Case AUTH/3667/6/22 ***NO BREACH OF THE CODE***

COMPLAINANT v ROCHE

Certification of the mobile version of a webpage and alleged off-licence promotion

CASE SUMMARY

This case was in relation to the mobile version of a webpage on the Roche resources website, within the congress and meetings section, which allegedly required separate certification and allegedly promoted Kadcyla (trastuzumab emtansine) and Perjeta (pertuzumab) outside of their marketing authorisations.

The Panel ruled no breach of the following Clauses of the 2021 Code as it did not consider that the complainant had established that the difference in final form between the desktop and mobile versions meant that the two versions should have been certified separately nor did it consider that, within the context of the webpage, the title of a video, 'Tailoring Treatment for Patients with HER-2 positive Early Breast Cancer', which was a virtual meeting, implied that Kadcyla and Perjeta were licensed for use in all patients with HER-2 positive early breast cancer as alleged.

No Breach of Clause 2	**Requirement that material must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**
No Breach of Clause 5.1	**Requirement to maintain high standards**
No Breach of Clause 8.1	**Requirement to certify promotional material**
No Breach of Clause 11.2	**Requirement not to promote a medicine for an unlicensed indication**

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

FULL CASE REPORT

An anonymous, contactable complainant who described him/herself as a health professional complained about a number of areas that were allegedly unbalanced promotion on the Roche Products Ltd Resources website for Kadcyla (trastuzumab emtansine) and Perjeta (pertuzumab).

COMPLAINT

The complainant was concerned that Roche did not abide by the letter and spirit of compliance regulations highlighting neglect around ethical obligations for patients. The complainant provided a link to the page in question (ref M-GB-00005336 Date of preparation: November 2021) and alleged the following:

1 There were differences in the final look of the desktop vs mobile version. On the desktop version under the banner 'FUTURE POSITIVE LITE', there was the following text, 'Resources > Congresses and Meetings > Future Positive Lite'. However, on the mobile phone form version, this text was entirely missing, instead there was a light blue colour bar underneath the 'FUTURE POSITIVE LITE' banner on the mobile phone version. It was a clear modification to final look/view between the desktop and mobile. The two forms of desktop view and mobile view should have been certified separately owing to these text and format differences. The complainant alleged that Clauses 8.1, 5.1 and 2 had not been adhered to as certification was a robust measure of promotion.

2 Directly underneath the prescribing information for Kadcyla and Perjeta, in big font size, there was the wording 'Tailoring Treatment for Patients with HER-2 positive Early Breast Cancer'. The complainant stated that the marketing authorisation for both products was not first line use within HER-2 positive Early Breast Cancer. The therapeutic indications for both products were far more specific than just HER-2 positive Early Breast Cancer as promoted in the claim:

> 'Perjeta was indicated for use in combination with trastuzumab and chemotherapy in:
>
> - the neoadjuvant treatment of adult patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer at high risk of recurrence (see section 5.1)
> - the adjuvant treatment of adult patients with HER2-positive early breast cancer at high risk of recurrence.
>
> Kadcyla as a single agent, was indicated for the adjuvant treatment of adult patients with HER2-positive early breast cancer who had residual invasive disease, in the breast and/or lymph nodes, after neoadjuvant taxane-based and HER2-targeted therapy.'

The complainant stated that the claim 'Tailoring Treatment for Patients with HER-2 positive Early Breast Cancer' was therefore inappropriate considering the exact subset of patients both products were indicated for was not provided and alleged breaches of Clauses 11.2, 5.1 and 2.

When writing to Roche, the Authority asked it to consider the requirements of Clauses 2, 5.1, 8.1 and 11.2 of the Code.

RESPONSE

Roche submitted that it was committed to the appropriate use of medicines, protecting the safety of patients and strove to maintain high standards in the ethical promotion of its medicines. It was therefore disappointing to receive a complaint of this nature.

The complaint referred to pages included in Roche's Resources website, an online resource provided for health professionals to be able to access news, information and resources about Roche medicines. There were two parts to the complaint which were dealt with in turn below.

Roche submitted that the complainant alleged that the Roche Resources website had not been certified for mobile use as there were differences in appearance between the desktop and mobile versions on certain pages. Specifically, the complainant commented on the desktop version under the banner 'Future Positive Lite' where there was the following text to aid navigation, 'Resources > Congresses and Meetings > Future Positive Lite'. This text was instead a light blue colour bar underneath the 'Future Positive Lite' banner on the mobile phone version (M-GB-0000-5336).

As part of Roche's response to this complaint, it referred back to its commentary and associated Panel ruling in Case AUTH/3552/8/21 as this case bore remarkable similarity.

Roche acknowledged that digital channels were typically designed to be used on a preferred device, eg a website for viewing on a desktop/laptop, an app for a smartphone or tablet. Roche Resources was built on a platform that adjusted the content to dynamically respond to the device the user had chosen to view it on. Roche certified content for the device it was primarily intended for (for Roche Resources this was a desktop) with the associated standard operating procedure (SOP) including a step that, at certification, the final signatories checked the content on other commonly used devices. Roche believed this approach was consistent with Clause 8.1 Supplementary Information regarding certifying dynamic content since the layout could change on different devices, but the context would remain the same.

Roche referred to the Panel's commentary in Case AUTH/3552/8/21 that the Code did not necessarily require a website to be certified multiple times for each different device it might be viewed upon, however, that it considered that the appearance of the material on different devices should be taken into consideration prior to certification to ensure that the content met the requirement of the Code.

As a result of Case AUTH/3552/8/21 and associated Panel ruling received in June 2022, a thorough review of Roche's Resources website, including content and associated processes, was undertaken. Specifically, SOPs for Examination and Certification, Digital Channels and Application of Digital Channels were reviewed and updated.

All SOPs had been further expanded on existing guidance that stated final signatories should be reviewing content on other commonly used devices to now include a mandatory requirement for signatories to capture in the comments section when approving materials in PromoMats which devices the content had been checked on. This change was communicated to the organisation and would be implemented and monitored on an ongoing basis.

In addition, as a result of the commentary in the Case AUTH/3552/8/21 ruling, Roche Resources was updated to include the statement, 'This website is designed for and intended to be viewed on a desktop/laptop' in the footer, thus making readers clear on the primary intended platform.

Roche provided a copy of the Veeva PromoMats certificate and PDF of certified content for M-GB-00005336 which was certified in November 2021 in line with Code and associated SOP requirements at the time. For completeness, Roche also provided screenshots of the content as viewed on an iPhone. Roche noted that the navigation bar content (Resources >Congresses and Meetings > Future Positive Lite) described as 'entirely missing' by the complainant above featured in the hamburger menu to aid navigation on a mobile device so Roche disagreed that this navigation bar was missing.

Roche submitted it prided itself on having the highest of standards and took incredibly seriously the nature of these complaints as well as associated corrective and preventative actions. As such, Roche was extremely disappointed to receive another complaint of this nature. However, on the basis of the considerations above, Roche strongly denied any breach of Clauses 8.1, 5.1 and 2 in this instance.

The second element to the complaint related to a query, again, on the 'Future Positive Lite' page of the Roche Resources website.

The 'Future Positive' branding related to a series of promotional meetings and this page, in particular, related to a promotional meeting video entitled 'Tailoring Treatment for Patients with HER-2 positive Early Breast Cancer'. The title, as noted above, appeared on the front of the video shown on the page as well as at the top of the page introducing the video.

The video, which had a clear disclaimer within it that it was a promotional video, which would include discussions relating to Roche's products. The overall page also detailed a summary of the discussion topics within the video content, a question and answer (Q&A) section based upon the topics within the video as well as access guidance (including the licenced indication) for the use of Kadcyla (trastuzumab emtansine) in early Breast Cancer.

The page also included clear and prominent links to the prescribing information for Kadcyla and Perjeta (pertuzumab) as well as links to adverse event reporting information.

Roche disagreed that the title 'Tailoring Treatment for Patients with HER-2 positive early Breast Cancer' constituted promotion of Kadcyla or Perjeta outside of their licenced indications. The rationale for this position is detailed below:

- The nature of this title 'Tailoring Treatment for Patients with HER-2 positive Early Breast Cancer' indicated that the content on the page, and specifically the video, was a summary of discussions from health professionals around how treatment might be tailored rather than any specific claim around the use of Kadcyla or Perjeta in a broad early breast cancer population. Indeed, the word, '*tailored*' implied that patients should be treated differently based upon certain characteristics.
- The 'Discussion Topics' section on the page directly below the title detailed the content of the presentation as well as providing some additional context to demonstrate that the discussion, and hence the content of the video, was about tailoring treatment to specific patient needs. Roche listed its speakers and examples of discussions including:

    - *the pathological evaluation before and after neoadjuvant treatment in eBC and how this information can be used to make personalised treatment decisions.*
    - *the objectives and benefits of neoadjuvant treatment, and how the use of neoadjuvant therapy provides an opportunity to adapt adjuvant treatment selection in the eBC setting.*
    - *the key efficacy and safety results from the Phase III KATHERINE trial and described the positioning of adjuvant Kadcyla (trastuzumab emtansine) in the HER2-positive eBC treatment pathway.*

- The Access Guidance statement at the base of the page clearly stated the reimbursement position for Kadcyla in the UK and this clearly stated the specific details of the indication for Kadcyla in the early breast cancer setting.
- Should a health professional choose to view the promotional video, this clearly positioned both Kadcyla and Perjeta within the early breast cancer pathway in accordance with the terms of their marketing authorisations.
- There was a clear and prominent link at the top of the page where viewers could access the prescribing information for both Perjeta and Kadcyla so any viewers would be clear as to the licensed indication for these medicines.

Roche did not believe that the title 'Tailoring Treatment for Patients with HER-2 positive Early Breast Cancer' implied that Kadcyla or Perjeta had a broader licence than their specific licensed indication. Kadcyla and Perjeta had, at all times, been promoted in accordance with the terms of their marketing authorisation. Accordingly, Roche vehemently denied any breach of Clauses 11.2, 5 and 2.

In summary, Roche reiterated its commitment to the maintenance of high standards and the assurance of robust processes in place to ensure that all materials were accurate and met the requirements of the ABPI Code of Practice.

PANEL RULING

The Panel noted the complaint concerned the Future Positive Lite webpage within the Congress section of the Roche Resources website for health professionals which allegedly required separate certification of the desktop and mobile version owing to text and format differences.

The Panel noted guidance issued by the PMCPA about whether material had to be certified for each platform it appeared on stated:

> 'Does material have to be certified for each platform it appears on, eg computer, tablet and mobile?
>
> Clause 8.1
>
> Companies must ensure that the final form viewed is not distorted and the requirements of the Code are complied with eg the legibility of the prescribing information.
>
> If companies have the technology to ensure that that which is viewed irrespective of the platform will be appropriately formatted and are confident that the final form will be identical on each platform then these do not require separate certification.'

The Panel noted the difference raised by the complainant was in relation to text included on the desktop version under the FUTURE POSITIVE LITE banner which read 'Resources > Congresses and Meetings > Future Positive Lite' which was missing from the webpage when viewed on a mobile device and instead included a light blue colour bar below the FUTURE POSITIVE LITE banner.

The Panel queried Roche's submission that the navigation bar content (Resources >Congresses and Meetings > Future Positive Lite), described as 'entirely missing' by the complainant above, featured in the hamburger menu to aid navigation on a mobile device. The

Panel noted that the navigation information referred to by the complainant appeared to be different from that which appeared within the hamburger menu when viewed on a mobile device; the latter appeared to be the tabs that appeared at the top of the desktop version of the webpage.

The Panel noted that Roche had not disputed that there were differences in appearance between the desktop and mobile versions. The question for the Panel was whether the differences meant that there were two final forms of the website, ie one for the desktop version and one for the mobile version and, if so, whether each had been separately certified.

In the Panel's view, the Code did not necessarily require a website to be certified multiple times for each different device it might be viewed upon, however, it considered that the appearance of the material on different commonly used devices should be taken into consideration prior to certification to ensure that if the final forms differed, they were subject to separate certification.

The Panel noted Roche's submission that digital channels were typically designed to be used on a preferred device and Roche Resources was built on a platform that adjusted the content to dynamically respond to the device the user had chosen to view it on. It further noted that Roche certified content for the device it was primarily intended for which for the Roche Resources website was a desktop. The Panel further noted Roche's submission that the associated SOP included a step that, at certification, the final signatories checked the content on other commonly used devices. It was not clear from the information and certificate provided by Roche whether this step had occurred in this particular instance.

Nonetheless, whilst the Panel noted the navigation reference, 'Resources > Congresses and Meetings > Future Positive Lite' appeared on the desktop version and not on the mobile version of the webpage, the Panel did not consider this necessarily required separate certification; in the Panel's view, this would be considered to be, on balance, a technical matter of webpage functionality and navigation as opposed to part of the substantive content of the webpage itself.

Mindful of the very narrow nature of the allegation, the Panel considered that the complainant had not established that the difference in final form between the desktop and mobile versions meant that the two versions should have been certified separately. The Panel therefore ruled **no breach of Clause 8.1** and consequently **no breach of Clauses 5.1 and 2**.

The Panel noted the complainant's second allegation that the marketing authorisation for both Kadcyla and Perjeta was not first line use within HER-2 positive Early Breast Cancer and the statement 'Tailoring Treatment for Patients with HER-2 positive Early Breast Cancer' was inappropriate considering the subset of patients both products were indicated for was not provided. Whilst the layout of the desktop and mobile versions appeared to be the same in this regard. The Panel noted that the complainant's second allegation appeared to be in relation to the desktop version of the webpage and the Panel made its rulings on this basis.

The Panel noted that the webpage at issue included a banner image stating 'Future Positive Lite' followed by details of how to report adverse events and links to the prescribing information for Kadcyla and Perjeta. Directly below this was the title of the first virtual meeting in the Future Positive Lite series 'Tailoring Treatment for Patients with HER-2 positive Early Breast Cancer' followed by a description of the aim of the virtual Future Positive Lite meeting series, which was to bring together the UK breast cancer community to share expertise, knowledge and solutions in the ever-changing landscape of breast cancer. The Continuing Professional Development

(CPD) logo appeared to the right of this description, beneath which it stated 'CPD accreditation for this meeting was certified by the CPD Certification Service'.

The next section, headed 'Discussion Topics' included details of the meeting including speakers and the topics to be discussed followed by the video of the meeting which showed the opening frame with the title 'Session 1: Tailoring treatment for patients with HER2+ early breast cancer' as a preview.

The Panel noted that the descriptions of the speakers' presentations indicated that different aspects of treatment with neo-adjuvant therapy would be discussed as well as the Phase III trial results supporting the positioning of adjuvant Kadcyla in the HER-2 positive early breast cancer treatment pathway. The Panel noted that all of the above information appeared within the same field of vision as the meeting title. It was thus, in the Panel's view, clear that the claim at issue raised by the complainant was the title of a meeting within the Future Positive Lite series.

The meeting had included a Q&A session, details of which was available as an expandable section below the video.

The Panel considered the overall impression created by the content and layout of the page; the statement highlighted by the complainant was the title of a meeting which discussed tailoring treatment for patients with HER2-positive early breast cancer. The Panel noted Roche's submission that *'tailored'* implied that patients should be treated differently based upon certain characteristics.

The Panel did not consider, on the balance of probabilities, that a health professional would misinterpret the broad title of the meeting as the therapeutic indications for Kadcyla and Perjeta. In the Panel's view, the complainant had not established that within the context of the webpage, the title of the meeting implied that Kadcyla and Perjeta were licensed for use in all patients with HER-2 positive early breast cancer as alleged. The Panel therefore ruled **no breach of Clause 11.2** and consequently ruled **no breach of Clauses 5.1 and Clause 2**.

Complaint received **26 June 2022**

Case completed **14 June 2023**