CASE AUTH/3732/1/23

HEALTH PROFESSIONAL v NOVARTIS

Allegations about Tasigna prescribing information on Novartis' website

CASE SUMMARY

This case related to the inclusion of Northern Ireland marketing authorisation numbers instead of Great Britain marketing authorisation numbers, on the Great Britain Prescribing Information document for Tasigna.

The outcome under the 2021 Code was:

Breach of Clause 5.1	**Failing to maintain high standards**

No breach of Clause 5.1	**Requirement to maintain high standards**

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, who described themselves as a health professional about Novartis Pharmaceuticals UK Ltd.

COMPLAINT

The complainant stated that the Novartis website [website link provided] promoted Tasigna (nilotinib). The website had a link to prescribing information. The linked prescribing information was updated in June 2022. It did not contain a Great Britain marketing authorisation number (breach of Clause 12.2).

When writing to Novartis, the Authority asked it to consider the requirements of Clauses 12.2 as cited by the complainant and, in addition, Clause 5.1 of the 2021 Code.

RESPONSE

Novartis submitted that the complainant alleged that Novartis had breached certain clauses of the Code pertaining to the prescribing information for Tasigna® (nilotinib) in Great Britain available on Novartis' website for UK health professionals.

Background

The complaint related to the prescribing information for Tasigna, which was available by way of a link on the Novartis health.novartis.co.uk website. The website hosted promotional information

about Novartis products, therapy area materials and professional resources aimed at UK health professionals and other relevant decision makers. Each time a health professional accessed the website they were asked to confirm that they were a health professional (or NHS relevant decision-maker).

The webpage in question contained a list of certain Novartis medicines, including Tasigna. The prescribing information for this product in Great Britain and Northern Ireland was contained within a link directly below the heading 'Tasigna'. The webpage was available at the following link: [website link provided].

Summary of the alleged breaches

The complainant alleged that, in breach of Clause 12.2 of the Code, the prescribing information did not contain the Great Britain marketing authorisation number.

As requested, in responding to the complaint, Novartis had borne in mind the requirements of Clauses 5.1 and 12.2 of the Code.

Novartis' response

Novartis' responses are given below:

Clause 12.2

Novartis fully understood that, as required by Clause 12.2 of the Code, the number of the relevant marketing authorisation must be included in the prescribing information for the product.

The prescribing information subject to the complaint was contained within a link directly below the heading 'Tasigna' on the webpage, which was hosted on the website.

The prescribing information was separated into Great Britain and Northern Ireland. Novartis regretted that, unfortunately, the marketing authorisation numbers for Northern Ireland had erroneously been included as the marketing authorisation numbers for Great Britain. The marketing authorisation numbers for Great Britain should, instead, have been as follows:

PLGB 00101/1152 50mg
PLGB 00101/1150 150mg
PLGB 00101/1151 200mg.

This was a technical oversight when approving the prescribing information and Novartis accepted a breach of Clause 12.2. Novartis highlighted the following:

(i) following receipt of the complaint, Novartis promptly arranged for the prescribing information to be updated to include the marketing authorisation numbers for Great Britain. This had been recertified in accordance with Novartis' robust internal processes ; and
(ii) following re-certification, Novartis had replaced the prescribing information contained within the link on the webpage.

Clause 5.1

As requested, in responding to the complaint, Novartis had borne in mind the requirements of Clause 5.1 of the Code. Novartis had robust internal approval processes and was committed to maintaining high standards. The prescribing information had been reviewed and certified through Novartis' internal processes. Although Novartis took any breaches of the Code very seriously, this was a technical oversight caused by human error and Novartis had taken prompt action to rectify the oversight in the Great Britain prescribing information. Tasigna had a marketing authorisation in Great Britain, therefore this was not a case of promoting an unlicensed medicine or use of the medicine outside the terms of the licence. The issue had not had a direct impact on patient safety. Novartis therefore refuted any alleged breach of Clause 5.1 of the Code.

Conclusion

In summary, Novartis conceded a breach of Clause 12.2. Notwithstanding, Novartis' opinion was that Clause 5.1 had not been breached on the basis that:

'
- Tasigna has a marketing authorisation in Great Britain, therefore this was not a case of promoting an unlicensed medicine or use of the medicine outside the terms of the licence. The issue has not had a direct impact on patient safety; and

- this is a technical oversight caused by a human error, which has been promptly rectified. Novartis has robust internal approval processes and is committed to maintaining high standards.'

Further information

In response to a request for further information by the Panel regarding Novartis' policies, procedures and processes, Novartis provided its Promotional and Non-Promotional Materials Standard Operating Procedure (SOP) enforced at the time of the certification of the prescribing information at issue.

To assist the Panel, Novartis stated it had set out the key aspects of the SOP:

> 'Section 4 (Principles) of the SOP mandated the following:
> (a) any promotional materials (which is widely defined as any materials that has a purpose of directly promoting a Novartis product by presenting information or claims, including documents and websites, as per section 10 (Definitions) of the SOP) must be certified,
> (b) prescribing information included with promotional materials must be in-line with the requirements detailed in the Code and be applicable for the territory of use (Great Britain and/or Northern Ireland), and
> (c) any materials for use in Great Britain and Northern Ireland must be approved separately in accordance with the individual regulatory requirements.
>
> Under section 5 (Procedure) of the SOP:
> (a) prior to dissemination, all final-form promotional materials must be certified in-line with the principles outlined in the SOP and the approval requirements set out in Appendix 2 (Approval Requirements), and
> (b) prescribing information must be certified by a medical final signatory (as per Appendix

(Approval Requirements)).'

Novartis submitted, based upon the above, it was of the opinion that Novartis has robust internal processes in relation to reviewing and certifying prescribing information.

Conclusion

Novartis stated in-line with its initial letter of response, that in Novartis' opinion, Clause 5.1 of the Code has not been breached, because:

'(a) patient safety has not been directly impacted as a result of the error noted in the Complaint, particularly since Tasigna has a marketing authorisation in both Great Britain and Northern Ireland, and there is no promotion of an unlicensed medicine or use of medicine outside of its authorisation terms,
(b) the error noted in the Complaint was a human error and Novartis promptly rectified the error noted in the Complaint (within four working days after receiving the Complaint, which involved reviewing the issue and going through the relevant processes, including certification by a medical final signatory), and
(c) Novartis has robust internal processes and is committed to maintaining high standards in the pharmaceuticals industry.'

PANEL RULING

The Panel noted the complaint related to the prescribing information for Tasigna (nilotinib), which was available by way of a link on the health.novartis.co.uk website on a webpage which contained a list of Novartis medicines.

Novartis submitted the prescribing information at issue for Tasigna in Great Britain and Northern Ireland was contained within a link directly below the webpage heading, 'Tasigna,' and that the prescribing information was separated into Great Britain and Northern Ireland; Novartis submitted it regretted that the marketing authorisation numbers for Northern Ireland had erroneously been included as the marketing authorisation numbers for Great Britain, which was a technical oversight.

The Panel noted that Clause 12.1 required the prescribing information listed in Clause 12.2 to be provided on all promotional material. Clause 12.2 listed the components of prescribing information and required, among other things, the number of the relevant marketing authorisation and the name and address of the holder of the authorisation or the name and address of the part of the business responsible for its sale or supply.

The Panel considered it was an established principle that a failure to meet the requirements of prescribing information as listed in Clause 12.2 was a breach of Clause 12.1. Clause 12.1 had not been cited in this case and the Panel therefore considered the matter under Clause 5.1. The Panel therefore made no ruling under Clause 12.2.

The Panel considered the inclusion of Northern Ireland marketing authorisation numbers instead of Great Britain marketing authorisation numbers, on a document headed 'Great Britain Prescribing Information: TASIGNA® (nilotinib)', meant that the requirements of Clause 12.2 had not been met; noting its comments above, **the Panel ruled a breach of Clause 5.1**.

The Panel noted Novartis' submission that the matter was a technical oversight caused by a human error and the material was promptly re-certified with the marketing authorisation numbers for Great Britain. The Panel noted Novartis' 'Promotional and Non-Promotional Materials' SOP stated that:

> 'Prescribing Information ("PI") included with promotional materials must be in line with the requirements detailed in the Code and be applicable for the territory of use ("GB" and/or "NI"). Materials for use in Great Britain ("GB") and Northern Ireland ("NI") must be approved separately in accordance with the individual regulatory requirements.'

The Panel considered the importance of prescribing information and that the omission of Great Britain marketing authorisation numbers meant the requirement to provide prescribing information suitable for health professionals in Great Britain had not been wholly met. The Panel also noted Novartis' submission that Tasigna had a marketing authorisation in Great Britain and therefore this was not a case of promoting an unlicensed medicine nor use of the medicine outside the terms of the licence.

Taking into account the above, the Panel considered in the particular circumstances of this case, the matter at issue was adequately covered by the Panel's ruling of a breach above and did not warrant an additional ruling in relation to high standards. **The Panel, on balance, ruled no breach of Clause 5.1**.

Complaint received **27 January 2023**

Case completed **5 April 2024**