Medicines Australia

Better health through research & innovation

COMPLAINT OUTCOME

1163 - OZEMPIC Media Activities

DETERMINATIONS OF THE MEDICINES AUSTRALIA CODE OF CONDUCT AND APPEALS COMMITTEES

The administration of the Code is supervised by the Code of Conduct Committee. The Code of Conduct Committee has the power to make a determination as to a breach of the Code and impose sanctions. The right of appeal is available to both the Complainant and Subject Company. An appeal is heard by the Appeals Committee which has the power to confirm or overturn the decision and to amend or remove any sanctions.

The decisions of the Code of Conduct and Appeals Committees are relevant to the date of publication of the materials subject to complaint and approved Product Information (PI) at that time. A complaint is not deemed finalised until the Subject Company has advised Medicines Australia that they will not appeal the outcome of the Code of Conduct Committee decision (following circulation of the Code minutes) or, in the case of an appeal, the minutes of the Appeals Committee meeting have been provided to both parties.

This report is an extract of the minutes of the complaint heard on 18 October 2021.

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DOWNLOAD THE CODE

The Code of Conduct and all associated materials are available on the Medicines Australia Website

COMPLAINT 1163 - OZEMPIC MEDIA ACTIVITIES

SUBJECT COMPANY	PRODUCT	COMPLAINANT
Novo Nordisk Australia (NN)	OZEMPIC (semaglutide)	Eli Lilly Australia (ELA)

COMPLAINT

ELA alleged that NN failed to act promptly in relation to general media publications that promoted off-label use of OZEMPIC for weight loss/weight management in mainstream media. ELA acknowledged that each publisher is responsible for their own content, it alleged that NN has failed to engage in a timely manner to correct misinformation contained in the publications. ELA asserted that therefore NN has failed to meet its obligations under the Code.

SECTIONS OF THE CODE

- Principle 1: All activities undertaken by companies have the purpose of supporting the quality use of medicines
- Principle 2: companies are committed to transparency in their interactions with healthcar professionals an dother stakeholders, to maintain trust and confidence in the industry.
- Principle 3: companies are responsible providing current, accurate, balanced, and scientifically valid information products to support their use.
- Section 11: Appropriate communication with relevant stakeholders

RESPONSE TO THE COMPLAINT

NN noted that it had neither direct or indirect involvement in the publications, particularly highlighting that it was not contacted by any journalist or media outlet in relation to the news story. NN did not have any contact with, encourage, or provide materials to any HCPs or patients in relation to the stories or in order to engage with relevant news outlets.

NN also considers the publications to be genuine news stories published by the media outlets, and therefore does not consider them to be promotional in nature, or to be considered advertisements.

CODE COMMITTEE DECISIONS

Failure to act within a timely manner to inform publishers of inaccurate content in their publications, and failure to provide correct information to publishers of general media articles who promoted the off-label use of OZEMPIC for weight loss/weight management

Failure to act within a timely manner to seek to have ongoing online publications removed that promote the off-label use of OZEMPIC for weight loss/weight management

- Principle 1: Compliant
- Principle 2: Compliant
- Principle 3: Compliant
- Section 11: No Breach

SANCTION

As no breach was found, no sanction was levied

CONSIDERATION OF THE COMPLAINT

The Committee noted that this complaint centred on several news articles related to OZEMPIC, a prescription only product registered on the ARGT for the treatment of diabetes (as a GLP-1 analogue) which appeared in mainstream press. These articles centred on the off-label use of OZEMPIC in the context of weight loss. In the complaint, ELA alleged that NN had not acted in a timely way to correct misleading information. The Committee noted the timeline below as relevant to their discussions:

- 22 August 2021: two articles published in mainstream newspapers:
  - Sunday Times: "No more weighting: The once-a-week injection that is stripping off the kilos because you don't feel hungry"
  - The West Australian: "Weight loss drug: OZEMPIC helping Australians shed kilos"
- 31 August 2021: 9News Broadcast "Diabetes treatment has added benefit of helping overweight people shed kilos"
- 1 September 2021: 9News repost same article to its online and social media platforms
- 1 September 2021: NN advise staff of the article and commence engagement with Medicines Australia on the appropriate way to manage
- 6 September 2021: ELA notified NN of concerns via letter
- 7 September 2021: NN responded to ELA that the company had no involvement in the publication of the materials
- 16 September 2021: Intercompany dialogue concluded, and complaint sent to Medicines Australia for review.

The Committee noted that from the time NN first became aware of the media, it took two weeks for the company to make any formal response directly to the media organisations. The Committee further noted that during the two-week window, NN sought advice from Medicines Australia and whether the delay in timeframe could be attributed to a delay in response from Medicines Australia. It was during these discussions that the Medicines Australia secretariat was excused from the meeting to allow the Committee to determine potential conflict of interest. Those discussions are not included in these minutes. The Committee determined that it was content for Medicines Australia to remain in the meeting and for the secretariat functions to continue.

The Committee acknowledged that the active ingredient in OZEMPIC, semaglutide, is currently in evaluation with the TGA in a different formulation and with a different trade name, for a weight loss indication. During the two-week window, NN contacted the TGA to confirm the trade name for the weight loss indication as WEGOVY. The Committee noted that it is not unusual for products undergoing evaluation with the TGA to be assigned a unique identifier by the company at application, with a trade name provided prior to final approval.

The Committee turned to discussing what degree of responsibility there is on a sponsor company over material that is broadcast by a third-party when that material is clearly promoting that product, but equally was not prompted by any activity of the sponsor company. The Committee noted by way of general discussion that the Therapeutic Goods Act (the Act) includes a broad definition of the term "advertise", such that the material that was the subject of the complaint might be regarded as advertising, regardless of whether it also constituted genuine news reporting. In any event, the Committee unanimously agreed that, in the absence of any evidence (or indeed any allegation) to the contrary, NN was not involved in the placement of these articles and no coordinated formal campaign had occurred.

In considering the responsibility a company may have to correct misinformation propagated by a third-party news outlet, the Committee discussed the likelihood of success a company would have in seeking any amendment. In this instance, there is clinical evidence supporting the outcomes reported in the news articles as well as an impending TGA registration for the indication. By correcting the information, NN would be providing information to a journalist about an unregistered indication and possibly influencing further discourse on the product. The Committee agreed that in this instance it is highly unlikely that NN would have been able to have the story removed or heavily modified.

Linked with this discussion on the obligation of companies to correct misinformation in media, the Committee focussed on the two-week window between publication and engagement with the media outlets. The Committee looked to the Code, specifically Overarching Principle 3 which ensures companies are responsible for providing current, balanced, accurate, and scientifically valid information. This principle of the Code permits companies to engage proactively within that framework. It does not obligate a company to correct misinformation propagated by a third-party.

The Committee acknowledged that NN undertook pertinent activities in remedying this activity, such as communicating with staff, engaging with Medicines Australia and the TGA, as well as intercompany discussions with ELA. The Committee agreed that, while the two-week window may be considered a slow response in modern news cycles, the difficulty of determining which information may need correcting and seeking an appropriate pathway forward would take time. The Committee agreed, therefore, that the two-week window for engaging with the media outlet is not inappropriate in this matter.

The Committee recognised that while the articles focussed on the off-label use of OZEMPIC for weight loss, they did reflect the pharmacological response of the product and is supported by evidence. Further, the Committee considered the risk of patient harm in the information being available in mainstream media. The Committee acknowledged that as a prescription product, the intervention of a healthcare professional is necessary to access the product, and the patient harm is low. The Committee agreed unanimously that taken together, overarching principles 1 and 3 may well obligate a company to engage with media and that a company's response should be directly related to the prospect of patient harm. Should there be an increased danger of patient harm the obligation to correct information is more likely to arise, and the appropriate timeframe for a response might well be considerably shorter.

However, it is the Committee's view is that NN provided a reasonable response to the material that was published noting that it was conducted without any input from them. The Committee agreed unanimously that with that context there is no breach of the Code.