CASE AUTH/3748/2/23

COMPLAINANT v OTSUKA EUROPE

Otsuka Europe website

CASE SUMMARY

This case related to a webpage headed 'Therapy Areas in Europe' on the Otsuka Europe website which made reference to its relationship with its 'partner' organisations Akebia and Aurinia.

The outcome under the 2021 Code was:

Breach of Clause 6.1	**Providing inaccurate information**

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 about Otsuka Pharmaceuticals Europe Ltd from an anonymous, non-contactable complainant who described themselves as an ex-employee.

COMPLAINT

The complaint wording is reproduced below:

> "The Otsuka website – [website link provided] – says "we work with patients and healthcare professionals to increase awareness of kidney disease including autosomal dominant polycystic kidney disease (ADPKD) and together with our partners Akebia and Aurinia, are exploring treatment options for patients with anaemia related to chronic kidney disease and Lupus Nephritis" This information was updated in December 2021 and now is out of date and false. Otsuka and Akebia said in June 2022 that they cancelled the agreement. This is another case of Otsuka giving wrong information."

When writing to Otsuka Europe, the Authority asked it to consider the requirements of Clause 6.1 of the 2021 Code.

OTSUKA EUROPE RESPONSE

The response from Otsuka Europe is reproduced below:

> "**Background**
>
> In 2016, Otsuka Pharmaceutical Co., Ltd. (Otsuka) entered into global license agreements with Akebia Therapeutics, Inc. (Akebia) for vadadustat (generic name), under

development as an oral treatment for anemia associated with chronic kidney disease (renal anemia). These licenses were signed in December 2016 for the US and April 2017 for Europe and other regions.

Otsuka and Akebia had been co-developing vadadustat for renal anemia; however, in March 2022, Akebia received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA). As a result, Otsuka decided to terminate its co-development of vadadustat and notified Akebia of the termination of its global license agreements in May 2022.

In June 2022, the companies signed a Termination and Settlement Agreement wherein 1) Akebia regained the rights to vadadustat in the US, EU & all countries previously held as Otsuka territories and 2) the related transfer of obligations was outlined. All of Otsuka's activities and responsibilities were to be completed by December 2022, with the following exceptions:

- Otsuka will transfer the final trial master file (TMF) for the MODIFY study to Akebia by 30 April 2023. This was completed in January 2023.
- Otsuka will conduct the EU packaging validation study and deliver final packaging validation reports to Akebia as prepared by the vendor. This is still ongoing.

Otsuka do not expect to have any ongoing or remaining obligations or responsibilities for vadadustat after 13 May 2023.

Complaint

Whilst the statement on our website raised by the complainant relating to collaboration with Akebia was correct when it was approved and published, Otsuka accepts that the statement is now inaccurate and obsolete. Therefore, we accept a breach of Clause 6.1 of the Code. Please find a copy of webpage and the certificate relating to this webpage enclosed. We have also enclosed the qualifications of the signatory for this material. We have now amended the webpage to remove reference to Akebia and anaemia related to chronic kidney disease."

PANEL RULING

The Panel noted that the material at issue was published on a webpage headed 'Therapy Areas in Europe' on the Otsuka Europe website. The Panel noted that Otsuka Europe was based in the UK and therefore its material had to comply with the UK Code.

The webpage included subheadings which gave a brief description of Otsuka's focus in three therapy areas: Neuroscience, Nephrology and Haemato-oncology, and its 'partner' organisations. The relevant text beneath the Nephrology subheading read:

> "We work with patients and healthcare professionals to increase awareness of kidney disease including autosomal dominant polycystic kidney disease (ADPKD) and together with our partners Akebia and Aurinia, are exploring treatment options for patients with anaemia related to chronic kidney disease and Lupus Nephritis."

The complainant alleged that this information was updated in December 2021 and was now out of date and false as Otsuka and Akebia stated in June 2022 that they had cancelled the agreement.

The Panel noted Otsuka Europe's submission that it notified Akebia of the termination of its global license agreements in May 2022, and in June 2022, the companies signed a Termination and Settlement Agreement wherein amongst other things Akebia regained the rights to the product in question, vadadustat, in the US, EU and all countries previously held as Otsuka territories. Otsuka Europe did not expect to have any ongoing or remaining obligations or responsibilities for vadadustat after 13 May 2023.

The Panel noted that Otsuka Europe made no comment about its relationship with Aurina.

The Panel considered the text in question that was live on the webpage at the time of the complaint in February 2023 was not an accurate reflection of the relationship between the companies and was therefore inaccurate contrary to the requirements of Clause 6 as alleged. **A breach of Clause 6.1 was ruled** as acknowledged by Otsuka.

Complaint received **28 February 2023**

Case completed **4 June 2024**