

CASE AUTH/3387/9/20

HEALTH PROFESSIONAL v SOBI

Alleged misleading title of a meeting

A doctor involved in commissioning, complained that the title of a meeting to be held by Swedish Orphan Biovitrum Ltd (Sobi) was misleading. The complainant referred to an email which stated that the event was funded and organised by Sobi and was being held in association with a named patient organisation. Readers were further informed that the webinar was not connected in any way to the review the National Services Division (NSD) was currently conducting into both the risk sharing scheme for inherited bleeding disorders products and the Scottish Inherited Bleeding Disorders Network (SIBDN).

The complainant alleged that the promotional email was misleading in terms of the title as it referenced the National Services Division and a review which it was currently undertaking. Sobi had not asked for the NSD's permission or endorsement. The complainant also alleged that the misleading email could be interpreted incorrectly by clinicians. The company had been asked to remove reference to the National Services Division.

The complainant explained that he/she had previously worked for another pharmaceutical company and had previously worked with a current Sobi senior employee and was somewhat therefore surprised at the cavalier attitude of the staff and lack of regard for the Code. The matter needed to be highlighted for bringing the industry into disrepute.

The complainant contacted the event organiser to raise his/her concerns and asked that a representative of Sobi call him/her but as yet this had failed to happen.

The detailed response from Sobi is given below.

The Panel noted that the subject line of the email in question stated: 'Beyond the National Services Division Review - Haemophilia Webinar 23rd September 6pm-7pm' and the title 'Beyond the National Services Division Review' was repeated in the first line of the email. Directly below this it stated, in bold underlined font, 'Sobi Webinar event Wednesday 23rd September 18:00-19:00'. The first paragraph of the email stated that the event was funded and organised by Sobi and that it was being held in association with a named patient organisation. The second paragraph of the email stated: 'This Haemophilia Webinar is not connected in any way to the review NSD [National Services Division] is currently conducting into both the risk sharing scheme for inherited bleeding disorders products and the Scottish Inherited Bleeding Disorders Network (SIBDN).' The email was sent in the name of a Sobi employee and included the Sobi logo at the bottom.

The Panel noted Sobi's submission that the event and email in question were non-promotional. The Panel disagreed with Sobi's assertion that Clause 7.2 did not apply to non-promotional material. The Panel noted that Clause 7.2 stated, *inter alia*, that information, claims and comparisons must be accurate, balanced, fair, objective and unambiguous and must be based on an up-to-date evaluation of all the evidence and reflect that evidence clearly. They must not mislead either directly or by implication, by distortion, exaggeration or undue emphasis. The supplementary information stated that the application of this clause was not limited to information or claims of a medical or scientific nature.

In the Panel's view, it was clear from the email that the webinar was organized by Sobi. The Panel noted the use of the term 'Beyond' in both the subject line and title of the webinar and the paragraph towards the beginning of the email explaining that the webinar was not connected in any way to the review that the National Services Division was conducting or the Scottish Inherited Bleeding Disorders Network (SIBDN). Given the email subject heading and clarification within the email the Panel did not consider, on the balance of probabilities, that recipients of the email would be misled by the reference to the National Services Division or the review in the email in question and the Panel therefore ruled no breach of the Code.

The Panel noted the complainant's allegation that Sobi had not asked for permission or endorsement from the National Services Division to include reference to it and a review which it was currently undertaking within the email at issue. In the Panel's view it was not necessarily unacceptable for Sobi to refer to the National Services Division and its review without permission provided the way in which it was done complied with the Code.

The Panel noted the complainant's comment that an NHS manager had contacted Sobi to ask it to remove references to National Services which had apparently been ignored. The complainant also stated that he/she had contacted the third-party event organiser to raise his/her concerns and asked that a representative of the company call him/her but that had failed to happen. The Panel noted that the complainant had not provided evidence in support of this allegation and Sobi had made no submission in this regard although its email to National Services dated 16 September cancelling the webinar referred to 'recent emails' which were not provided as part of its response. The complainant submitted a complaint copying in Sobi, on 11 September. The Panel noted that on receipt of that email, Sobi cancelled the webinar on 16 September and informed the complainant that it was cancelled on that same date. The Panel acknowledged that extreme dissatisfaction was usually necessary on the part of a busy health professional before he or she was moved to submit a complaint to the Authority. It was not clear on the information before the Panel when the complainant had contacted the event organizer or when the NHS manager had contacted Sobi, nonetheless it was implicit that at the very least the contact by the manager was before the email in question was dispatched. The Panel noted that the email in question was approved by Sobi on 10 September and the complainant submitted his/her complaint to the Authority on 11 September.

The Panel queried whether there had been a meaningful attempt by Sobi to discuss the concerns raised. On the limited information before the Panel the timelines and the

content of relevant communications was not sufficiently clear. The Panel considered that given its comments above: that recipients of the email in question would not have been misled by the reference to the National Services Division or its review; that references to NHS bodies were not necessarily precluded so long as they otherwise comply with the Code; the lack of clarity over timelines; and the lack of evidence about the content of communications between the parties, the Panel did not consider that the complainant had established on the balance of probabilities that Sobi had failed to maintain high standards with respect to the references to the National Services Division, its review and the alleged failure to withdraw such references. No breach of the Code was ruled.

A doctor involved in commissioning, complained that the title of a meeting to be held by Swedish Orphan Biovitrum Ltd (Sobi) was misleading. The complainant referred to an email which read:

'Subject: Beyond the National Services Division Review - Haemophilia Webinar 23rd September 6pm-7pm

"Beyond the National Services Division Review"

Sobi Webinar event Wednesday 23rd September 18:00-19:00'

The email stated that the event was funded and organised by Sobi and was being held in association with a named patient organization. Readers were further informed that the webinar was not connected in any way to the review NSD [National Services Division] was currently conducting into both the risk sharing scheme for inherited bleeding disorders products and the Scottish Inherited Bleeding Disorders Network (SIBDN).

COMPLAINT

The complainant alleged that the promotional email was misleading in terms of the title as it referenced the National Services Division and a review which it was currently undertaking. Sobi had not asked for the NSD's permission or endorsement and the email was misleading and could be interpreted incorrectly by clinicians.

The complainant noted that the company had been asked to remove reference to National Services by an NHS manager but that it had ignored that advice and gone ahead and sent out the email.

The complainant explained that he/she had previously worked with a current Sobi senior employee and was somewhat therefore surprised at the cavalier attitude of the staff and lack of regard for the Code. The matter needed to be highlighted for bringing the industry into disrepute.

The complainant stated that he/she had contacted the event organiser supporting Sobi to raise his/her concerns and asked that a representative of Sobi call him/her but as yet this had failed to happen.

When writing to Sobi, the Authority asked it to consider the requirements of Clauses 7.2 and 9.1 of the Code.

RESPONSE

Sobi explained that the webinar was intended to be a non-promotional event, funded and organised by Sobi in association with the named patient organisation. The intended audience included members of the Scottish Parliament, health professionals and members of the patient organisation. As set out in the invitation:

This Haemophilia Webinar is not connected in any way to the review NSD is currently conducting into both the risk sharing scheme for inherited bleeding disorders products and the Scottish Inherited Bleeding Disorders Network (SIBDN).

The webinar aims to take a wider view of what should be aspired to in terms of health outcomes for people with bleeding disorders in Scotland and to highlight the successes of haemophilia care in Ireland as a comparable country.'

A copy of the invitation, which was approved as non-promotional material, was provided. Sobi submitted that as the webinar was not a promotional event, the invitation did not require any certification under Clause 14.1 of the Code. The invitation did not refer to any brand names of medicines or summary of product characteristic (SPC) information.

Following the complaint on 11 September 2020, Sobi cancelled the webinar on 16 September 2020 and communicated this to the complainant directly by email.

Sobi noted that the webinar, which included invitees who were not health professionals, was always planned to be a non-promotional event. The invitation was therefore not a 'promotional email'. This was confirmed by the approval (copy provided).

In relation to the reference to the National Services Division (NSD), which was part of NHS Scotland, there were no restrictions under the Code that would prevent companies from referencing NHS bodies or NHS reviews in non-promotional meetings. Sobi noted that Clause 9.5 prohibited companies from referencing the Commission on Human Medicines, the Medicines and Healthcare products Regulatory Agency or the licensing authority in any promotional materials. However, case law confirmed that this list of bodies was interpreted narrowly. With respect to a reference to The National Institute for Health and Care Excellence (NICE) in promotional materials, the PMCPA had ruled:

'Although Clause 9.5 prohibited reference to certain bodies in promotional material, NICE was not one of them. No breach of Clause 9.5 was ruled.' (ref AUTH/2052/10/07)

Sobi submitted that in any event, Clause 9.5 did not apply to non-promotional materials such as the invitation. To prevent any confusion over the purpose of referencing the NSD in the title of the webinar, Sobi expressly clarified in the invitation that the webinar was not connected in any way to the review NSD was currently conducting and the use of the word 'beyond' in the title further emphasised that this was not an NSD affiliated event. Sobi was therefore surprised by the complainant's assertion that the title was misleading. Nonetheless, in accordance with the company's commitment to maintaining the highest standards under the Code and in acknowledgment of the complainant's concerns, Sobi cancelled the event on 16 September 2020 to prevent any potential confusion. The clarification provided in the invitation and Sobi's swift and decisive action following its receipt of the complainant's complaint was further

evidence that Sobi maintained high standards in compliance with Clause 9.1. Subsequent to the complaint, Sobi had been in further contact with the complainant by email and by virtual meeting to reassure him/her that the company took his/her concerns very seriously.

With regard to Clause 7.2, Sobi considered that that clause in relation to the accuracy of information, claims and comparison, was not applicable in this instance. As explained above, the webinar was planned to be held as a non-promotional event. As a result, the invitation (and the intended content of the webinar before it was cancelled) did not contain any references to medicines, either in the form of information, claims, comparisons or otherwise.

Sobi stated, in summary that the emailed invitation in question related to a non-promotional event. Sobi maintained that it had complied with all applicable provisions of the Code in its organisation of the non-promotional webinar and that it had maintained high standards at all times. Sobi regretted that the webinar title and the invitation caused concern for the complainant. Sobi noted that it had fully investigated the matter and, acting in good faith, promptly cancelled the webinar within a few days of the complaint. Nonetheless, Sobi respectfully maintained that merely referencing the NSD and its ongoing review as a topic of discussion during a non-promotional event did not amount to a breach of the Code.

PANEL RULING

The Panel noted that the subject line of the email in question stated: 'Beyond the National Services Division Review - Haemophilia Webinar 23rd September 6pm-7pm' and the title 'Beyond the National Services Division Review' was repeated in the first line of the email. Directly below this it stated, in bold underlined font, 'Sobi Webinar event Wednesday 23rd September 18:00-19:00'. The first paragraph of the email stated that the event was funded and organised by Sobi and that it was being held in association with the patient organisation. The second paragraph of the email stated: 'This Haemophilia Webinar is not connected in any way to the review NSD [National Services Division] is currently conducting into both the risk sharing scheme for inherited bleeding disorders products and the Scottish Inherited Bleeding Disorders Network (SIBDN).' The email was sent in the name of a Sobi employee and included the Sobi logo at the bottom.

The Panel noted the complainant's allegation that the promotional email was misleading as the title referred to the National Services Division and the review and Sobi had not asked for permission or endorsement from the National Services Division to include reference to it and that the email could be interpreted incorrectly by clinicians.

The Panel noted Sobi's submission that the event and email in question were non-promotional. The Panel disagreed with Sobi's assertion that Clause 7.2 did not apply to non-promotional material. The Panel noted that Clause 7.2 stated, *inter alia*, that **information** [emphasis added], claims and comparisons must be accurate, balanced, fair, objective and unambiguous and must be based on an up-to-date evaluation of all the evidence and reflect that evidence clearly. They must not mislead either directly or by implication, by distortion, exaggeration or undue emphasis. The supplementary information to Clause 7 stated that the application of this clause was not limited to information or claims of a medical or scientific nature.

In the Panel's view, it was clear from the email that the webinar was organized by Sobi. The Panel noted the use of the term 'Beyond' in both the subject line and title of the webinar and the paragraph towards the beginning of the email explaining that the webinar was not connected in

any way to the review that the National Services Division was conducting or the Scottish Inherited Bleeding Disorders Network (SIBDN). Given the email subject heading and clarification within the email the Panel did not consider, on the balance of probabilities, that recipients of the email would be misled by the reference to the National Services Division or the review in the email in question and the Panel therefore ruled no breach of Clause 7.2.

The Panel noted the complainant's allegation that Sobi had not asked for permission or endorsement from the National Services Division to include reference to it and a review which it was currently undertaking within the email at issue. In the Panel's view it was not necessarily unacceptable for Sobi to refer to the National Services Division and its review without permission provided the way in which it was done complied with the Code.

The Panel noted the complainant's comment that an NHS manager had contacted Sobi to ask it to remove references to National Services which had apparently been ignored. The complainant also stated that he/she had contacted the third-party event organiser to raise his/her concerns and asked that a representative of the company call him/her but that had failed to happen. The Panel noted that the complainant had not provided evidence in support of this allegation and Sobi had made no submission in this regard although its email to National Services dated 16 September cancelling the webinar referred to 'recent emails' which were not provided as part of its response. The complainant submitted a complaint copying in Sobi, on 11 September. The Panel noted that on receipt of that email, Sobi cancelled the webinar on 16 September and informed the complainant that it was cancelled on that same date. The Panel acknowledged that extreme dissatisfaction was usually necessary on the part of a busy health professional before he or she was moved to submit a complaint to the Authority. It was not clear on the information before the Panel when the complainant had contacted the event organizer or when the NHS manager had contacted Sobi, nonetheless it was implicit that at the very least the contact by the manager was before the email in question was dispatched. The Panel noted that the email in question was approved by Sobi on 10 September and the complainant submitted his/her complaint to the Authority on 11 September.

The Panel queried whether there had been a meaningful attempt by Sobi to discuss the concerns of NHS Scotland at the very least when contact was made by the manager given the ongoing concerns of the National Services Division. On the limited information before the Panel the timelines and the content of relevant communications was not sufficiently clear. The Panel considered that given its comments above: that recipients of the email in question would not have been misled by the reference to the National Services Division or its review; that references to NHS bodies are not necessarily precluded so long as they otherwise comply with the Code; the lack of clarity over timelines; and the lack of evidence about the content of communications between the parties, the Panel did not consider that the complainant had established on the balance of probabilities that Sobi had failed to maintain high standards with respect to the references to the National Services Division, its review and the alleged failure to withdraw such references. No breach of Clause 9.1 was ruled.

Complaint received **11 September 2020**

Case completed **15 March 2021**