CASE AUTH/3641/4/22

COMPLAINANT v TEVA

Concerns about DuoResp Spiromax website and when viewed on a mobile device

CASE SUMMARY

This case was in relation to the DuoResp Spiromax (budesonide/formoterol) website particularly when viewed on a mobile device.

The Panel ruled a breach of the following Clauses of the 2021 Code because;

- **the final form of the website differed for the mobile version compared to the desktop version and each should have been certified separately which had not occurred**
- **the presentation of a prescribing information link within a hamburger menu in relation to the three webpages did not meet the Code's requirement for a clear prominent statement**
- **Teva had not adequately reviewed the website on mobile devices to ensure that it met the requirements of the Code when displayed on such devices:**

Breach of Clause 8.1	**Failure to certify promotional material**
Breach of Clause 12.6	**Failing to include a clear, prominent statement as to where prescribing information could be found**
Breach of Clause 5.1	**Failing to maintain high standards**

The Panel ruled no breach of the following Clauses of the 2021 Code on the basis that the complainant had not established that;

- **having the same job code on each page and section of the website meant that it had not been certified as required by the Code**
- **members of the public were encouraged by Teva to access information not appropriate for them as alleged**

And although Teva did not spot that the prescribing information tab had become contracted into a hamburger menu, it had reviewed how the website would appear on a mobile device as part of the website certification and the prescribing information was available from the hamburger menu icon on the top right side and at the end of the webpage when accessed from a mobile phone, therefore in the particular circumstances of this case, the Panel did not consider that a ruling of a breach of Clause 2 was warranted in this regard:

No Breach of Clause 8.1	**Requirement to certify promotional material**
No Breach of Clause 26.2	**Requirement that information about prescription only medicines which is made available to the public must be factual, balanced, must not raise unfounded hopes of successful treatment or encourage the public to ask**

	their health professional to prescribe a specific prescription only medicine
No Breach of Clause 5.1	**Requirement to maintain high standards**
No Breach of Clause 2	**Requirement that activities or material must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**

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 themselves as a health professional complained about the DuoResp Spiromax (budesonide/formoterol) website when viewed on a mobile device.

The complainant alleged that Teva was not following the Code and was producing uncompliant material which was very alarming.

When writing to Teva, the Authority asked it to consider the requirements of Clauses 2, 5.1, 8.1, 12.6 and 26.2 of the Code.

Teva stated that it took compliance with the Code extremely seriously and had fully investigated this matter. Teva noted that the complainant provided no supporting documents and therefore believed the complaint should be dismissed as there was no *prima facie* evidence provided. Teva noted that it had been provided with pdf screenshots, however, due to formatting in the screenshotting process these differed from the live and certified view on mobiles as text clearly overlapped which was not the case when viewing on mobiles.

The allegations were considered as follows.

1 Alleged lack of a separate area for members of the public on the homepage (https://duoresp.co.uk/)

COMPLAINT

The complainant alleged that the homepage (Ref DUOR-GB-00078 Date of Preparation: February 2022) did not have a separate area for the public meaning they were encouraged to access information not appropriate for them as only patients and health professional sections were shown on the homepage in breach of Clauses 26.2, 5.1 and 2.

RESPONSE

Teva submitted that the webpage highlighted was the product website for DuoResp Spiromax (budesonide/formoterol). The website's purpose was to provide appropriate product information to health professionals (the complainant had stated that they were a health professional) or to

patients who had already been prescribed the inhaler. This website could be accessed by health professionals by receiving a direct link to the website through a Teva direct-communication, leave-behind material or targeted health professional media advertisements. Patients might access the website through the direct link provided by a health professional or from patient support material provided to them by a health professional once they had been prescribed the inhaler. Teva submitted that it had taken steps to prevent members of the public accessing the website. For example, the website text file was marked with 'Do not index' so that it was not recognised by search engine robots and did not show up on the results if 'DuoResp' or 'DuoResp Spiromax' was typed into Google or any other search engine. This had been re-checked internally and confirmed following receipt of the complaint.

Upon arriving at the website, on any device, the homepage had two options to click, either:

'I am a patient who has been prescribed DuoResp Spiromax (budesonide/formoterol)'

or

'I am a healthcare professional'.

Teva submitted that once either of those links had been clicked to confirm the user's identity, they were directed to the area of the website that had information specifically prepared for that audience only. For the patient selection, the specific medicine was listed so that only appropriate patients who had been prescribed DuoResp Spiromax should choose to access the website rather than all patients, which could ultimately be seen as members of the public, or members of the public as this would be inappropriate for the product content included. As per Case AUTH/3252/10/19 – Complainant v Lilly, this was an established principle where companies could provide information about a specific medicine to patients for whom the prescribing decision had already been made provided that such information complied with the Code.

Additionally, at the top of each page accessed after the homepage, the intended audience was clearly labelled with the relevant statement:

'This information is for patients prescribed DuoResp Spiromax (budesonide/formoterol).'

or

'This information is intended for UK healthcare professionals'.

Teva submitted that this statement appeared on all pages on all views – desktop, tablet and mobile.

Teva submitted that there was no Code requirement for information to be available for members of the public on a promotional and non-promotional product website which was not indexed via search engines as previously stated. Teva referred to Case AUTH/3271/10/19 – Complainant v Napp, when the Panel ruled a breach because the user could select if they were 'a patient or a member of the general public' but the content was aimed specifically at patients who had been prescribed the medication. As the DuoResp Spiromax website did not state it provided information for the public nor did it contain content that was suitable for members of the public and it was not indexed *via* search engines, Teva believed there was no breach of the Code. On

the contrary, having a member of the public section on a product website would contravene Clause 26.1 and case precedent by indicating medicine information was relevant to those who had not been prescribed DuoResp Spiromax.

Teva noted that Clause 16.1 stated 'Promotional material about prescription only medicines directed to a UK audience which is provided on the internet must comply with all relevant requirements of the Code'. As above, the intended audience for the information provided was clearly labelled as not including members of the public and including healthcare professionals or patients who had been prescribed DuoResp Spiromax. Regardless, Teva believed the information included in the patient section complied with the Code, including Clause 26.2 as it was factual and presented in a balanced way.

Teva submitted that this was therefore consistent with the Code and there was no breach of Clauses 5.1, 26.2 and 2 as alleged.

PANEL RULING

The Panel noted that the website was the product website for DuoResp Spiromax and the homepage had two choices, readers could indicate whether they were a patient prescribed the medicine or a health professional; there was no option for members of the public. The Panel noted that, according to Teva, the website could be accessed by health professionals by receiving a direct link to the website through a Teva direct-communication and patients might access the website through the direct link provided by a health professional or from patient support material provided to them by a health professional once they have been prescribed the inhaler. The Panel noted Teva's submission regarding the steps taken to prevent members of the public accessing the website in that the website was not indexed and would not be recognised by search engine robots and would not show up in the results for a search for DuoResp or DuoResp Spiromax.

The Panel noted the supplementary information to Clause 26.2, Website Access, which referred to websites providing information for the public as well as promotion to health professionals and the need to have the sections for each target audience clearly separated and the intended audience identified. This was to avoid the public needing to access material for health professionals unless they choose to. The MHRA Blue Guide advised that the public should not be encouraged to access material which was not intended for them. The Panel noted that whilst this supplementary information did not specifically mention material for patients who had been prescribed a specific medicine, companies could, nonetheless, provide information about a specific medicine to patients for whom the prescribing decision had already been made so long as such information complied with the relevant requirements of the Code. In the Panel's view, the principles of the supplementary information were relevant and the intended audience should be identified. When identifying the audience, companies should be clear about whether they were identifying patients in a broad sense or patients who had been prescribed a specific medicine.

The Panel noted Teva's submission that once either 'I am a patient who has been prescribed DuoResp Spiromax (budesonide/formoterol)' or 'I am a healthcare professional' had been clicked to confirm the user's identity, they were directed to the area of the website that had information specifically prepared for that audience only.

The Panel did not agree with Teva's submission that there was no Code requirement for information to be available for members of the public on a promotional and non-promotional product website which was not indexed via search engines. In the Panel's view, there were more factors to consider than whether or not the website was indexed via search engines. The Panel noted that the supplementary information to Clause 16.1, Website Access, stated that 'Unless access to promotional material about prescription only medicines is limited to health professionals and other relevant decision makers, a pharmaceutical company website or a company sponsored website must provide information for the public as well as promotion to health professionals with the sections for each target audience clearly separated and the intended audience identified'. This was to avoid the public needing to access material for health professionals unless they choose to. The MHRA Blue Guide advised that the public should not be encouraged to access material which was not intended for them.

Whilst the Panel considered it would have been helpful if the homepage had provided a third option for members of the public who had not been prescribed the medicine, in the particular circumstances of this case, the absence of such an option did not mean that members of the public were encouraged by Teva to access information not appropriate for them as alleged. The Panel, therefore based on the complainant's allegation ruled **no breach of Clauses 26.2, 5.1 and 2.**

2 Alleged lack of separate certification for a mobile device

COMPLAINT

The complainant alleged that the website had not been certified separately for a mobile device. In this regard, the complainant stated that on the homepage for desktop, the Teva logo was shown at bottom of the page but for the mobile phone version, the Teva logo was at top of page. The complainant stated that this was a major change in final form so both versions for mobile and desktop should have been certified separately and alleged breaches of Clauses 8.1, 5.1, and 2.

In addition, the complainant stated that a clear statement of where prescribing information could be found was missing on the mobile version vs the desktop version of the webpage https://duoresp.co.uk/hcp/indication. The complainant alleged that this was a change in final form and essentially the mobile webpage had not been certified in breach of Clauses 8.1, 5.1, and 2.

RESPONSE

Teva was unsure as to how the complainant had any knowledge of certification. As per Clause 8.1, promotional material must not be issued unless its final form, to which no subsequent amendments would be made, had been certified by one person on behalf of the company in the manner provided for by this clause. Teva provided evidence that this step was completed via reviewing and certifying a 'screenshot' preview of the tablet and mobile displays which were added into the website content job bag as attachments. This process resulted in the desktop, tablet and mobile display of the website content being formally certified with the same approval code. The Code did not stipulate that each view should have a separate job code. All forms were certified in the job bag with a single code. Teva noted there were a vast number of tablet and mobile devices available, each with slightly different dimensions. In order to maintain high

standards, Teva certified different views of the same content in the same job for desktop, mobile and tablet views as, again, the Code did not mandate different job bag codes.

Teva submitted that this was therefore consistent with the Code and there was no breach of Clauses 8.1, 5.1 and Clause 2 as alleged.

Teva submitted that health professional users on mobile devices could access the prescribing information from all pages within the hamburger menu icon lines at the top left of the landing page. Similarly, to Case AUTH/3446/12/20 – Complainant v Jazz Pharmaceuticals, in Teva's investigation the company discovered that the platform used did not keep the prescribing information tab as a 'sticky' static top menu as seen in the desktop and tablet displays and contracted into a hamburger menu icon in the mobile display. Therefore, Teva believed this was consistent with the Code Clauses 8.1 and 12.6 and case precedent.

PANEL RULING

The Panel noted that the complainant alleged that the website had not been certified separately for a mobile device and provided differences in the position of the Teva logo between the desktop and mobile version of the website homepage and lack of a clear statement of where prescribing information could be found on the mobile version vs the desktop version of the webpage as examples in this regard. Whilst the complainant raised Clauses 8.1, 5.1 and 2 separately in relation to each example, the Panel ruled once in relation to the allegation regarding the website not having been certified separately for a mobile device, noting the two examples provided by the complainant in this regard and that the entire website was certified once under the same approval code.

The Panel noted Teva's submission that the complainant provided no supporting documents and the pdf screenshots provided by the case preparation manager differed from the live and certified view on mobiles due to formatting in the screenshotting process.

The Panel noted that the complainant had provided links to, and the job codes and date of preparation, of the webpages at issue. The Panel noted, however, that whilst the case preparation manager downloaded and saved pdfs of the webpages from the links provided by the complainant and sent those to Teva as well as a screenshot of the homepage, screenshots of the links when opened on a mobile device were not downloaded, saved and provided to the company. Teva provided copies of the material as viewed on a mobile device in its response and the Panel made its rulings on this basis.

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, e.g. 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 e.g. 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 that the difference between the desktop and mobile versions highlighted by the complainant were in relation to the positioning of the Teva logo which the complainant stated was at the bottom of the desktop homepage and at the top of the mobile homepage and the lack of a clear statement of where prescribing information could be found on the mobile version vs the desktop version of the https://duoresp.co.uk/hcp/indication webpage.

Teva had not disputed that there were differences in this regard. The question for the Panel was whether the differences meant that there were two final forms of the website, i.e., one for the desktop version and one for the mobile version and, if so, whether each had been 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 devices should be taken into consideration prior to certification to ensure that the content met the requirements of the Code when viewed on each different commonly used type of electronic device, e.g. desktop, laptop, tablet, smartphone etc.

The Panel noted Teva's submission including that a screenshot preview of the tablet and mobile displays were reviewed and certified with the same approval code as the website.

The Panel considered that whilst it appeared that in this instance the final form of the material as it would appear on mobile devices was reviewed by the signatory as part of the final check under the same job bag number as the desktop version, the website was not identical on each platform; the position of Teva's logo on the homepage was different on each as was the availability of a clear statement as to where the prescribing information could be found. The Panel therefore considered that the final form of the website differed for the mobile version compared to the desktop version and each should have been certified separately which had not occurred. The Panel therefore ruled a **breach of Clause 8.1.**

The Panel considered that Teva should have spotted that the prescribing information tab had become contracted into a hamburger menu icon when reviewing the website as it appeared on mobile devices and on the evidence before it, the Panel considered that it appeared that Teva had not adequately reviewed the website on mobile devices to ensure that it met the requirements of the Code when displayed on such devices. The Panel considered that high standards had not been maintained in this regard and it thus ruled **a breach of Clause 5.1**.

Clause 2 was a sign of particular censure and reserved for such use. The Panel noted that the prescribing information was available when the website in question was accessed from a mobile phone: from the hamburger menu icon on the top right side and at the end of the webpage and although Teva did not spot that the prescribing information tab had become contracted into a hamburger menu, it had reviewed how the website would appear on a mobile device as part of the website certification. In the particular circumstances of this case, the Panel therefore did not consider that a ruling of a breach of **Clause 2** was warranted and **no breach** was ruled.

3 Alleged lack of a clear statement of where prescribing information could be found on the three webpages of the mobile display of the DuoResp Spiromax website

COMPLAINT

The complainant alleged a clear statement of where prescribing information could be found was missing on the mobile version vs the desktop version of the webpage https://duoresp.co.uk/hcp/indication.

The complainant further alleged that none of the pages on the mobile version had a clear statement of where prescribing information could be found in breach of Clause 12.6 a further two times. The 2 pages with this issue were: https://duoresp.co.uk/hcp/placebo https://duoresp.co.uk/hcp/Rep.

RESPONSE

Teva stated that with regard to accessing prescribing information on the DuoResp Spiromax website from a mobile phone, there was a statement on the first page after selecting they were a health professional which read:

> **For more information, please find the Summary of Product Characteristics and Prescribing Information here.'**

Teva submitted that this text was large and was certified as a clear prominent statement. In addition, health professional users on mobile devices could access the prescribing information from all pages within the hamburger menu icon lines at the top left of the landing page. Similarly, to Case AUTH/3446/12/20 – Complainant v Jazz Pharmaceuticals, in Teva's investigation the company discovered that the platform used did not keep the prescribing information tab as a 'sticky' static top menu as seen in the desktop and tablet displays and contracted into a hamburger menu icon in the mobile display. The hamburger menu availability of the prescribing information was ruled not in breach of the Code and Teva believed this set precedent. As Teva also had a clear and prominent statement on the first page as stated above, Teva submitted that there was no breach.

Therefore, Teva believed this was consistent with the Code Clauses 8.1 and 12.6 and case precedent. There were clear prominent links to prescribing information. As per the ruling in Case AUTH/3446/12/20 and as mentioned above, Teva refuted breaching Clause 2 as prescribing information was available on the website when accessed from all devices including mobile.

PANEL RULING

The Panel noted that Clause 12.6 required that promotional material provided on the internet must include a clear prominent statement as to where the prescribing information could be found.

The Panel noted that contrary to Teva's submission whilst the hamburger menu availability of the prescribing information was ruled not in breach of Clause 4.1 of the 2019 Code in Case AUTH/3446/12/20 as there was no evidence before it that the prescribing information was not available on the website in question when accessed from a mobile phone, the 'Prescribing Information' tab becoming 'contracted' into the hamburger menu did not meet the requirements of 'a clear, prominent statement' due to its position and the Panel therefore ruled a breach of Clause 4.6 of the 2019 Code in that case (Case AUTH/3446/12/20).

Turning to the current case, Case AUTH/3641/4/22, the Panel noted Teva's submission that during its investigation it discovered that the platform used did not keep the prescribing information tab as a 'sticky' static top menu as seen in the desktop and tablet displays and contracted it into a hamburger menu icon in the mobile display. Health professional users on mobile devices could access the prescribing information from all pages within the hamburger menu icon lines at the top left of the landing page.

Whilst the Panel noted Teva's submission that when accessing the DuoResp Spiromax website homepage on a mobile phone, there was a statement on the first page after readers selected that they were a healthcare professional which read 'For more information, please find the Summary of Product Characteristics and Prescribing Information here', the Panel considered that the presentation of a prescribing information link within a hamburger menu in relation to the three webpages in question as cited by the complainant did not meet the Code's requirement for a clear prominent statement and a **breach of Clause 12.6** was ruled in relation to each.

4 Alleged overlooked requirement to approve each page of the website separately

COMPLAINT

The complainant was concerned that it was odd the way the website had been certified as the final form of each page and section was different, but the approval code was the same for all. The complainant stated that the approval code should have been different for each page and section. This did not seem correct and a breach of Clauses 8.1, 5.1 and 2 was alleged. The complainant questioned the ability of the individual who approved this material and how this had ever been allowed to happen in the first place.

RESPONSE

Teva submitted that there was no mandate in the Code to have different job codes for each page or section for the same content over different views on desktop, tablet and mobile. Teva drew attention to the Veeva Certificate and a screenshot of the material where it could be seen that the website was certified with the final form of a desktop, tablet and mobile display included. This was consistent with Clause 8.1 as again, there was no specific requirement for different approval codes for each page or each display. Teva noted that the approval codes on materials were used for tracking purposes and record certification through the Veeva PromoMats platform by that pharmaceutical company. It was the responsibility of each company to abide by their own guidance for approving materials and their associated approval codes, as long as certification abided by the Code which in this instance Teva submitted that it did.

Teva submitted that it was therefore consistent with the Code and there was no breach of Clauses 8.1, 5.1 and Clause 2 as alleged.

Teva stated that it refuted all allegations of breaches of the Code as highlighted above and taking this into account, Teva refuted breaching Clause 2.

PANEL RULING

The Panel noted that there was no requirement in the Code to have different job codes for each separate page of a website as alleged.

The Panel noted that the use of an approval code was not a requirement of the Code. It was mentioned in the guidelines on company procedures as follows:

> Each certificate should bear a reference number with the same reference number appearing on the material, item etc in question or some other means so that there can be no doubt as to what has been certified and the certificate can be matched to the material. A particular reference number should relate to only one item, material etc.
>
> Different sizes and different layouts of a piece of promotional material should be separately certified and each should have its own unique reference number.

The Panel did not consider that the complainant had established that having the same job code on each page and section of the website meant that it had not been certified as required by the Code. Therefore, based on the complainant's narrow allegation, the Panel **ruled no breach of Clauses 8.1, 5.1 and 2** as alleged.

Complaint received **28 April 2022**

Case completed **22 March 2023**