

CASE AUTH/3747/2/23

COMPLAINANT v OTSUKA UK

Promotion of unlicensed medicines on LinkedIn

CASE SUMMARY

This case related to a LinkedIn post by Otsuka US that had been ‘liked’ by a senior UK employee of Astex Therapeutics Limited which was part of the wider Otsuka group.

The outcome under the 2021 Code was:

Breach of Clause 3.1	Promoting a medicine prior to the grant of its marketing authorisation
Breach of Clause 5.1	Failing to maintain high standards
Breach of Clause 6.1	Making a claim that was misleading by exaggeration
Breach of Clause 9.1	Failing to ensure members of staff are fully conversant with the Code and the relevant laws and regulations
Breach of Clause 14.4	Making an exaggerated claim that could not be substantiated

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

FULL CASE REPORT

A complaint was received from an anonymous, non-contactable complainant about Otsuka Pharmaceuticals UK Limited.

COMPLAINT

The complaint wording is reproduced below (retyped):

“I would like to draw your attention to the post on LinkedIn by Otsuka. This post promotes an unlicensed medicine. Also, the language used is inappropriate and exaggerated – describing Ulotaront as “a major advancement for the adjunctive treatment of major depressive disorder” – even though it hasn’t even had a phase 3 readout.

[Screenshot of LinkedIn post provided]

The post has been liked by a UK employee of Astex, an Otsuka company, and so the ABPI code will apply. I question whether Otsuka/Astex have trained staff appropriately on social media as it is very clear that this is not something that UK employees should be liking or sharing, particularly senior staff.

[Screenshot of LinkedIn post ‘like’ provided].”

When writing to Otsuka UK, the Authority asked it to consider the requirements of Clauses 3.1, 5.1, 6.1, 9.1 and 14.4 of the 2021 Code.

OTSUKA UK RESPONSE

The response from Otsuka UK is reproduced below:

“Background

In 2021, Sunovion Pharmaceuticals Inc., its parent company Sumitomo Dainippon Pharma Co., Ltd. and Otsuka Pharmaceutical Co., Ltd. entered into a worldwide license agreement for the joint development and commercialization of four compounds including ulotaront (SEP-363859). To our knowledge Sunovion do not currently have an office based in the UK.

The LinkedIn post cited in the complaint was published on Otsuka Pharmaceutical Companies US LinkedIn account and included information describing the collaboration between Sunovion and Otsuka in relation to a clinical study for ulotaront. This post was approved by the US following the relevant requirements in Otsuka America Pharmaceuticals Inc. A copy of the post and linked document were provided.

Astex Therapeutics Limited, based in Cambridge, UK, is part of the global Otsuka group and a wholly-owned subsidiary of Otsuka America, Inc. Otsuka Pharmaceuticals UK Ltd and Astex Therapeutics Limited are independent companies who carry out separate day-to-day activities, have separate management teams, and each company follow different policies and procedures.

Whilst the initial LinkedIn post was not intended for UK audience, we agree that when the Astex Therapeutics Limited employee liked the post this brought it into scope of the ABPI Code. As Astex Therapeutics Limited is part of the wider Otsuka group, we have provided the response.

The complainant raises three main concerns, as noted below:

- The LinkedIn post promotes an unlicensed medicine.
- Language used is inappropriate, exaggerated, and unsubstantiated.
- Training regarding social media is insufficient.

We will address each of these areas separately.

Promotion prior to licence

The LinkedIn post included information about an unlicensed medicine ulotaront (SEP-363859), it was liked by an Otsuka group employee who is based in the UK and therefore brought it into scope of the ABPI Code as detailed above. We accept that by engaging with this post they in effect further disseminated the post to their connections on LinkedIn and as this included information about ulotaront (SEP-363859) this had promoted the medicine prior to the grant of the marketing authorisation. Therefore, Otsuka Pharmaceuticals UK Ltd accepts a breach of Clause 3.1 of the Code.

Language used is inappropriate, exaggerated and unsubstantiated

We acknowledge and accept that the language used was not in accordance with the requirements of Clauses 6.1 and 14.4 and in effect included an exaggerated claim. This was not reviewed and certified for use in the UK as it was not intended for use in the UK. Ulotaront has not yet been approved by any regulatory authorities, thus we agree that any claim about its impact or relevance for the management of patients are at this stage unsubstantiated. Therefore, Otsuka Pharmaceuticals UK Ltd accepts breaches of Clauses 6.1 and 14.4 of the Code.

Training regarding social media is insufficient

Astex Therapeutics Limited follow a global policy on the use of social media which was issued by Otsuka Holdings Co., Ltd.. This policy requires that local laws and regulations are adhered to and is available on the intranet for all staff to refer to. The Astex Therapeutics Limited staff who are based in the UK have not had additional training with regards to these specific local requirements from a UK ABPI Code of Practice perspective. We are therefore not confident that these employees were fully conversant with the relevant areas of the Code relating to social media and acknowledge a breach in this regard. Therefore, Otsuka Pharmaceuticals UK Ltd accepts a breach of Clause 9.1 of the Code.

We acknowledge that high standards have not been maintained in this regard. Therefore, Otsuka Pharmaceuticals UK Ltd accepts a breach of Clause 5.1 of the Code.

Upon receipt of this complaint, action was taken to ensure that the individual from Astex Therapeutics Limited named in the complaint removed the 'like' from this post. In addition, the post was also reviewed to establish if any other employees based in the UK from Otsuka and Astex Therapeutics Limited had also engaged with the post. Unfortunately, there was one other individual from Astex Therapeutics Limited who was identified and was also followed up accordingly.

Since the receipt of this complaint, we have shared our current Otsuka Pharmaceutical Europe Ltd social media training slides and working practice document with Astex Therapeutics Limited. Astex Therapeutics Limited have issued and trained their staff on the use of social media requirements and have agreed to ensure this is also placed on their intranet. New staff will also receive this as part of their induction training."

PANEL RULING

The complaint related to a LinkedIn post by Otsuka US which stated:

"We are thrilled to announce, in collaboration with Sunovion Pharmaceuticals, that the first patient has been enrolled in a clinical study for ulotaront (SEP-363856), a major advancement for the adjunctive treatment of major depressive disorder (MDD). This announcement is significant to the development of future innovations for the unmet needs of the people and communities we humbly serve, as we strive to further advance the spectrum of mental healthcare. Read more here: [link provided] #DefyLimitation #mentalhealth #MDD."

The Panel understood that if an individual 'liked' a post, it increased the likelihood that the post would appear in his/her connections' LinkedIn feeds, appearing as '[name] likes this'. In the Panel's view, activity conducted on social media that could potentially alert one's connections to the activity might be considered proactive dissemination of material. Any material associated with a social media post, for example a link within a post, would be regarded as being part of that post.

The Panel noted that the original LinkedIn post at issue included the name, indication and claims such as 'a major advancement for the adjunctive treatment of major depressive disorder (MDD)' for the medicine ulotaront, along with a linked press release titled 'Otsuka and Sunovion Initiate Clinical Development of Ulotaront for the Adjunctive Treatment of Major Depressive Disorder'.

The Panel noted that the original LinkedIn post, which had been issued by Otsuka US, had been 'liked' by a senior UK employee of Astex Therapeutics Limited which was part of the wider Otsuka group. The Panel considered that the UK employee's engagement with the post, on the balance of probabilities, had proactively disseminated the material to his/her connections on LinkedIn and had thus brought the post within the scope of the UK Code, as acknowledged by Otsuka.

The Panel noted the promotional nature of the post and that ulotaront had not been approved by any regulatory authorities. The Panel therefore considered that the senior employee's activity on LinkedIn constituted the promotion of ulotaront prior to the grant of its UK marketing authorisation. **A breach of Clause 3.1 was ruled**, as acknowledged by Otsuka.

The Panel noted Clause 6.1 of the 2021 Code required, amongst other things, that information, claims and comparisons must not mislead either directly or by implication, by distortion, exaggeration or undue emphasis.

Clause 14.4 included that promotion must encourage the rational use of a medicine by presenting it objectively and without exaggerating its properties. Exaggerated or all-embracing claims must not be made and superlatives must not be used except for those limited circumstances where they relate to a clear fact about a medicine. Claims should not imply that a medicine or an active ingredient has some special merit, quality or property unless this can be substantiated.

The Panel did not have a copy of the clinical evidence before it but noted that the post described ulotaront as a 'major advancement' and further noted Otsuka's acknowledgement that the language used in the post included an exaggerated claim and that any claim about ulotaront's impact or relevance would be unsubstantiated at that stage. **The Panel ruled a breach of Clauses 6.1 and 14.4 accordingly as acknowledged by Otsuka.**

The Panel considered that companies should have comprehensive and up-to-date social media policies that provide clear and unequivocal guidance on what was, and what was not, acceptable and it was extremely important that employees were trained upon them and followed them.

Astex Therapeutics Limited had been issued with a global policy on the use of social media by Otsuka which required that local laws and regulations were adhered to and was available on the intranet for all staff to refer to. In this regard, the Panel noted Otsuka's acknowledgement that

UK employees of Astex had not had additional training with regards to local requirements from a UK ABPI Code of Practice perspective and that it was not confident that these employees were fully conversant with the relevant areas of the Code relating to social media. The Panel accordingly **ruled a breach of Clause 9.1.**

The Panel considered that in 'liking' the original LinkedIn post, the UK employee had, in effect, created their own piece of promotional material which had been distributed to their connections, including members of the public, for a medicine prior to its marketing authorisation. The Panel was concerned with the inadequate processes and training in place and considered high standards had not been maintained. **The Panel therefore ruled a breach of Clause 5.1.**

Complaint received 28 February 2023

Case completed 4 June 2024