

**CASE AUTH/3738/2/23**

**VOLUNTARY ADMISSION BY NOVO NORDISK**

**Certification of a website**

**CASE SUMMARY**

This case was in relation to a voluntary admission by Novo Nordisk about failure to appropriately certify a weight management and obesity hub hosted on the website of a named association that supported pharmacists in the UK (“the association”), which was part of a broader collaborative working project between Novo Nordisk and the association. The voluntary admission was made following an investigation by Novo Nordisk in relation to Case AUTH/3711/11/22.

Novo Nordisk admitted several failures of its certification process. Some errors occurred due to the association making changes to the live site when Novo Nordisk had expected changes to be made off-line so that the changes could be certified prior to making the site live. One error related to a change made by the association without the knowledge of Novo Nordisk. The Panel was concerned that this change and other compliance failures only came to Novo Nordisk’s attention further to receipt of a complaint to the Authority (Case AUTH 3711/11/11). In the Panel’s view, Novo Nordisk had inadequate control and oversight of this hub. A robust certification system underpinned self-regulation. The Panel ruled a breach of the following Clauses of the 2021 Code for Novo Nordisk failing to appropriately certify three versions of the hub and its poor governance of it:

<b>Breach of Clause 8.3</b>	<b>Failing to certify material relating to collaborative working</b>
<b>Breach of Clause 5.1</b>	<b>Failing to maintain high standards</b>

Given that allegations in relation to the content of the hub and the training course were dealt with in Cases AUTH/3711/11/22 and AUTH/3525/6/21, respectively, the Panel considered that the matter in relation to this voluntary admission (uncertified versions of the hub) was adequately covered by its rulings above and therefore, on balance, the Panel ruled no breach of the following Clause of the 2021 Code:

<b>No Breach of Clause 2</b>	<b>Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry</b>
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**This summary is not intended to be read in isolation.  
For full details, please see the full case report below.**

## FULL CASE REPORT

A voluntary admission was received from Novo Nordisk Ltd about the certification of a weight management and obesity hub hosted on the website of a named association which supported pharmacists in the UK (“the association”).

As Paragraph 5.6 of the Constitution and Procedure required the Director to treat a voluntary admission as a complaint the matter was taken up with Novo Nordisk.

## VOLUNTARY ADMISSION

During an investigation into Case AUTH/3711/11/22, Novo Nordisk discovered that there were issues with the process of certification of certain materials. Novo Nordisk made a voluntary admission, as outlined below.

As described in Novo Nordisk’s response to Case AUTH/3711/11/22 on 19 December 2022, Novo Nordisk had a collaborative working arrangement with the named association. One element of the collaborative working project between Novo Nordisk and the association was the development of a weight management and obesity hub (herein referred to as ‘the hub’) which was hosted on the association’s website. Novo Nordisk clarified that only the hub was produced as a result of the collaborative working project and Novo Nordisk had no control over any other element of the association’s website. The hub was made available to pharmacists who were members of the association. A username and password were required to access the hub.

Novo Nordisk’s investigation had highlighted that the hub content was first certified on 17 March 2022 and it was made available to members on this date. The content had been updated three times since that date. It was removed from the association’s website on 25 November 2022 following the complaint in Case AUTH/3711/11/22, which was received on 23 November 2022. Novo Nordisk confirmed that the hub was not available at this time and the collaborative working project was being terminated.

The four versions of the hub were:

Version number	Job code	Certified in PromoMats	Withdrawn in PromoMats
1	UK22OB00005	17/03/22	18/08/22
2	UK22OB00129	10/05/22	18/08/22
3	UK22OB00184	04/08/22	12/10/22
4	UK22OB00237	12/10/22	25/11/22

The process of approval was as follows:

- A pdf of the hub was created by the association which was submitted to Novo Nordisk for an initial review. Any changes requested by Novo Nordisk at this stage were incorporated into the pdf by the association then returned to Novo Nordisk for review in PromoMats.

- Once this was completed, the hub was taken offline (versions 2 and 3) for changes to be applied.
- A password-protected private link to the hub was provided to Novo Nordisk for certification (versions 1,2,3). This was previewed on screen before being published on the live site for the association's members.

During the investigation into the matters raised in Case AUTH/3711/11/22, Novo Nordisk discovered the following issues with regard to certification of the hub. In summary, the issues were:

- Changes were made to version 3 in order to create version 4 and these were done prior to certification of the pdf job bag for version 4. These changes were made to the live site, not the off-line version.

The association confirmed that the signatory reviewed and certified the live site and not an off-line version.

- The approved versions in PromoMats (pdfs) and the live hub were not exact matches.

In some instances, changes were made to the live hub post-certification either by the association alone or with direction from Novo Nordisk. This occurred with versions 2, 3 and 4.

One change to the certified version 2 of the hub (UK22OB00129), which was done without the knowledge of Novo Nordisk, was the inclusion of a link to a YouTube video. The association confirmed that this was included on 10 June 2022 and removed on 3 August 2022. It had not given a reason why it was added without informing Novo Nordisk. This appeared to be the video which was the subject of the complaint in Case AUTH/3711/11/22. It had come to light whilst investigating the certification issues.

Novo Nordisk employees involved with the hub including its certification had been interviewed. The interview notes were provided. Based on the information given in the interviews, the signatory thought they were certifying the off-line version of version 4 of the hub webpage before going live i.e., their understanding was that it was visible only to the Novo Nordisk signatory and another employee and not the association's members. Only after certification of version 4 were the signatories made aware that they had been checking the live version. One signatory was made aware in November 2022, the other signatory could not recall the date they were made aware of this.

Despite a request from Novo Nordisk, the association was unable to provide an explanation for why changes were made to version 2 of the hub without Novo Nordisk being informed. Additionally, Novo Nordisk believed the hub was not online between 23 September 2022 and 11 October 2022, when changes were being made to version 3 to create version 4. The association subsequently confirmed that the hub was live during this time, and this was an error.

In conclusion, Novo Nordisk did not have sufficient oversight and management of the project and did not ensure that the correct processes for certification were followed. Therefore, Novo Nordisk submitted that it was in breach of Clauses 8.3 and 5.1.

Novo Nordisk provided copies of the interviews with the employees involved with the project.

When writing to Novo Nordisk, the Authority asked it to provide any further comments in relation to the requirements of Clauses 5.1 and 8.3 of the 2021 Code. In addition, Novo Nordisk was asked to comment in relation to Clause 2.

## **RESPONSE**

In response to the case preparation manager's request, Novo Nordisk provided versions 2 to 4 of the hub, including the certificate and meta-data, the agreement and project initiation document for the collaborative working project with the association and Novo Nordisk's relevant standard operating procedures (SOPs).

Novo Nordisk submitted that once the certification issues with the hub were identified, it verbally asked the association in late November 2022 to take the hub down, which they did, and this instruction was confirmed by the association in writing on 20 December 2022. Ultimately, the hub was not made live again. The collaborative working project was in the process of being terminated. Relevant members of staff had been informed of this case and it would be communicated more widely at a forthcoming Code Club. A corrective and preventive action plan (CAPA) was being developed as part of the overall improvement activities that Novo Nordisk was conducting as a response to the PMCPA audit in December 2022.

The association had not yet destroyed all items that related to the collaborative working project as it was necessary to preserve a number of items in order to produce for Novo Nordisk a report of the project which would assist them in developing and publishing a summary of the project's outcomes, as required by the supplementary information to Clause 20.

Novo Nordisk stated that the certification process is the foundation of self-regulation and in some cases deficiencies in relation to this could be considered to amount to bringing the industry into disrepute. However, in this case Novo Nordisk did not consider that its failings amounted to a breach of Clause 2.

## **PANEL RULING**

The Panel noted that the voluntary admission concerned a failure to appropriately certify a weight management and obesity hub hosted on a named association's website, which was part of a broader collaborative working project between Novo Nordisk and the association. The hub in question was available to pharmacists who were members of the association and was accessible using a user name and password. The Panel noted that Clause 8.3 required that certain materials including materials relating to collaborative working as described in Clause 20 and its supplementary information were certified in advance in a similar manner to that provided for by Clause 8.1. Clause 8.1 stated, amongst other things, that promotional material must not be issued unless its final form, to which no subsequent amendments will be made, has been certified by one person on behalf of the company in the manner provided for by that clause.

The Panel noted that there had been 4 versions of the hub between March and October 2022 and that it was taken down by the association at the request of Novo Nordisk on 25 November 2022.

The Panel noted Novo Nordisk's account of the certification failures in relation to versions 2-4 of the hub. The Panel did not have a copy of the relevant version of Novo Nordisk's Standard Operating Procedure that was current at the time of certification; that provided was effective 10 November 2022, which was after the certification of version 4 of the hub on 12 October 2022.

The Panel noted that Novo Nordisk admitted several failures of its certification process in relation to versions 2, 3 and 4 of the hub; in some instances, changes were made to the live hub post-certification either by the association alone or with direction from Novo Nordisk.

The Panel had no evidence before it that Novo Nordisk had instructed the association to circumvent the requirements of the Code, rather the Panel understood from Novo Nordisk's submission that some errors occurred due to the association making changes requested by Novo Nordisk to the live site when Novo Nordisk had expected the association to make the changes to the site off-line so that the changes could be certified prior to making the site live.

The Panel considered that the errors were such that versions 2 to 4 of the hub had not been certified as required by Clause 8.1 and its supplementary information and therefore Novo Nordisk had failed to satisfy the relevant requirements of Clause 8.3; a **breach of Clause 8.3** was ruled as acknowledged by Novo Nordisk.

The Panel noted that the written agreement between Novo Nordisk and the association, signed by both parties in December 2021, stated in clause 8d: 'The Organisation (the association) shall take account of the comments and requests of Novo Nordisk on any proposed publications or other materials relating to the Project, and materials must be finalised through Novo Nordisk's internal review and approval process. As far as possible, the Parties will agree the timing of any intended publications before commencement of the Project. Novo Nordisk may veto publication if it can demonstrate that publication would be contrary to the ABPI Code of Practice, or to the applicable laws, or if it presents a reputational risk to Novo Nordisk.'

The Panel noted Novo Nordisk's submission that one change to the certified version 2 of the hub, performed by the association without the knowledge of Novo Nordisk, was the inclusion of a link to a YouTube video.

Noting the clause in the written agreement, it appeared that Novo Nordisk had been let down by the association when it made a change to the hub without Novo Nordisk's knowledge. However, it was concerning that the change and other compliance failures only came to Novo Nordisk's attention further to receipt of a complaint to the Authority (Case AUTH 3711/11/11). It was also concerning that there were times that Novo Nordisk had believed the site was down when it was in fact live. In the Panel's view, Novo Nordisk had inadequate control and oversight of this hub. In addition, the Panel considered that the employee statements provided by Novo Nordisk revealed poor communication and governance in relation to the approval process.

The Panel noted that a robust certification system underpinned self-regulation. The Panel noted that Novo Nordisk had failed to appropriately certify three versions of the hub. The Panel considered that the poor governance by Novo Nordisk in relation to this hub was such that Novo Nordisk had failed to maintain high standards; a **breach of Clause 5.1** was ruled as acknowledged by Novo Nordisk.

Clause 2 was a sign of particular censure and was reserved for such use. Given that allegations in relation to the content of the hub and the training course were dealt with in Cases

AUTH/3711/11/22 and AUTH/3525/6/21, respectively, the Panel considered that the matter in relation to this voluntary admission (uncertified versions of the hub) was adequately covered by its rulings of breaches of Clauses 5.1 and 8.3 above and therefore, on balance, the Panel ruled **no breach of Clause 2**.

**Complaint received**      **14 February 2023**

**Case completed**        **30 October 2023**