

CASE AUTH/3742/2/23

VOLUNTARY ADMISSION BY TAKEDA UK LIMITED

Promotion to the public

CASE SUMMARY

This was a voluntary admission by Takeda UK Limited relating to a letter sent to suppliers to inform them about new payment terms. The recipients of the letter were mostly providers of general business services and a small number of healthcare organisations.

The Panel ruled a breach of the following Clauses of the 2021 Code because the letter, which had not been certified, included promotional language about three licensed medicines and another medicine still under development:

Breach of Clause 3.1	Promotion of a medicine prior to the grant of its marketing authorisation
Breach of Clause 5.1	Failing to maintain high standards
Breach of Clause 8.1	Failing to certify promotional material
Breach of Clause 11.1	Promotion of a medicine prior to the grant of its marketing authorisation
Breach of Clause 26.1	Advertising a prescription only medicine to the public

**This summary is not intended to be read in isolation.
For full details, please see the full case report below.**

FULL CASE REPORT

Takeda UK Limited made a voluntary admission about a letter sent to suppliers to inform them about new payment terms. In line with Takeda's commitment to abide by the letter and spirit of the Code and to maintain high standards in their activities at all times, Takeda decided to make this voluntary admission and had concerns that there may have been a breach of Clauses 26.1, 11.1 and 5.1 of the ABPI Code.

VOLUNTARY ADMISSION

Takeda UK submitted that a letter was sent out to 266 of the company's UK-based suppliers on 7 February 2023. This letter was created and distributed by Takeda's Global Procurement Office located in Boston USA. Takeda provided the Authority with a copy of the letter as part of its voluntary admission.

Takeda stated that the letter was to inform suppliers that Takeda Pharmaceuticals would be implementing new global payment terms effective 1 February 2023. However, the letter also mentioned 3 licensed Takeda medicines and a further recently acquired asset which was still

under development. The indication for one of the licensed medicines and potential future indications for the asset in clinical development were also mentioned.

The Takeda affiliate in the UK (Takeda UK Limited) first became aware of the letter on the afternoon of Friday, 10 February 2023 after it had been sent out to vendors across multiple geographies. The letter was at no stage reviewed or approved by any employee of Takeda UK Limited.

Takeda UK stated that a thorough internal investigation was ongoing to better understand how this lapse occurred and that they would be working with colleagues in the global organisation to put processes in place to ensure that no similar lapse could occur in the future.

When writing to Takeda UK, the Authority asked it to consider the requirements of Clauses 3.1, 5.1, 8.1, 11.1 and 26.1 of the Code.

RESPONSE

Takeda UK provided further comments and voluntarily admitted breaches of Clauses 26.1, 11.1, 5.1, 3.1 and 8.1.

Clause 26.1

Takeda submitted that the letter that was created and distributed by Takeda's Global Procurement Office in Boston was sent to a range of vendors contracted to Takeda UK, including providers of general business services as well as a small number of healthcare organisations (HCOs). In Takeda's view, providing promotional content concerning the company's medicines to providers of general business services constituted a breach of Clause 26.1.

Clause 11.1

The letter was sent to a small number of HCOs contracted by Takeda UK, including companies who provide homecare services to patients taking a number of Takeda medicines. In Takeda's view, the fact that the letter mentioned potential indications for a Takeda asset in clinical development constituted a breach of Clause 11.1.

Clause 5.1

Takeda accepted that the inclusion of promotional content in a letter sent to both general business suppliers and HCOs was inappropriate. Takeda believed that this incident did not reflect the high standards required by the Code.

Clause 3.1

In Takeda's view, the fact that the letter mentioned an asset in development, along with potential future indications, prior to the grant of marketing authorisation, constituted a breach of Clause 3.1.

Clause 8.1

No employee of the Takeda UK organisation had sight of the letter prior to it being distributed directly by the Global Procurement Office. Having accepted that the letter included promotional content, Takeda accepted that its distribution without prior certification constituted a breach of Clause 8.1.

PANEL RULING

The Panel noted that Takeda UK made a voluntary admission in relation to a letter created and distributed by Takeda's Global Procurement Office.

The Panel noted the letter at issue was to inform Takeda's suppliers that it would be implementing new payment terms in order to 'efficiently manage our working capital and support our commitment to provide life-transforming treatments to patients in need'. The letter went on to state 'In 2022, we were proud to launch Livtency and Exkivity, which offer new hope for transplant and lung cancer patients, and we received approval for Qdenga, a vaccine with the potential to significantly improve public health in dengue-endemic countries. We also in-licensed a promising new molecule that has the potential to address a range of patient needs, including psoriasis, IBD, and lupus'.

Takeda submitted that the letter made reference to three licensed Takeda medicines and a further recently acquired asset which was still under development; the indication for one of the licensed medicines and potential future indications for the asset in clinical development were also mentioned.

The Panel noted Takeda's submission that the letter was created and distributed by Takeda's Global Procurement Office located in Boston USA on 7 February 2023, and the UK affiliate first became aware of the letter on the afternoon of Friday, 10 February 2023 after it had been sent out to vendors across multiple geographies; the letter was at no stage reviewed or approved by any employee of Takeda UK Limited.

The Panel noted it was an established principle that UK companies were responsible for the acts and omissions of their overseas affiliates that came within the scope of the UK Code.

The Panel noted Takeda's submission that the letter was sent to 266 of the company's UK-based suppliers and it therefore followed that the matter fell within the scope of the UK Code.

The Panel, noting the recipients of the letter were mostly providers of general business services, considered the audience constituted members of the public; the letter had also been sent to a small number of HCOs, including companies who provide homecare services to patients taking a number of Takeda medicines.

The Panel considered the letter could not be seen as anything other than promotional; the letter made reference to Takeda's medicines and indications and contained promotional language including 'life-transforming treatments', 'new hope', 'potential to significantly improve' and 'promising'.

Clause 26.1 of the Code stated that prescription only medicines must not be advertised to the public. The Panel, noting the audience included members of the public and that the letter

included promotional content, considered prescription only medicines had been promoted to the public and **a breach of Clause 26.1 was ruled**, as acknowledged by Takeda.

Clauses 3.1 and 11.1 stated that a medicine must not be promoted prior to the grant of marketing authorisation. The Panel noted the letter made reference to a Takeda medicine that was in clinical development and its potential indications prior to its marketing authorisation. The Panel therefore ruled **a breach of Clause 3.1** in relation to the letter being sent to general business services suppliers.

The Panel noted the letter had also been sent to HCOs; in this regard, the Panel noted a HCO was defined in the Code as 'either a healthcare, medical or scientific association or organisation such as a hospital, clinic, foundation, university or other teaching institution or learned society whose business address, place of incorporation or primary place of operation is in Europe or an organisation through which one or more health professionals or other relevant decision makers provide services'.

In the Panel's view, noting Takeda's acceptance of Clause 11.1, recipients would have also included health professionals and/or other relevant decision makers, on the balance of probabilities. Therefore, **a breach of Clause 11.1** was ruled in relation to the letter being sent to suppliers that were HCOs, as acknowledged by Takeda.

The Panel considered that the letter contained promotional content and had not been certified, as required by the Code, and ruled **a breach of Clause 8.1**, as acknowledged by Takeda.

The Panel noted its rulings of breaches of Clauses 26.1, 3.1, 11.1 and 8.1 above in relation to promotion to the public, promotion prior to the marketing authorisation and failure to certify promotional material; in this regard, the Panel considered that high standards had not been maintained, as acknowledged by Takeda, and **a breach of Clause 5.1** was ruled.

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Complaint received **16 February 2023**

Case completed **29 November 2023**