as highlighted by Indivior, stated 'These webinars have been sponsored by Camurus Ltd. The funding enabled [the registration body and network for addiction professionals] to provide clinical and digital designer time, hosting and advertising'. Noting its comments above, the Panel considered that the declarations of sponsorship did not fairly reflect Camurus' role and responsibility in relation to the activity and a breach of Clause 9.10 of the Code was ruled.

The Panel noted Camurus' submission that the sponsorship agreement between it and the registration body and network for addiction professionals clearly confirmed the intended audience as health professionals and other relevant decision makers. Despite this, the Panel noted that the material in relation to the first webinar had been accessible to the public. The Panel noted that when so advised by Indivior, Camurus took steps with the registration body and network for addiction professionals to remedy matters and that, before the second webinar took place on 14 May 2020 in that health professional self-certification was incorporated into the registration process.

The Panel noted that it was unclear how the hosting webinar page subsequently became accessible to the public without self-certification; it was not anticipated that by entering '[the registration body and network for addiction professionals]' and 'Buvidal webinar' an internet search could bypass the self-certification system and arrive directly at the webinar page. However, Camurus anticipated that very few (if any) members of the public would have accessed the webinars in that way due to the obscure nature of the search, although it accepted that it would have been possible for them to do so.

The Panel noted that in relation to the live 7 May webinar, it appeared that there was no self-certification of health professional status at that time and thus it was not restricted to health professionals and other relevant decision makers.

The Panel further considered that it was unfortunate that despite only intending to be available to health professionals, the webinars could still be accessed on a public You Tube page via a Google search using foreseeable and standard search terms which by-passed the self-certification requirements that had been imposed after the 7 May webinar. The Panel noted that the YouTube page provided as a screenshot by Indivior invited the public to subscribe to the registration body and network for addiction professionals channel stating that 'This webinar provides information regarding treatment selection of prolonged-release formulations including basic pharmacology and issues regarding introducing Buprenorphine into service provision'. There was no mention on the YouTube page in question that the material was for health professionals.

The Panel noted its comments above and considered that a prescription only medicine had been promoted to the public, breaches of Clauses 26.1, 26.2 and 28.1 were ruled.

The Panel noted that Camurus had since also amended its corporate sponsorship forms to ensure that measures taken by third-parties to ensure that online content was restricted to intended audiences were documented for review prior to approval of the funding request. The Panel noted its comments and rulings above and considered that overall Camurus had failed to maintain high standards and a breach of Clause 9.1 was ruled.

The Panel noted its comments and rulings above including breaches of Clauses 4.1 and 4.9 and considered that Camurus appeared to have a poor understanding of the Code, including the distinction between promotional and non-promotional material. The Panel noted that an adverse event reporting statement was an important safety requirement and given that Buprenorphine was an opioid, it was particularly important. In the Panel's view, Camurus had brought discredit upon, and reduced confidence in, the industry and a breach of Clause 2 was ruled.

Complaint received **22 October 2020**

Case completed **22 June 2021**