

## COMPLAINANT v NAPP

### Introductory panel on BMJ hosted page

A complainant who described him/herself as a concerned UK health professional, alleged that the Invokana content hosted on the bmj.com website appeared to be promotional. As there was no prescribing information or unique identifier, the complainant was concerned that the material had not been appropriately approved by the company. Invokana, marketed by Napp Pharmaceuticals Ltd, was used in the treatment of adults with insufficiently controlled type 2 diabetes as an adjunct to diet and exercise.

The detailed response from Napp is given below.

The Panel noted that the material at issue appeared on what was described as a BMJ hosted page which, according to Napp, featured 15 panels that each referred to a pharmaceutical company or a medicine. The top of the webpage read 'Click on the Panels to find out more about our hosted content'. Napp submitted that twelve of the panels linked to promotional material and that each panel allowed the reader to click through to a microsite. Napp submitted that the introductory panels were not standalone promotional items, they were they were the links to the actual promotional content; the BMJ had confirmed that the panels were not promotional material.

The Panel considered, contrary to Napp's inference, that merely because a panel linked to promotional material that did not mean that the panel itself was not promotional. Whether such a panel was promotional would depend, *inter alia*, on its content. The Panel noted the broad definition of promotion at Clause 1.2 of the Code. The Panel noted that the panel in question on the BMJ hosted webpage bore the prominent brand name in logo format, above text which read 'The renal reason to intensify'. The brand name was repeated towards the bottom of the panel and above the word 'Diabetes'. When hovering over the panel a pop-up box appeared which read 'Visit microsite' inviting the reader to click through beneath text within the pop-up box which invited the reader to find out how Invokana could help to reduce the risk of major adverse renal events in certain diabetics highlighting 3 clinical areas that were discussed in the microsite.

The Panel noted Invokana's licensed indication as adjunctive therapy, in monotherapy or in combination, for the treatment of type 2 diabetes in certain patients. The Panel also noted that the microsite to which the panel linked was titled 'The renal reason to intensify' and discussed improvements in renal outcomes with Invokana.

The Panel noted Napp's reference to the BMJ's view that the panels in question were not advertisements or promotional materials. The Panel noted that companies should independently satisfy themselves whether such materials were Code compliant and not rely on the views or intentions of a publisher in that regard.

**The Panel considered that the pop-up box was an integral part of the panel, contained promotional claims and was promotional for Invokana. Even if a reader did not hover over the panel such that the pop up box appeared its content in isolation, in the Panel's view, satisfied the broad definition of promotion; it referred to diabetes, the brand name in logo format and indirectly to renal benefits. In the Panel's view, given that the panel in question was promotional and noting that readers might not click through to the microsite which did contain prescribing information, it should include a clear and prominent statement as to where prescribing information could be found by way of a clear and prominent direct single click. The Panel ruled a breach of the Code in relation to the failure to include such a statement.**

**The Panel noted that the panel in question, including its pop-up box, had been certified as required. No breach of the Code was ruled.**

A complainant who described him/herself as a concerned UK health professional complained about the promotion of Invokana (canagliflozin) on bmj.com by Napp Pharmaceuticals Ltd. Invokana was used in the treatment of adults with insufficiently controlled type 2 diabetes as an adjunct to diet and exercise.

## **COMPLAINT**

The complainant noted the Invokana content hosted on the bmj.com website appeared to be promotional. As there was no prescribing information or unique identifier, the complainant was concerned that the material had not been appropriately approved by the company.

When writing to Napp, the Authority asked it to consider the requirements of Clauses 4.1 and 14.1 of the Code.

## **RESPONSE**

Napp explained that the website in question was intended for health professionals and was on the BMJ hosted page. The BMJ hosted page had a number of panels each of which referred to a pharmaceutical company or a medicine. At the top of that page in a prominent position was the statement 'Click on the panels below to find out more about our latest hosted content'. There were 15 introductory panels 'to give our users access to resources produced by external organisations'. Twelve of the 15 panels linked to promoting medicines and included a description of the therapy area eg iron deficiency anaemia, diabetes, oncology, psychiatry etc. Each introductory panel followed an identical format whereby 'hovering' over any panel turned the mouse 'arrow' pointer into a finger icon, indicating a mouse click was required to link to the actual panel's content. In addition, when hovering over any of the panels the wording 'VISIT MICROSITE' appeared at the bottom of the panel as an invitation to the health professional viewer.

Invokana was one of 12 panels aimed to direct a health professional to BMJ-hosted microsites, which contained digital promotional material. The introductory panels themselves, however, were not promotional items as standalone materials; they were the links to the actual promotional content. The BMJ had confirmed that 'The introductory panels are not adverts or promotional materials'.

Napp disagreed that there was no prescribing information for Invokana and no unique identifier (job bag code). Napp noted that the promotional microsite content for Invokana was provided by the PMCPA in its letter notifying the company of the complaint; the letter from the case preparation manager stated 'I have printed pages from [Napp's] website from the link provided by the complainant and these are enclosed'. The pages were hosted on the BMJ microsite and not by Napp. This was evident from the address bar at the top of the page 'hosted.bmj.com/Invokana'.

The introductory panels therefore clearly direct the health professional to the digital promotional material. As per Clause 4.4 (and its supplementary information) the prescribing information (as required by Clause 4.1 and its supplementary information) was provided by way of a clear and prominent direct single click link at the top of the first page of the BMJ microsite. On clicking on the provided link (as per Clause 4.4) the viewer was taken to the Invokana summary of product characteristics (SPC) of the electronic medicines website, as allowed by Clause 4.2 instead of i-viii. Napp therefore refuted a breach of Clause 4.1.

Additional required prescribing information, as per Clause 4.2, of the legal classification of the product, and medicine cost were provided at the end of the microsite material, as well as adverse event reporting (as per Clause 4.9).

Finally, the date of preparation and 'unique identifier' (job code) was also included (ie UK/INV-19023). A copy of the certificate was provided together with the copies of the BMJ microsite promotional material. Napp denied a breach of Clause 14.1.

In summary and conclusion, Napp disagreed with the complainant that the material had no prescribing information and no unique identifier. Napp considered that it had provided a comprehensive explanation that it had not breached Clauses 4.1 or 14.1, as it had provided the prescribing information and had certified the material.

## **PANEL RULING**

The Panel noted that the material at issue appeared on the BMJ website on what was described as a BMJ hosted page which, according to Napp, featured a number of panels that each referred to a pharmaceutical company or a medicine. The top of the webpage read 'Click on the Panels to find out more about our hosted content.' Napp submitted that twelve of the 15 panels linked to promotional material and that each panel allowed the reader to click through to a microsite. Napp submitted that the introductory panels were not standalone items, they were linked to actual promotional content and that the BMJ had confirmed that the panels were not promotional material.

The Panel considered, contrary to Napp's inference, that merely because a panel linked to promotional material that did not mean that the panel itself was not promotional. Whether such a panel was promotional would depend, *inter alia*, on its content. The Panel noted the broad definition of promotion at Clause 1.2 of the Code. The Panel noted that the panel in question on the BMJ hosted webpage bore the prominent brand name in logo format, above text within a bold red strip which read 'The renal reason to intensify'. The brand name was repeated towards the bottom of the panel and above a blue strip within which in white font text read 'Diabetes'. When hovering over the panel a pop-up box appeared which read 'Visit microsite' inviting the reader to click through beneath text within the pop-up box which invited the reader to find out

how Invokana could help to reduce the risk of major adverse renal events in certain diabetics highlighting 3 clinical areas that were discussed in the microsite.

The Panel noted Invokana's licensed indication as adjunctive therapy, in monotherapy or in combination, for the treatment of type 2 diabetes in certain patients. The Panel also noted that the microsite to which the panel linked was titled 'The renal reason to intensify' and discussed improvements in renal outcomes with Invokana.

The Panel noted Napp's reference to the view of the BMJ that the panels on the BMJ hosted webpage in question were not advertisements or promotional materials. The Panel noted that companies should independently satisfy themselves whether such materials were Code compliant and not rely on the views or intentions of a publisher in this regard. The Panel noted that whether a panel was promotional would be decided on a case by case basis dependent on, *inter alia*, its content.

The Panel considered that the pop-up box was an integral part of the panel, contained promotional claims and was promotional for Invokana. Even if a reader did not hover over the panel such that the pop up box appeared its content in isolation, in the Panel's view, satisfied the broad definition of promotion; it referred to diabetes, the brand name in logo format and indirectly to renal benefits. In the Panel's view, given that the panel in question was promotional and noting that readers might not click through to the microsite which did contain prescribing information, it should include a clear and prominent statement as to where prescribing information could be found by way of a clear and prominent direct single click. The Panel ruled a breach of Clause 4.1 in relation to the failure to include prescribing information in relation to the panel.

The Panel noted that the panel in question, including its pop-up box, had been certified as required by Clause 14.1. No breach of Clause 14.1 was ruled.

The Panel noted that the complainant also referred to the absence of a unique identifier on the material at issue. The Code did not refer to unique identifiers but they were referred to in the Guidelines on company procedures relating to the Code of Practice in relation to Certification of promotional material which appeared at the back of the Code booklet on page 54. Unique identifiers were considered good practice as a way of ensuring that a certificate was linked to a specific piece of material. The Panel noted that the job bag, which included the microsite and the panel, did bear a unique number that appeared on the microsite. No Clause had been raised in relation to this matter so the Panel made no ruling.

The Panel noted that Napp also commented on Clauses 4.2, 4.4 and 4.9. The Panel made no rulings on these Clauses as they had not been cited by the Case Preparation Manager and were not the subject matter of the complaint.

**Complaint received**      **7 October 2019**

**Case completed**         **12 February 2020**