CASE AUTH/3451/1/21

COMPLAINANT v TEVA

Teva respiratory websites

An anonymous, contactable complainant who described him/herself as a health professional and later became uncontactable, complained about the Teva UK corporate website and the company's 'Let's Talk Respiratory' website.

The detailed response from Teva is given below.

1 Teva corporate website (www.tevauk.com)

The complainant stated that when the reader first opened up the website, a disclaimer came up and if readers selected that they were a health professional, a dropdown option came up which allowed them to choose from options including, pain nurse, fertility specialist, oncology nurse. No matter which type of health professional was chosen (so any non-respiratory focused health professional), the respiratory promotional page opened up which was not appropriate as promotion should be tailored to the audience to whom it was directed. For example, promotional material for general practitioners might not be appropriate for hospital doctors and, similarly, material for clinicians might not be appropriate for use with other relevant decision makers. The complainant stated that it beggared belief that an oncology nurse or a urology health professional could be promoted respiratory information.

The complainant noted that five products were mentioned on the page, DuoResp Spiromax (budesonide and formoterol), Braltus Zonda (tiotropium), Qvar (beclometasone dipropionate), Cinqaero (reslizumab) and Tymbrineb (tobramycin). There was, however, no prominent prescribing information link or information on how to find the prescribing information for any of those products unless the reader accidentally clicked on the green plus sign next to them and were lucky enough to scroll right the way down. There was no prescribing information provided for Tymbrineb or Qvar. The complainant further noted that there was no adverse event reporting on the page. It did not appear that the page had been certified as there were so many errors.

The complainant noted that another webpage had brand names/images of all Teva products provided along with information/videos etc without prescribing information or the adverse event reporting statement being provided. The information on all of Teva medicines could be accessed by members of the public. In that regard, the complainant provided a link to a page which had information on DuoResp Spiromax alongside a picture of the inhaler showing branding and the ability to ask questions. There was even a 'How do I use my DuoResp Spiromax (Budesonide/formoterol fumarate dihydrate) Inhaler? Please watch this video for more information on how to use your DuoResp Spiromax (Budesonide/formoterol fumarate dihydrate) Inhaler'. The complainant alleged that that would not be appropriate for members of the public to see as the inhaler

branding was present. It was the same for various products including on the page for acitretin.

The Panel noted Teva's submission that its corporate website, tevauk.com, was open access until readers selected the pages that were intended for health professionals. When doing so, a pop-up box appeared asking readers to confirm that they were a health professional and requesting that they select their area of specialisation which could have been 'other health professional' if they preferred not to disclose their specialism. The Panel noted Teva's submission that the selection of health professional specialty was for Teva's information so it could gather insights into and understand who was using the website, and to inform the company's plans about additional content; it was not used to send bespoke information or redirect readers post the selection. Upon confirmation that they were health professionals, readers could access all information for health professionals on the whole website which included all Teva products marketed in the UK.

The Panel noted that the relevant clause of the Code stated that material should only be sent or distributed to those categories of persons whose need for, or interest in, it could reasonably be assumed. The supplementary information stated that material should be tailored to the audience to whom it was directed. In the Panel's view, the clause applied to material proactively sent or distributed to recipients and not to material which a health professional proactively sought out as in the case of material on a company's website.

Noting its comments above, the Panel did not consider that the availability of the information on the health professional respiratory section of the tevauk.com website, to all health professionals, was in breach of the Code as alleged and no breach was ruled.

The Panel noted Teva's submission that when the health professional respiratory in focus webpage was first loaded, only the five medicines brand and generic names were visible and no other product information. The Panel noted from the webpages provided by Teva, which were current at the time of the complaint, that when the green plus sign next to each product was selected, additional information was displayed for each of the five products. The Panel noted Teva's submission that the prescribing information was presented when promotional information was visible, which was why locating the prescribing information along with an adverse statement within the content area, which was hidden until expanded, was appropriate in this instance.

The Panel noted that a hyperlink to the prescribing information for DuoResp Spiromax was visible towards the end of the second page of expanded information for DuoResp Spiromax. Similarly, a hyperlink to the prescribing information for Braltus and Cinqaero was visible and appeared on the first page of expanded information for each. The Panel, however, noted that the Code required that in the case of promotional material on the internet, there must be a clear, prominent statement as to where the prescribing information could be found. In the Panel's view, noting that the entire webpage for health professionals was promotional, there should have been a clear and prominent statement as to where prescribing information could be found for each of the products listed at the outset and before clicking on the green plus sign for each. The Panel therefore ruled a breach of the Code in relation to each of the five products.

The Panel further noted Teva's submission that where a claim was made next to a product name, an additional link to prescribing information was provided with a single

click; no claims were made with regard to Tymbrineb and Qvar, and only factual reference information provided linked to the SPC. The Panel, however, noted its comments above with regards to the promotional nature of the health professional webpage. Prescribing information for Tymbrineb and Qvar should have been provided but was not. The Panel therefore ruled a breach of the Code in relation to Tymbrineb and Qvar.

The Panel noted that whilst it appeared from Teva's submission that the adverse event reporting statement was included within the prescribing information, which was linked from the webpages for Braltus Zonda, DuoResp Spiromax and Cinqaero, the Panel did not have a copy of the prescribing information before it. Regardless of its inclusion in the prescribing information, the Panel noted that there was no reference to an adverse event reporting statement at the outset and before clicking on the green plus sign for each medicine or within the expanded information for each medicine when the green plus sign was clicked, including that for Qvar and Tymbrineb. The Panel considered that this was particularly important for Cinqaero given that it was subject to additional monitoring. The Panel therefore ruled a breach of the Code.

The Panel noted Teva's submission that all information on the website had been certified and reviewed periodically and recertified as required by the Code and provided the certificates. The Panel did not consider that there was evidence to show that the webpage had not been certified as alleged and it therefore ruled no breach of the Code.

The Panel noted its rulings above and considered that Teva had failed to maintain high standards and a breach of the Code was ruled.

Whilst the Panel noted Teva's submission that the adverse event reporting statement did appear within the prescribing information for Braltus Zonda, DuoResp Spiromax and Cinqaero, there was no prescribing information for Tymbrineb and Qvar. The Panel noted the lack of adverse event reporting statement within the content of the webpages themselves; and was particularly concerned that there was no such statement anywhere in the materials for Tymbrineb and Qvar and that Cinqaero was subject to additional monitoring and only appeared to have the relevant statement within its prescribing information. The Panel noted that the black triangle was an important safety requirement and on balance the cumulative effect of its comments, and rulings of breaches meant that a breach of Clause 2 was warranted, a breach was ruled accordingly.

The Panel noted that the complainant referred to another webpage which could be accessed by members of the public which he/she alleged was inappropriate as it included the brand names/images of all Teva products together with information/videos etc without prescribing information or adverse event reporting information. In that regard, the complainant specifically provided a link to a page which he/she stated provided information on DuoResp Spiromax alongside an image showing branding and the ability to ask questions. The complainant noted that it also included a video titled 'How do I use my DuoResp Spiromax (Budesonide/formoterol fumarate dihydrate) Inhaler?'.The complainant alleged that it was the same for various products including acitretin.

The Panel noted that the complainant did not appear to have a complaint about the first cited page link which listed products alphabetically by generic name referring briefly to

patient information leaflets, presentation and the medical information service. This page did not include brand names etc referred to by the complainant which appeared on links from that webpage. The Panel considered that all of the allegations on this point related to the budesonide and acitretin webpage.

The Panel noted that should information about a specific medicine directed at patients for whom the prescribing decision had already been made be provided on the public section of a company website, the sections for each target audience should be clearly separated and the intended audience identified at the outset. Text above the video link was insufficient in this regard. The Panel noted that it appeared that the video which was aimed at patients for whom the prescribing decision had already been made was an integral part of the reference information aimed more broadly at the general public. The Panel therefore ruled a breach of the Code. The Panel considered that Teva had failed to maintain high standards and a breach of the Code was ruled.

The Panel noted that in order to obtain further information including the product's indication, the reader had to download the patient information leaflet or SPC or watch the video which appeared beneath. The Panel noted that the video titled 'How to use your DuoResp Spiromax (Budesonide/formoterol fumarate dihydrate) inhaler appeared to be given as a response to the first of five FAQs 'How do I use my DuoResp Spiromax (Budesonide/formoterol fumarate dihydrate) inhaler' and stated Please watch this video for more information on how to use DuoResp Spiromax. The Panel noted that the first slide of the video stated 'This video is intended for patients prescribed DuoResp Spiromax'. It was the only FAQ response visible on the page; the other FAQs could be read if the 'View all questions' link below the video or the FAQ tab towards the top of the page were selected and were general in nature including how does Teva choose what colours to use on packaging, what to do if the reader suffered a side effect or adverse event and how to get a new copy if the PIL if it was lost.

The Panel noted the narrow nature of the allegation, that the information including reference to brand names and the video which included inhaler branding was not suitable for the general public. The Panel noted that Teva had described the material as reference information as set out in the supplementary information of the Code. The Panel noted Teva's submission that the page listed the Teva products as reference information and provided training for patients who recognized and differentiated the devices better visually; the current brand image mentioned by the complainant was with reference to differentiating inhalers and training for patients.

The Panel noted its ruling above and considered that this adequately covered the complainant's concerns in relation to the video. The Panel noted that the complainant bore the burden of proof and did not consider that the complainant had established, on the balance of probabilities, that the inclusion of brand names and imagery on the webpage intended for the public was contrary to the Code or that the requirements in relation to promotion were triggered. The Panel, therefore, based on the complainant's narrow allegation, ruled no breaches of the Code.

The Panel noted that at the bottom of the DuoResp Spiromax webpage it stated 'If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the Patient Information Leaflet. You can also report side effects

directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. The Panel therefore ruled no breach of the Code.

In relation to acitretin, the Panel noted that the information provided on the acitretin webpage, was similar to that for budesonide, although there was no video. The FAQs on the actitretin webpage were all general in nature including how does Teva choose what colours to use on packaging, what to do if the reader suffered a side effect or adverse event and how to get a new copy if the PIL if it was lost.
The Panel noted its comments above and did not consider that the complainant had established, on the balance of probabilities, that the inclusion of brand names and images was promotional for actitretin as alleged and thus that the requirements of of the Code in relation to promotion were triggered or was not in line with the requirements of the Code based on his/her allegation. The Panel, therefore, based on the complainant's narrow allegation, ruled no breaches of the Code.

The Panel noted that the acitretin webpage did appear to be directed to both the public and patients that had been prescribed acitretin; certain text on the webpage addressed patients. The Panel noted that the webpage included the statement 'This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See www.mhra.gov.uk'. Further the bottom of the page included, albeit in small font, information about how to report side effects. The Panel therefore ruled no breach of the Code.

Whilst the Panel had concerns about the adequacy of audience signposting, which it considered was covered by its comments and rulings above, the Panel did not consider that the complainant had established that using the brand name and images of Teva products in relation to budesonide and acitretin was in breach of the requirement that material should only be distributed to those categories of persons whose need for, or interest in, it could reasonably be assumed. In the Panel's view, this clause applied to material proactively sent or distributed to recipients and not to material which a health professional proactively sought out as in the case of material on a company's website. The Panel, based on the complainant's narrow allegation, ruled no breach of the Code.

The Panel noted its comments and rulings in relation to the budesonide and acitretin patient pages and did not consider that the particular circumstances of this case warranted a ruling of a breach of Clause 2 which was used as a sign of particular censure and reserved for such use. No breach of the Code was ruled.

2 'Let's Talk Respiratory' website (letstalkrespiratory.com)

The complainant noted that the website included a talk on key insights from clinical guidelines on the diagnosis and management of asthma and chronic obstructive pulmonary disease (COPD). The presentation included mention of inhaled corticosteroids (ICS) and inhaled corticosteroids combined with long acting beta agonists (ICS/LABA) and ICS-formoterol with snippets from the guidelines. The complainant noted that Teva had a product for both of these drug classes ie Qvar (ICS) and DuoResp Spiromax (ICS/formoterol). The complainant noted that there was no prescribing information provided for those products. Although only drug class was mentioned, this was a promotional talk hosted on a website initiated and generated by

Teva so it was obvious there was a clear focus on DuoResp and Qvar. Furthermore, the mention of ICS-formoterol with a small asterisk at the bottom stated that it was not licensed in the UK which was off-label promotion for DuoResp Spiromax as the SPC licence for DuoResp Spiromax was not in line with what the Global Initiative for Asthma (GINA) guidelines recommended ICS-formoterol for.

The complainant noted that on the side of the video/webpage it was hosted on, there was the option to share the video via Facebook, Twitter or LinkedIn which demonstrated a lack of knowledge from Teva as members of the public could be promoted to and alleged that it was disguised and open promotion of Teva products by sharing on social media. The complainant noted that the option to share content via Facebook, LinkedIn or Twitter was available also on the knowledge section of the same website which was highly inappropriate.

The complainant alleged that another article (ref UK/RESP/17/0028au) on the website about using budesonide/formoterol 'as needed' to prevent asthma was disguised promotion. The complainant stated that there was no prescribing information provided for DuoResp again considering the article was about budesonide/formoterol. It had a promotional intent and all promotional requirements had not been met and yet again it was an article that could be shared on social media. The complainant alleged that same breaches of the Code as with the video above.

The Panel noted Teva's submission that 'Let's Talk Respiratory' was a non-promotional website dedicated to education and included supportive materials, resources and some of the latest news in respiratory for both health professionals and patients. The Panel further noted Teva's submission that the presentation in question reflected key insights from the various clinical guidelines for asthma and COPD and no products were mentioned in the non-promotional educational video including aspects of those various guidelines.

The Panel considered that, regardless of whether such presentations were categorised by the company as promotional or non-promotional, all such presentations should have good quality clear educational content; that a presentation had good quality educational content did not in itself determine whether the presentation was promotional or non-promotional. The very broad definition of promotion in the 2019 Code was particularly relevant. In that regard, the Panel noted that it was an accepted principle under the Code that it was possible, given the broad definition of promotion, for material to be promotional without mentioning the product by name.

The Panel noted Teva's submission regarding how health professionals and members of the public were directed to the relevant sections of the site, including the use of the field force in relation to health professionals and its advertising on the health professional section of Teva's corporate website which, in the Panel's view, was promotional. The Panel noted Teva's submission that the field force was briefed that LTR was non-promotional and shouldn't be used alongside any promotional calls. The Panel further noted Teva's submission that all topics on the website were generated by the health professional led editorial board to ensure topics and subsequent contents were completely independent to Teva; Teva did, however, review and certify it to ensure consistency with the Code. The Panel noted that the website appeared to have been

funded by Teva; that there was an editorial board did not necessarily mean that the website was non promotional given the broad definition of promotion as noted above.

The Panel noted Teva's submission that the presentation in question was an educational, non-promotional resource which focused on published guidelines. The Panel noted that the beginning of the presentation explained the differences in the guidelines with regards to diagnosing asthma and COPD particularly within the context of the Covid pandemic. One slide out of nineteen titled 'How different are we?' included a diagram which briefly mentioned the initial steps in treating asthma by class noting the differences between the National Institute for health and Care Excellence (NICE), British Thoracic Society (BTS) and GINA guidelines. According to the slide, NICE Asthma 2020 stated that LTRA were the next step after ICS monotherapy, BTS Asthma 2019 stated that ICS/LABA was the next step after ICS monotherapy, and GINA Asthma 2020 stated that ICS/formoterol was the first step* in preference to ICS monotherapy. The Panel noted that the asterisk took the reader to a small footnote at the bottom of the slide which read 'Currently off-license use in the UK'.

The Panel noted Teva's submission that the presenter detailed that the GINA recommendation was not licensed as was appropriate. The Panel noted that from the transcript of the presentation at issue provided by Teva, the speaker stated 'Where we have a bit of an outlier is with GINA. So, GINA, their first step, the preferred step is to use ICS/formoterol, and even though this is unlicensed in the UK, it's something that has been demonstrated in studies to be an effective way of reducing the amount of steroid that's used, but without having an effect on the number of exacerbations. So, ICS/formoterol is probably something that will be used increasingly in an as required manner. But for now, NICE and BTS largely talk about ICS monotherapy and then moving on in subsequent steps to ICS/LABA on a regular basis'.

The Panel noted that whilst the presentation did not specifically mention DuoResp Spiromax or Qvar, it referred to ICS/formoterol and ICS/LABA. The Panel noted that a number of ICS/formoterol combination inhalers were available on the market and DuoResp Spiromax was one of three budesonide/formoterol inhalers on the market. Nonetheless, in the Panel's view, the website promoted ICS/formoterol and ICS within the combination of an ICS/LABA and Teva marketed both of these products, namely Qvar (ICS) and DuoResp Spiromax (ICS/formoterol).

In the Panel's view, given the very broad definition of promotion and noting its comments above, including that it was a company website albeit with an editorial board, that health professionals were directed to it including from the health professional section of Teva's corporate website which in the Panel's view was promotional and Teva's involvement in its review, the website could not be considered anything other than promotional for Teva's medicines.

The presentation was an integral part of the website. The Panel considered that the presentation at issue should have included Qvar and DuoResp Spiromax prescribing information and a clear prominent statement of where it could be found and did not include either. The Panel therefore ruled breaches of the Code.

The Panel noted Teva's submission that there was the ability to report adverse events via the website at the bottom of all the relevant pages. The Panel therefore ruled no breach of the Code.

Noting its view that the website and video in question were promotional, the Panel considered that the recommendation to use ICS-formoterol as a reliever when required as often as needed was inconsistent with its licensed indication. According to its SPC, DuoResp Spiromax was indicated in the regular treatment of asthma, where use of a combination (inhaled corticosteroid and long-acting β2 adrenoceptor agonist) was appropriate in patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short-acting β2 adrenoceptor agonists or in patients already adequately controlled on both inhaled corticosteroids and long-acting β2 adrenoceptor agonists.

The Panel did not consider that the small footnote at the bottom of the page, which stated that it was not licensed in the UK, was sufficient to negate promotion that was inconsistent with the particulars listed in its SPC. A breach of the Code was ruled. The Panel considered that Teva had failed to maintain high standards in this regard and a breach of the Code was ruled.

The Panel noted that a ruling of a breach of Clause 2 was a sign of particular censure and reserved for such. The Panel noted its rulings and comments above but considered that the matter was not such as to bring discredit upon, or reduce confidence in, the industry. No breach of the Code was ruled.

The Panel did not consider that the presentation was intended for patients taking a specific prescription only medicine and therefore ruled no breach of the Code in relation to the requirement for a side effect reporting statement to be included on the material .

The Panel, noting its comments above, considered that the sharing of the promotional presentation via social media would constitute the promotion of a Teva prescription only medicine to the public. The Panel noted that the complainant bore the burden of proof and had not established that it had been shared and thus the Panel ruled no breaches of the Code in this regard.

The complainant alleged that an article on the website about using budesonide/formoterol 'as needed' to prevent asthma was disguised promotion. The complainant stated that there was no prescribing information provided for DuoResp again considering the article was about budesonide/formoterol. It had a promotional intent and all promotional requirements had not been met and yet again it was an article that could be shared on social media. The complainant alleged that same breaches of the Code as with the video presentation above.

The Panel noted that the article at issue, also on the letstalkrespiratory.com website, was entitled 'Research roundup: Budesonide-formoterol used as needed to prevent asthma exacerbations: a trial reflecting real-world practice'. The Panel noted Teva's submission that the article referred to a scientific publication in the New England Journal of Medicine and as per other content of the website was non-promotional and was intended as non-promotional education as per the original paper and reflected the author's conclusions of the study and did not promote any product.

The Panel noted that the article stated 'The authors suggest that budesonide-formoterol taken as needed was superior to both as-needed SABA and maintenance budesonide plus as-needed SABA at reducing the risk of severe exacerbations. As such therapy with budesonide-formoterol taken when the patient perceived their symptoms to be worsening can avoid symptoms becoming severe enough to warrant further urgent care. The study extends previous finding regarding the use of reliever therapy to avoid asthma exacerbations, providing evidence from a study that reflects real-world clinical practice'.

The Panel noted Teva's submission regarding how health professionals and members of the public were directed to the relevant sections of the site including the use of the field force in relation to health professionals and its advertising on the health professional section of Teva's corporate website which in the Panel's view was promotional. The Panel further noted Teva's submission that all topics on the website were generated by the health professional led editorial board to ensure topics and subsequent contents were completely independent to Teva; Teva did, however, review and certify it to ensure consistency with the Code.

The Panel noted that whilst the presentation did not specifically mention DuoResp Spiromax, it referred to budesonide/formoterol and included, in the Panel's view, promotional claims for it. The Panel noted that a number of budesonide/formoterol combination inhalers were available on the market and DuoResp Spiromax was one of three budesonide/formoterol inhalers on the market. Nonetheless, the Panel considered that the website promoted budesonide/formoterol and Teva marketed this product, namely DuoResp Spiromax. In the Panel's view, noting its comments above regarding how health professionals were directed to it, and Teva's involvement in its review, the article could not be considered anything other than promotional for Teva's medicine. The Panel considered that the article in question should have included DuoResp Spiromax prescribing information and a clear prominent statement of where it could be found and did not include either. The Panel therefore ruled breaches of the Code.

The Panel noted Teva's submission that there was the ability to report adverse events via the website at the bottom of all the relevant pages. The Panel, therefore, ruled no breach of the Code.

The Panel did not consider that the article was intended for patients taking a specific prescription only medicine and therefore ruled no breach of the Code in relation to the requirement for a side effect reporting statement to be included on the material.

The Panel noted the complainant's allegation that there was the option to share the article via Facebook, Twitter or LinkedIn. The Panel, noting its comments above, considered that the sharing of the promotional article via social media would constitute the promotion of a Teva prescription only medicine to the public. The Panel noted that the complainant bore the burden of proof and had not established that it had been shared and thus the Panel ruled no breaches of the Code.

An anonymous, contactable complainant who later became non-contactable described him/herself as a health professional, complained about the Teva UK corporate website and the company's 'Let's Talk Respiratory' website. The complainant provided links to both websites.

1 Teva corporate website (www.tevauk.com)

COMPLAINT

The complainant stated that the first part of the website which he/she had major concerns around was https://www.tevauk.com/healthcare-professionals/article-pages/healthcare-professionals-our-medicines/respiratory-in-focus/ (Teva ref HC608). The complainant noted that when the reader first opened up the website, a disclaimer with the following text came up:

> 'Are you a health professional? To access this section of the Teva UK Limited website you need to be a member of the healthcare profession because the materials included in this area of our website are specifically prepared for that audience only. To understand why that is - please visit: Working in a regulated environment. Please click on the appropriate button below to confirm that you are a health professional. If you are not a health professional, you will be taken to an area of the website that is appropriate for you.'

The complainant noted that if readers clicked on 'Yes, I am', a dropdown option came up which allowed them to choose what kind of health professional they were with options including, pain nurse, fertility specialist, oncology nurse. No matter which type of health professional was chosen (so any non-respiratory focused health professional), the respiratory promotional page opened up which was not appropriate as promotion should be tailored to the audience to whom it was directed as per Clause 11.1. For example, promotional material for general practitioners might not be appropriate for hospital doctors and, similarly, material for clinicians might not be appropriate for use with other relevant decision makers. The complainant stated that it beggared belief that an oncology nurse or a urology health professional could be promoted respiratory information.

Five products were mentioned on the page, DuoResp Spiromax (budesonide and formoterol), Braltus Zonda (tiotropium), Qvar (beclometasone dipropionate), Cinqaero (reslizumab) and Tymbrineb (tobramycin). There was no prominent prescribing information link or information on how to find the prescribing information for any of those products unless the reader accidentally clicked on the green plus sign next to them and were lucky enough to scroll right the way down. However, even when a reader clicked on the green plus sign, there was no prescribing information provided for Tymbrineb or Qvar. The complainant further noted that there was no adverse event reporting on the page. It did not appear that the page had been certified as there were so many errors.

The complainant alleged breaches of Clauses 14.1, 4.1, 4.2, 4.6, 4.9, 11.1, 9.1 and 2.

The complainant noted that another webpage on the same website also had major issues (http://products.tevauk.com/patients/our-medicine-range). All the brand names/images of all Teva products were provided along with information/videos etc without prescribing information or adverse event reporting being provided. Also, all of the information on all of Teva medicines could be accessed by members of the public. In that regard, the complainant provided a link to a page which had information on DuoResp Spiromax alongside a picture of the inhaler showing branding and the ability to ask questions. There was even a 'How do I use my DuoResp Spiromax (Budesonide/formoterol fumarate dihydrate) Inhaler? Please watch this video for more information on how to use your DuoResp Spiromax (Budesonide/formoterol fumarate dihydrate) Inhaler'. The complainant alleged that that would not be appropriate for members of the public to see as the inhaler branding was present. It was the same for various products including the page http://products.tevauk.com/p/acitretin-610.

The complainant alleged that that particular part of the website breached Clauses 14.1, 4.1, 4.2, 4.6, 4.9, 11.1, 28.1, 28.3, 26.2, 26.3, 9.1 and 2 on several occasions.

RESPONSE

Teva submitted that its corporate website tevauk.com was open access until readers selected the pages that were for health professionals and when doing so, a pop-up box appeared where readers needed to confirm that they were health professionals and a request for them to select their area of interest, should they so wish. The pop-up box stated:

> 'Are you a health professional?
>
> To access this section of the Teva UK Limited website you need to be a member of the healthcare profession because the materials included in this area of our website are specifically prepared for this audience only.
>
> To understand why that is - please visit: Working in a regulated environment (active link provided).
>
> **Please click on the appropriate button below to confirm that you are a health professional.**
>
> **If you were not a health professional, you would be taken to an area of the website that was appropriate for you**.'

When selecting, a further pop-up asked the reader 'I am a..' and then proceeded to list a number of options, so that Teva could understand the nature of readers to the website and this assisted with creating further content. This was not used to send bespoke information or redirect readers post the selection, and selection by the reader upon confirmation that they were health professionals allowed them to access information for health professionals on the whole website. This included reference information such as summaries of product characteristics (SPCs) and patient information leaflets (PILs) on all Teva products marketed in the UK and relevant therapy areas, and abbreviated prescribing information where necessary.

Teva explained that readers chose, by clicking a link, which overall section of content they wished to view next in the website, if the page was restricted to health professionals, they would see the health professional self-qualification pop-up the first time they selected a health professional type page, they made a self-confirmation and then the site recorded a cookie which lasted 1 'session' (up to 1 hour).

A session cookie contained information that was stored in a temporary memory location and then subsequently deleted after the session was completed or the web browser was closed.

Teva stated that within the health professional pop-up, once users confirmed they were health professionals by clicking 'Yes I Am', Teva asked the sub-specialisation of the health professional from a defined list of choices, which were focused on therapy areas or NHS roles. Readers could select 'other health professional' if they preferred not to disclose the specialist area of interest.

The selection of health professional specialty was for Teva information and to record the choice in Google analytics (anonymously) so Teva could gather insights into which health professional specialty was selected to allow it to understand who was using the website, and to inform the company's plans about additional content. The intention was not to direct health professionals to any particular part of the website, as the health professional searches were not limited to their own area of interest.

Teva stated that if readers accessed the health professional pages either by entering the specific URL or through a search engine such as Google, the same health professional confirmation pop-up appeared requesting them to again confirm they were health professionals and confirmed what type of health professional they were and on selection again allowed them to access the URL they had entered and the whole website. Teva submitted that this reflected usual practice on websites for the pharmaceutical industry.

Teva noted from the URL provided by the complainant that the page at issue was a respiratory content page (or would have been selected as respiratory in nature from the overall website or via a search engine). It was therefore appropriate under the Code for readers to confirm that they were health professionals.

Teva noted that Clause 11.1 of the Code stated, 'Material should only be sent or distributed to those categories of persons whose need for, or interest in, it could reasonably be assumed'. The supplementary information stated, 'Material should be tailored to the audience to whom it is directed. For example, promotional material devised for general practitioners might not be appropriate for hospital doctors and, similarly, material devised for clinicians might not be appropriate for use with other relevant decision makers'.

Teva stated that patients as a whole did not suffer exclusively from one disease and health professionals needed access to information for all therapy areas. In The King's Fund report 'Long term conditions and multi morbidity' it was stated, 'There will be rising demand for the prevention and management of multi-morbidity rather than of single diseases' (link provided). The material on the website was not directed at any one specialty, for example, respiratory specialist but all health professionals that might be searching or requiring information published on the website. For example, oncology nurses might require information for patients who were also being treated for asthma or COPD. It would be frustrating and unprofessional if they were unable to reach such information and forcibly directed elsewhere. The complainant clearly indicated here that he/she was interested in respiratory content through the URL provided and therefore it was correct that respiratory content was provided, irrelevant of which health professional subspecialty he/she self-selected.

The information was therefore appropriate for the categorisation of health professional and this was the categorisation of the audience as per the pop-up box with the information appropriate for all manners of health professionals. Teva had a vast portfolio of over 800 products comprising of specialty and generic medicines, and the contents were designed to assist users to garner information as to their requirements, in a user-guided fashion.

Teva submitted that with regard to the products mentioned by the complainant and on the page in question, there was a list of certain products and there was a large plus sign, which upon clicking accessed further information, a commonly used functionality in many websites, including other pharmaceutical companies and indeed the PMCPA website. In the detail of

Cinqaero and Tymbrineb, there was only top line information as reference information and reference to the SPC clearly on the site.

The Teva website had direct links to the SPC, PIL and abbreviated prescribing information in the product catalogue/Teva's medicines section for all products and visitors to the website could readily access that information. However, where a claim was made next to a product name, an additional link to prescribing information was provided with a single click. No claims were made with regard to Tymbrineb and Qvar, and only factual reference information provided linked to the SPC. The listing of Braltus Zonda, DuoResp Spiromax and Cinqaero had additional information and hence the provision of a direct link to prescribing information was provided.

The 'click to expand' method was a common design feature used within web pages to allow users to see content in a page when it was first loaded on screen at a summary or overview level. Users could scan the page for the content items that most interested them and click to expand a section to receive more detail.

An accordion menu was a vertically stacked list of headers that could be clicked to reveal or hide content associated with them. It was one of many ways to expose content to readers in a progressive manner. Allowing readers to control the content by expanding it or deferring it for later let them decide what to read and what to ignore.

Prescribing information relating to the specific medicine brand was prominently presented within the content item. It closely followed the promotional claims and was presented as a link to a pdf version.

When the page was first loaded only the medicine brand and generic names were visible, no other product information was visible. The prescribing information was presented when promotional information was visible, which was why locating the prescribing information along with an adverse statement within the content area, which was hidden until expanded was appropriate in this instance.

All information on the website had been certified and reviewed periodically and recertified as required by the Code and certificates attached.

Teva submitted that this was consistent with the Code and it denied the alleged breaches of Clauses 2, 9.1, 4.1, 4.2, 4.6, 4.9, 9.1, 11.1 and 14.1.

Teva noted that the complainant then further detailed another URL (http://products.tevauk.com/patients/our-medicine-range). This was a patient page and would be accessed via the main website or again directly if the URL was known or via a search engine. The page listed the Teva products as reference information and was therefore specifically excluded from the definition of promotion as stated in Clause 1.1. This was also in line with the Clause 26.2 supplementary information, which stated:

> 'Reference information is intended to provide a comprehensive up-to-date resource that companies should make available on their websites or by way of a link from their website or by some other means. The primary purpose of reference information is to be library resource for members of the public giving information relating to prescription only medicines, which have marketing authorizations. Pharmaceutical companies are not obliged to provide reference information but it is considered good practice to provide as a

minimum the regulatory information comprising the summary of product characteristics (SPC), the package leaflet (PIL) and the public assessment report (PAR) (UK or European) where such a document exists.'

At the bottom of every page selected by users clicking 'view all medicines' was the adverse event statement. This provision of reference information was recognized as being consistent with the Code in Case AUTH/3270/10/19, where similarly information provided or use of brand name and logo was ruled by the Panel not to promote medicines to members of the public or to encourage them to ask their health professional to prescribe; it was not in breach of the Code.

Teva stated that with regard to any brand images used on certain products, there was case precedence that it was not a breach of the Code for product images to be used for patients where appropriate and non-promotional and indeed for identification purposes for patients, packs shots or images of inhalers for such patients was useful reference information. In the case of DuoResp Spiromax, the 'brand image' complained about was a pack shot and the video detailing the name of the product and a placebo training device, and the imagery as used on patient material (which patients might have been given by the prescriber) was non-promotional and there to aid recognition for patients, and clearly stated it was intended for patients prescribed DuoResp Spiromax. There was also clear guidance for the recommendation of use of brand names for inhalers due to the difference in devices that were available and, in addition, the DuoResp SPC emphasised the correct technique required in order for treatment to be effective, 'DuoResp Spiromax should be used correctly in order to achieve effective treatment. As such, the patients should be advised to read the patient information leaflet carefully and follow the instructions for use as detailed in the leaflet'.

Teva submitted that the website provided training for the patients. Patients recognised and differentiated the devices better visually. The current brand image mentioned by the complainant was with reference to differentiating inhalers and training for the patients.

In this instance, the disclaimer on the video clearly stated that the video was for the training of patients who had been prescribed the inhaler.

Teva noted that the PIL also had the description of the technique required using images for training, which demonstrated the importance of use of images for appropriate training. Teva had followed the same principles in the video to educate patients on the correct technique and this was non-promotional.

Teva noted that the complainant detailed further the A-Z range page, a reference list of medicines; this was a non-promotional product catalogue list and provided as reference information on the website as good practice recommended in the supplementary information to Clause 26.2.

Medical Information contact details were available at the top and signposting to adverse event reporting was present at the bottom of the page.

Teva stated that prescribing information was used only for promotional information and intended for prescribers. Promotional information was therefore not included on the patient page therefore the absence of prescribing information was entirely appropriate and consistent with the Code.

Teva stated the same applied to acitretin where there was reference information (PIL and SPC and patient alert card), as there were additional risk minimization measures (RMMs) in place and a pack shot was added for correct identification by the patients. The website provided reference information and communication of the requirements for pregnancy prevention in the alert card as an additional RMM, including the adverse event statement. As per Clause 1.2 of Code supplementary information, 'Clause 1.2 Risk Minimisation Plans and Material, As part of the marketing authorization process companies can be required to have risk minimisation plans and material approved by the [Medicines and healthcare products Regulatory Agency] as part of the company's pharmacovigilance obligations. Such approved documentation is exempt from the definition of promotion and can be delivered by a representative or included on a company website without being considered to be promotion of the medicine to which it refers'.

Teva submitted that this was therefore consistent with the Code and it denied the alleged breaches of Clauses 2, 4.1, 4.2, 4.6, 4.9, 9.1, 11.1, 14.1, 28.1, 28.3, 26.2 and 26.3.

In response to a request for further information, Teva provided copies of the webpages at issue and current at the time of the complaint for each of the five products, DuoResp Spiromax (budesonide and formoterol), Braltus Zonda (tiotropium), Qvar (beclometasone dipropionate), Cinqaero (reslizumab) and Tymbrineb (tobramycin), on the health professional respiratory in focus section of the website and the webpages which included information on DuoResp Spiromax and acitretin for members of the public.

PANEL RULING

The Panel noted the complainant's concern that it was inappropriate that the respiratory promotional webpage on the tevauk.com website could be viewed by non-respiratory focused health professionals.

The Panel noted Teva's submission that its corporate website, tevauk.com, was open access until readers selected the pages that were intended for health professionals. When doing so, a pop-up box appeared asking readers to confirm that they were a health professional and requesting that they select their area of specialisation which could have been 'other health professional' if they preferred not to disclose their specialism. The Panel noted Teva's submission that the selection of health professional specialty was for Teva's information so it could gather insights into and understand who was using the website, and to inform the company's plans about additional content; it was not used to send bespoke information or redirect readers post the selection. Upon confirmation that they were health professionals, readers could access all information for health professionals on the whole website which included all Teva products marketed in the UK.

The Panel noted that Clause 11.1 stated that material should only be sent or distributed to those categories of persons whose need for, or interest in, it could reasonably be assumed. The supplementary information stated that material should be tailored to the audience to whom it was directed. In the Panel's view, Clause 11.1 applied to material proactively sent or distributed to recipients and not to material which a health professional proactively sought out as in the case of material on a company's website.

Noting its comments above, the Panel did not consider that the availability of the information on the health professional respiratory section of the tevauk.com website, to all health professionals, was in breach of Clause 11.1 as alleged and no breach was ruled.

The complainant further alleged that within the respiratory section of the website described above, DuoResp Spiromax (budesonide and formoterol), Braltus Zonda (tiotropium), Cinqaero (reslizumab), Qvar (beclometasone dipropionate) and Tymbrineb (tobramycin) were listed but no prominent link to prescribing information or reference to where to find it was included unless the reader accidentally clicked on the green plus sign next to the product name for DuoResp Spiromax, Braltus Zonda and Cinqaero and scrolled right the way down. With regard to Qvar (beclometasone dipropionate) and Tymbrineb (tobramycin), the complainant alleged that there was no prescribing information provided even when a reader clicked on the green plus sign. The complainant further noted that there was no adverse event reporting statement on the page which did not appear to have been certified.

The Panel noted Teva's submission that when the health professional respiratory in focus webpage was first loaded, only the five medicines brand and generic names were visible and no other product information. The Panel noted from the webpages provided by Teva, which were current at the time of the complaint, that when the green plus sign next to each product was selected, additional information was displayed for each of the five products. The Panel noted Teva's submission that the prescribing information was presented when promotional information was visible, which was why locating the prescribing information along with an adverse statement within the content area, which was hidden until expanded, was appropriate in this instance.

The Panel noted that a hyperlink to the prescribing information for DuoResp Spiromax was visible towards the end of the second page of expanded information for DuoResp Spiromax. Similarly, a hyperlink to the prescribing information for Braltus and Cinqaero was visible and appeared on the first page of expanded information for each. The Panel, however, noted that Clause 4.6 required that in the case of promotional material on the internet, there must be a clear, prominent statement as to where the prescribing information could be found. In the Panel's view, noting that the entire webpage for health professionals was promotional, there should have been a clear and prominent statement as to where prescribing information could be found for each of the products listed at the outset and before clicking on the green plus sign for each as required by Clause 4.6. The Panel therefore ruled a breach of Clause 4.6 in relation to each of the five products.

Clause 4.1 required the prescribing information listed in Clause 4.2 to be provided on all promotional material. Clause 4.2 listed the components of prescribing information. It was not possible to breach Clause 4.2 in this instance; failure to provide the required information would be a breach of Clause 4.1. The Panel therefore ruled no breach of Clause 4.2.

The Panel noted that the complainant had only alleged a breach of Clause 4.1 in relation to Qvar and Tymbrineb. The Panel further noted Teva's submission that where a claim was made next to a product name, an additional link to prescribing information was provided with a single click; no claims were made with regard to Tymbrineb and Qvar, and only factual reference information provided linked to the SPC. The Panel, however, noted its comments above with regards to the promotional nature of the health professional webpage. Prescribing information for Tymbrineb and Qvar should have been provided but was not. The Panel therefore ruled a breach of Clause 4.1 in relation to Tymbrineb and Qvar.

The Panel noted that whilst it appeared from Teva's submission that the adverse event reporting statement was included within the prescribing information, which was linked from the webpages for Braltus Zonda, DuoResp Spiromax and Cinqaero, the Panel did not have a copy of the prescribing information before it. Regardless of its inclusion in the prescribing information, the

Panel noted that there was no reference to an adverse event reporting statement at the outset and before clicking on the green plus sign for each medicine or within the expanded information for each medicine when the green plus sign was clicked, including that for Qvar and Tymbrineb. The Panel considered that this was particularly important for Cinqaero given that it was subject to additional monitoring. The Panel therefore ruled a breach of Clause 4.9. In reaching its decision on this point, the Panel did not consider that a separate adverse event reporting statement was needed for each product promoted.

The Panel noted Teva's submission that all information on the website had been certified and reviewed periodically and recertified as required by the Code and provided the certificates. The Panel did not consider that there was evidence to show that the webpage had not been certified as alleged and it therefore ruled no breach of Clause 14.1.

The Panel noted its rulings of breaches of Clause 4.1 and 4.9 and considered that Teva had failed to maintain high standards and a breach of Clause 9.1 was ruled.

Whilst the Panel noted Teva's submission that the adverse event reporting statement did appear within the prescribing information for Braltus Zonda, DuoResp Spiromax and Cinqaero, there was no prescribing information for Tymbrineb and Qvar. The Panel noted the lack of adverse event reporting statement within the content of the webpages themselves; and was particularly concerned that there was no such statement anywhere in the materials for Tymbrineb and Qvar and that Cinqaero was subject to additional monitoring and only appeared to have the relevant statement within its prescribing information. The Panel noted that the black triangle was an important safety requirement and on balance the cumulative effect of its comments, and rulings of breaches meant that a breach of Clause 2 was warranted, a breach was ruled accordingly.

The Panel noted that the complainant referred to another webpage on the same website (http://products.tevauk.com/patients/our-medicine-range) which could be accessed by members of the public which he/she alleged was inappropriate as it included the brand names/images of all Teva products together with information/videos etc without prescribing information or adverse event reporting information. In that regard, the complainant specifically provided a link to a page https://products.tevauk.com/p/budesonide-38?productId=10248) which he/she stated provided information on DuoResp Spiromax alongside an image showing branding and the ability to ask questions. The complainant noted that it also included a video titled 'How do I use my DuoResp Spiromax (Budesonide/formoterol fumarate dihydrate) Inhaler?'. The complainant alleged that it was the same for various products including acitretin.

The Panel noted that the complainant did not appear to have a complaint about the first cited page link which listed products alphabetically by generic name referring briefly to patient information leaflets, presentation and the medical information service. This page did not include brand names etc referred to by the complainant which appeared on links from that webpage. The Panel considered that all of the allegations on this point related to the budesonide and acitretin webpage.

The Panel noted that Clause 26.1 prohibited the advertising of prescription only medicines to the public. Clause 26.2 permitted information to be supplied directly or indirectly to the public but such information had to be factual and presented in a balanced way. The Panel also noted the reference to a library resource in the supplementary information to Clause 26.2. The Panel noted that Clause 28 covered the Internet and other digital platforms, its supplementary

information, Access, stated that unless access to promotional material about prescription only medicines was 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 chose to. The Panel noted that 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 relevant requirements of the Code. The Panel noted that Clause 28.1 and its supplementary information did not mention material for patients who had been prescribed a specific medicine but considered that the same principle would apply.

The Panel noted that in this regard, should information about a specific medicine directed at patients for whom the prescribing decision had already been made be provided on the public section of a company website, the sections for each target audience should be clearly separated and the intended audience identified at the outset. Text above the video link was insufficient in this regard. The Panel noted that it appeared that the video which was aimed at patients for whom the prescribing decision had already been made was an integral part of the reference information aimed more broadly at the general public. The Panel therefore ruled a breach of Clause 28.1. The Panel considered that Teva had failed to maintain high standards and a breach of Clause 9.1 was ruled.

The Panel noted that the webpage provided by Teva for budesonide which was current at the time of the complaint was described by Teva as a patient product page and began by explaining that Teva marketed budesonide containing medicines and that the patient information leaflets could be downloaded, along with other information such as frequently asked questions where applicable. It stated that for further information about Teva's medicine(s), the reader could contact Teva's Medical Information Service, contact details were provided. The page then listed the two Teva medicines containing budesonide, by brand name and generic including two different strengths of DuoResp Spiromax. For each product, the pack type, pip-code, product license number, product code and classification were provided and an image of the pack rather than the inhaler itself. The Panel noted Teva's submission that the reason for choosing to feature images of its respiratory products including for identification purposes for patients was that it was useful reference information. Readers were invited to enlarge the image at which point the name and strength of the product could clearly be seen. The Panel noted that in order to obtain further information including the product's indication, the reader had to download the patient information leaflet or SPC or watch the video which appeared beneath. The Panel noted that the video titled 'How to use your DuoResp Spiromax (Budesonide/formoterol fumarate dihydrate) inhaler appeared to be given as a response to the first of five FAQs 'How do I use my DuoResp Spiromax (Budesonide/formoterol fumarate dihydrate) inhaler' and stated Please watch this video for more information on how to use DuoResp Spiromax. The Panel noted that the first slide of the video stated 'This video is intended for patients prescribed DuoResp Spiromax'. It was the only FAQ response visible on the page; the other FAQs could be read if the 'View all questions' link below the video or the FAQ tab towards the top of the page were selected and were general in nature including how does Teva choose what colours to use on packaging, what to do if the reader suffered a side effect or adverse event and how to get a new copy if the PIL if it was lost.

The Panel noted the narrow nature of the allegation, that the information including reference to brand names and the video which included inhaler branding was not suitable for the general

public. The Panel noted that Teva had described the material as reference information as set out in the supplementary information to Clause 26.2. The Panel noted Teva's submission that the page listed the Teva products as reference information and provided training for patients who recognized and differentiated the devices better visually; the current brand image mentioned by the complainant was with reference to differentiating inhalers and training for patients.

The Panel noted its ruling of a breach of Clause 28.1 above and considered that this adequately covered the complainant's concerns in relation to the video. The Panel noted that the complainant bore the burden of proof and did not consider that the complainant had established, on the balance of probabilities, that the inclusion of brand names and imagery on the webpage intended for the public was contrary to Clause 26.2 or that the requirements of Clauses 14.1, 4.1, 4.2, 4.6 and 4.9 were triggered. The Panel, therefore, based on the complainant's narrow allegation, ruled no breach of Clauses 14.1, 4.1, 4.6, 4.9 and 26.2.

The Panel noted that Clause 26.3 required that any material which related to a medicine and which was intended for patients taking that medicine must include the statement below or a similar one: 'Reporting of side effects: If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at [a web address which links directly to the MHRA Yellow Card site]. By reporting side effects you can help provide more information on the safety of this medicine'.

The Panel noted that at the bottom of the DuoResp Spiromax webpage it stated 'If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the Patient Information Leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard in line with Clause 26.3. The Panel therefore ruled no breach of Clause 26.3.

In relation to acitretin, the Panel noted that the information provided on the acitretin webpage, was similar to that for Budesonide, although there was no video. The FAQs on the actitretin webpage were all general in nature including how does Teva choose what colours to use on packaging, what to do if the reader suffered a side effect or adverse event and how to get a new copy if the PIL if it was lost.

The Panel noted its comments above and did not consider that the complainant had established, on the balance of probabilities, that the inclusion of brand names and images was promotional for actitretin as alleged and thus that the requirements of Clauses 14.1, 4.1, 4.2, 4.6 and 4.9 were triggered or was not in line with the requirements of Clause 26.2 based on his/her allegation. The Panel, therefore, based on the complainant's narrow allegation, ruled no breach of Clauses 14.1, 4.1, 4.6, 4.9, 26.2 and 28.1.

The Panel noted that the Acitretin webpage did appear to be directed to both the public and patients that had been prescribed acitretin; certain text on the webpage addressed patients. The Panel noted that the webpage included the statement 'This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See www.mhra.gov.uk'. Further the bottom of the page included, albeit in small font, 'If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at [a web address which links directly to

the MHRA Yellow Card site]. By reporting side effects you can help provide more information on the safety of this medicine'. The Panel therefore ruled no breach of Clause 26.3.

Whilst the Panel had concerns about the adequacy of audience signposting, which it considered was covered by its comments and rulings above, the Panel did not consider that the complainant had established that using the brand name and images of Teva products in relation to budesonide and acitretin was in breach of Clause 11.1. In the Panel's view, Clause 11.1 applied to material proactively sent or distributed to recipients and not to material which a health professional proactively sought out as in the case of material on a company's website. The Panel, based on the complainant's narrow allegation, ruled no breach of Clause 11.1.

Clause 28.3 stated that information about medicines covered by Clauses 28.1 and 28.2 which is provided on the internet and which is intended for members of the public must comply with Clause 26.2. The Panel noted its comments and rulings above and consequently ruled no breach of Clause 28.3.

The Panel noted its comments and rulings in relation to the budesonide and acitretin patient pages and did not consider that the particular circumstances of this case warranted a ruling of a breach of Clause 2 which was used as a sign of particular censure and reserved for such use. No breach of Clause 2 was ruled.

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During its consideration of this part of the case, the Panel was concerned to note that the webpage with an implicit invitation to contact medical information about DuoResp Spiromax, might have solicited enquiries about the medicine from patients/public. The Panel considered that those who took the trouble to seek out the website might want to access as much information as possible. The Panel noted that whilst providing general contact details on a website was good practice, it considered that by inviting members of the public to contact the company for more information about DuoResp Spiromax, particularly by inviting questions on 'how it works', Teva had solicited requests about a specific prescription only medicine and had thus gone beyond the provision of reference information and reactive information in response to a direct, unsolicited request allowed under Clause 26.2 as referred to in the supplementary information to that clause. The Panel considered that it would be helpful if Teva reviewed the website to ensure that relevant audiences were adequately signposted. The Panel asked that Teva be advised of its concerns.

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2 'Let's Talk Respiratory' website (letstalkrespiratory.com)

COMPLAINT

The complainant noted that the website included a talk on key insights from clinical guidelines on the diagnosis and management of asthma and chronic obstructive pulmonary disease (COPD) (link provided). At 18:15 in that presentation, there was mention about inhaled corticosteroids (ICS) and inhaled corticosteroids combined with long acting beta agonists (ICS/LABA) and ICS-formoterol with snippets from the guidelines. The complainant noted that Teva had a product for both of these drug classes ie Qvar (ICS) and DuoResp Spiromax (ICS/formoterol). The complainant noted that there was no prescribing information provided for

those products. Although only drug class was mentioned, this was a promotional talk hosted on a website initiated and generated by Teva so it was obvious there was a clear focus on DuoResp and Qvar. The reference code for this presentation was RESP-GB-NP-00028 with date of preparation September 2020. The complainant alleged that the video breached Clauses 4.1, 4.2, 4.6 and 4.9. Furthermore, the mention of ICS-formoterol with a small asterisk at the bottom stated that it was not licensed in the UK which was off-label promotion for DuoResp Spiromax as the SPC licence for DuoResp Spiromax was not in line with what the Global Initiative for Asthma (GINA) guidelines recommended ICS-formoterol for, which was to use as a reliever when required as often as needed. The complainant noted that DuoResp Spiromax was indicated in the regular treatment of asthma, where use of a combination (inhaled corticosteroid and long-acting β2 adrenoceptor agonist) was appropriate: - in patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short-acting β2 adrenoceptor agonists. or - in patients already adequately controlled on both inhaled corticosteroids and long-acting β2 adrenoceptor agonists. The complainant alleged breaches of Clauses 3.2, 9.1 and 2 as the video promoted off-label usage of DuoResp Spiromax.

The complainant noted that on the side of the video/webpage it was hosted on, there was the option to share the video via Facebook, Twitter or LinkedIn which demonstrated a lack of knowledge from Teva as members of the public could be promoted to. The complainant alleged breaches of Clauses 26.2, 26.3, 9.1 and 2 and also Clauses 12.1 and 9.9 as it was disguised and open promotion of Teva products by sharing on social media. The complainant noted that the option to share content via Facebook, LinkedIn or Twitter was available also on https://letstalkrespiratory.com/section/knowledge/. This was highly inappropriate.

The complainant alleged that another article (ref UK/RESP/17/0028au) on the website about using budesonide/formoterol 'as needed' to prevent asthma (link provided) was disguised promotion. The complainant stated that there was no prescribing information provided for DuoResp again considering the article was about budesonide/formoterol. It had a promotional intent and all promotional requirements had not been met and yet again it was an article that could be shared on social media. The complainant alleged that same breaches of the Code as with the video above.

RESPONSE

Teva stated that its 'Let's Talk Respiratory' was an educational programme of supportive materials, resources and some of the latest news in respiratory for both health professionals and patients.

The talk on the website was non-promotional and indeed the whole website was dedicated to non-promotional activity and education, and as per Clause 1.2, was excluded from the definition of promotion as it was factual accurate information, it contained no product claims and was not for the promotion of any medicine.

'Let's Talk Respiratory' had an educational focus to support health professionals and patients. In the health professional section there was no prescribing information as there was no promotional content anywhere on the site. All topics on the website were generated by the health professional led editorial board - the purpose of the editorial board and management from an external agency was to ensure topics and subsequent contents were completely independent to Teva, although Teva reviewed and certified to ensure consistency with the Code.

The presentation in question reflected key insights from the various clinical guidelines for asthma and COPD. There was no product mentioned in the non-promotional educational video including aspects of those various guidelines. The video was part of the masterclass series, where the aim of the content was not promotional sharing information on guidelines, not promoting therapies aligned with Teva products, so did not require prescribing information.

The topic was originally identified in October 2019 by the committee which was consulted about the planned live Masterclasses series that was then later converted into an online series during the pandemic.

The external management agency identified a named health professional as a good choice to speak on the topic because he/she was a GP interested in respiratory medicine and involved with various respiratory groups.

The video was an educational resource which focussed on published guidelines and not a promotional item detailing the steps in treating asthma by class and also the differences between the British Thoracic Society (BTS)/National Institute for health and Care Excellence (NICE) and GINA guidelines. Noting that GINA recommended budesonide/formoterol as a reliever inhaler and referred to this recommendation as off-label, the speaker detailed that this GINA recommendation was not licensed as was appropriate, and in addition, the slide stated that this was not a licensed indication. It was clear that the talk was non-promotional and referred to the guidelines and did not focus on Teva products as alleged and did not promote products off licence.

In relation to the footnote asterisk as stated by the complainant – it was a consistent size and placement across the presentation and reflected the facts as per the guidelines appropriately in addition to that verbalised by the speaker.

Teva submitted that this was therefore consistent with the Code and there was no breach of Clauses 4.1, 4.2, 4.6, 4.9 and also as it had not promoted a product there was no breach of Clause 3.2, 9.1 and 2 as alleged.

Teva noted that the complainant further commented that there was an option to share via social media. As previously stated, the information was non-promotional and by sharing the ability for the viewer to share educational content on social media was not a breach of Clauses 26.2, 26.3, 9.1, 2, 12.1 and 9.9 as alleged.

Teva noted that the complainant had also commented on an article entitled ‘Research roundup: Budesonide-formoterol used as needed to prevent asthma exacerbations: a trial reflecting real-world practice’. That article referred to a scientific publication in the New England Journal of Medicine and as per other content of the website was non-promotional and mentioned no Teva product and provided on the webpage a link to download CPD certificate for continuing professional development. The article was intended as non-promotional education as per the original paper and reflected the author’s conclusions of the study and was not promotional for any product.

This was therefore consistent with the Code and there was no breach of Clause 3.2, 9.1 and 2 as alleged.

Teva stated that with regard to the 'Lets Talk Respiratory' website, there was no promotion of the health professional site to the public, nor was there any promotional content in the health professional website that required prescribing information and, although non-promotional, there was the ability to report adverse events via the website at the bottom of all the relevant pages. Teva therefore refuted all allegations of breaches of the Code.

In response to a request for further information, Teva described how health professionals and members of the public were signposted to the 'Lets Talk' respiratory website, including how readers navigated through the website to the video and article in question, and how the materials were described on the pages in question and, if relevant, on any intervening pages.

Teva noted that when either a health professional or a member of the public accessed www.letstalkrespiratory.com for the first time, they were asked to confirm whether they were a health professional or a member of the public. After that point, website cookies would automatically send the individual to that part of the site.

Teva submitted that during January 2021, health professionals were signposted to the Let's Talk Respiratory site in general and the Digital Masterclass series in a number of ways. The first signpost was communication through the field force. With regard to the Let's Talk Respiratory (LTR) site in general, the field force would have discussed LTR with health professionals through both verbal and digital communications, explaining LTR and the value it could bring to health professionals in helping with CPD points and education. An approved email for the field force to use following on from conversations had with health professionals who requested more information on LTR was sent as required. A briefing document was developed alongside the approved email to inform the field force how to use the approved email, this stated that LTR was non-promotional and shouldn't be used alongside any promotional calls.

The Digital Masterclasses were also signposted in a similar way through the field force in both verbal and digital communications. There were two flyers developed. The first was an over-view flyer of what was to come with the digital masterclass series and the other had the speakers and topics due to be released throughout September – December 2020. These flyers and a briefing document sent to the field force explaining that the flyers could be sent via email or via post to health professionals that consented to receive them. This briefing document also stated the non-promotional nature of LTR and the digital masterclass series and that it shouldn't be discussed within any promotional calls. An approved email was also developed for the field force to send to the health professionals who requested more information on the Digital Masterclass series. A further briefing document was developed to explain how to use the approved email, stating this email was non-promotional and should not be used in the same conversation as a promotional call.

The second way health professionals were signposted to the Let's Talk Respiratory site was through advertisements published on educational sites for health professionals; Patient.info, The BMJ, Nursing Times, Nursing in Practice, C+D. These advertisements launched in November 2020 and were active until July 2021. When these advertisements were clicked on, health professionals were directed to the LTR health professional site and landed on the homepage of the site. Before the homepage was able to be landed on, on first access to the site the health professional had to confirm whether they were a health professional or a member of the public to ensure they were being directed to the correct content.

Advertisements were also developed to promote the Digital Masterclass series, those advertisements were published on educational sites for health professionals; Patient.info, The BMJ, Nursing Times, Nursing in Practice, C+D, as well as GP Online and MIMs online. The advertisements on GP online and MIMs learning were active October – January. When the health professional clicked on the advertisement it directed health professionals to the homepage of the LTR site, however before landing on the page the health professional had to confirm whether they were a health professional or a member of public. The digital masterclass overview page was included on the homepage under featured content.

In addition, at the date of the complaint (05/01/2021) the Teva UK website (as referred to previous emails) signposted to LTR in the following ways:

> a) from the health professional Section landing page - a banner in the top area describing the LTR website content for health professionals and a link
> b) from the health professional page "Respiratory in focus" – a content item describing the LTR website content for health professionals and a link
> c) from the product list as an FAQ displayed under specific respiratory medicines, shown only to health professionals, describing the LTR website content for healthcare professionals along with the Let's Talk Respiratory introduction video. Example provided here is Budesonide page showing DuoResp Spiromax item listing.

Further to the above signposts, MIMs online also had an LTR advertisement on one of its pages, https://www.mims.co.uk/respiratory-visual-guide where health professionals could click through to access the LTR site. Again, the health professional had to confirm they were a health professional before gaining access to the site.

Teva explained that patients could be sign posted to the patient Let's Talk Respiratory site through several ways. The first was through conversations with their health professional who would be informed about the patient site through the field force. The health professional could then direct the patient to a particular article on the site or the site in general. The second was through social media posts, directed at patients. Within these posts, a link to the patient website was present, directing the patient to the correct site. The third, was through another Teva owned, non-promotional site Life Effects. All of the respiratory articles written on Life Effects had a link to the patient LTR site at the bottom of the article.

In addition, at the date of the complaint (5 January 2021) the Teva UK website for patients (as referred to previous emails) signposted to LTR in the following ways:

> ‘ d) from the patient page focused on respiratory – a content item describing the LTR website content for patients and a link

Teva provided information on how readers navigated through the website to the video in question.

Further to this route, the article might also appear at the bottom of other articles under the heading ‘you may also like’.

Teva explained that the materials were described on the pages in question and if relevant, on any intervening pages. On the page of 'Key Insights from the clinical guidelines on the diagnosis and management of asthma and COPD' the description was as follows:

> *'[named speaker describes how the diagnosis and management of respiratory diseases has changed in light of COVID-19, and how the interpretation of the clinical guidelines might need to be adapted. Part of the Let's Talk Respiratory Digital Masterclasses series.'*

The Digital Masterclass Overview page didn't describe the individual topics other than the title but described the series as:

> *'The 2020 Let's Talk Respiratory Digital Masterclasses programme is an exciting series of bite-sized educational pieces for you to access from the comfort of your own home. We've invited key experts to share their clinical and practical expertise to give you valuable learning that can contribute to your CPD requirements. Watch on-demand webinars, then post your questions to the expert to be answered in a follow up session; take our interactive e-learning modules, and listen to experts discussing multidisciplinary team working.'*

Similarly, on the speaker information flyer, disseminated by the field force, the individual topics were not described only mentioned by the title and speaker presenting the topics. The overall digital masterclass series was described as:

> *'A series of bite-size, on-demand educational sessions, provided by experienced clinicians working across acute and chronic respiratory disease. Providing an opportunity to enhance your clinical, technical and professional skills and knowledge in your own time with learning that can count towards your yearly CPD requirements.'*

Followed by the list of topics and speakers.

Teva's submitted that with regards to the Research round-up article, the page had no description due to the title describing the overarching principles of the topic: *'Research roundup: Budesonide-formoterol used as needed to prevent asthma exacerbations: a trial reflecting real-world practice'* and note of the *author 'Let's Talk Knowledge editorial team'* alongside the research article authors and title *'Beaseley R, Holliday M, Reddel HK, et al. Controlled trial of budesonide-formoterol as needed for mild asthma'.*

The article in question was created in collaboration with the Editorial Board for Let's Talk Respiratory. Teva had no influence over content. Topics and content were selected and written by independent experts, and this process was supported by a third party media group. The Let's Talk Knowledge editorial team were key in the process of content identification and development. They were a multidisciplinary team of respiratory health professionals. The Editorial Board provided insight into areas of respiratory care, identified topics of relevance and reviewed the content before being published on the LTR site.

PANEL RULING

The Panel noted Teva's submission that 'Let's Talk Respiratory' was a non-promotional website dedicated to education and included supportive materials, resources and some of the latest news in respiratory for both health professionals and patients. The Panel further noted Teva's submission that the presentation in question reflected key insights from the various clinical guidelines for asthma and COPD and no products were mentioned in the non-promotional educational video including aspects of those various guidelines.

The Panel considered that, regardless of whether such presentations were categorised by the company as promotional or non-promotional, all such presentations should have good quality clear educational content; that a presentation had good quality educational content did not in itself determine whether the presentation was promotional or non-promotional. The very broad definition of promotion at Clause 1.2 of the 2019 Code was particularly relevant. In that regard, the Panel noted that it was an accepted principle under the Code that it was possible, given the broad definition of promotion, for material to be promotional without mentioning the product by name.

The Panel noted Teva's submission regarding how health professionals and members of the public were directed to the relevant sections of the site, including the use of the field force in relation to health professionals and its advertising on the health professional section of Teva's corporate website which, in the Panel's view, was promotional. The Panel noted Teva's submission that the field force was briefed that LTR was non-promotional and shouldn't be used alongside any promotional calls. The Panel further noted Teva's submission that all topics on the website were generated by the health professional led editorial board to ensure topics and subsequent contents were completely independent to Teva; Teva did, however, review and certify it to ensure consistency with the Code. The Panel noted that the website appeared to have been funded by Teva; that there was an editorial board did not necessarily mean that the website was non promotional given the broad definition of promotion as noted above.

The Panel noted Teva's submission that the presentation in question was an educational, non-promotional resource which focused on published guidelines. The Panel noted that the beginning of the presentation explained the differences in the guidelines with regards to diagnosing asthma and COPD particularly within the context of the Covid pandemic. One slide out of nineteen titled 'How different are we?' included a diagram which briefly mentioned the initial steps in treating asthma by class noting the differences between the National Institute for health and Care Excellence (NICE), British Thoracic Society (BTS) and GINA guidelines. According to the slide, NICE Asthma 2020 stated that LTRA were the next step after ICS monotherapy, BTS Asthma 2019 stated that ICS/LABA was the next step after ICS monotherapy, and GINA Asthma 2020 stated that ICS/formoterol was the first step* in preference to ICS monotherapy. The Panel noted that the asterisk took the reader to a small footnote at the bottom of the slide which read 'Currently off-license use in the UK'.
The Panel noted Teva's submission that the presenter detailed that the GINA recommendation was not licensed as was appropriate. The Panel noted that from the transcript of the presentation at issue provided by Teva, the speaker stated 'Where we have a bit of an outlier is with GINA. So, GINA, their first step, the preferred step is to use ICS/formoterol, and even though this is unlicensed in the UK, it's something that has been demonstrated in studies to be an effective way of reducing the amount of steroid that's used, but without having an effect on the number of exacerbations. So, ICS/formoterol is probably something that will be used increasingly in an as required manner. But for now, NICE and BTS largely talk about ICS monotherapy and then moving on in subsequent steps to ICS/LABA on a regular basis'.

The Panel noted that whilst the presentation did not specifically mention DuoResp Spiromax or Qvar, it referred to ICS/formoterol and ICS/LABA. The Panel noted that a number of ICS/formoterol combination inhalers were available on the market and DuoResp Spiromax was one of three budesonide/formoterol inhalers on the market. Nonetheless, in the Panel's view, the website promoted ICS/formoterol and ICS within the combination of an ICS/LABA and Teva marketed both of these products, namely Qvar (ICS) and DuoResp Spiromax (ICS/formoterol).

In the Panel's view, given the very broad definition of promotion and noting its comments above, including that it was a company website albeit with an editorial board, that health professionals were directed to it including from the health professional section of Teva's corporate website which in the Panel's view was promotional and Teva's involvement in its review, the website could not be considered anything other than promotional for Teva's medicines.

The presentation was an integral part of the website. The Panel considered that the presentation at issue should have included Qvar and DuoResp Spiromax prescribing information and a clear prominent statement of where it could be found and did not include either. The Panel therefore ruled a breach of Clauses 4.1 and 4.6. Clause 4.1 required the prescribing information listed in Clause 4.2 to be provided on all promotional material. Clause 4.2 listed the components of prescribing information. It was not possible to breach Clause 4.2; failure to provide the required information would be a breach of Clause 4.1. The Panel therefore ruled no breach of Clause 4.2.

The Panel noted Teva's submission that there was the ability to report adverse events via the website at the bottom of all the relevant pages. The Panel therefore ruled no breach of Clause 4.9.

Noting its view that the website and video in question were promotional, the Panel considered that the recommendation to use ICS-formoterol as a reliever when required as often as needed was inconsistent with its licensed indication. According to its SPC, DuoResp Spiromax was indicated in the regular treatment of asthma, where use of a combination (inhaled corticosteroid and long-acting β2 adrenoceptor agonist) was appropriate in patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short-acting β2 adrenoceptor agonists or in patients already adequately controlled on both inhaled corticosteroids and long-acting β2 adrenoceptor agonists.

The Panel did not consider that the small footnote at the bottom of the page, which stated that it was not licensed in the UK, was sufficient to negate promotion that was inconsistent with the particulars listed in its SPC. A breach of Clause 3.2 was ruled. The Panel considered that Teva had failed to maintain high standards in this regard and a breach of Clause 9.1 was ruled.

The Panel noted that a ruling of a breach of Clause 2 was a sign of particular censure and reserved for such. The Panel noted its rulings and comments above but considered that the matter was not such as to bring discredit upon, or reduce confidence in, the industry. In the Panel's view, the ruling of a breach of Clause 9.1 was sufficient additional censure in relation to the breach of Clause 3.2. No breach of Clause 2 was ruled.

The Panel noted the complainant's allegation that on the side of the video/webpage it was hosted on, there was the option to share the video via Facebook, Twitter or LinkedIn.

The Panel noted that Clause 26.3 required a side effect reporting statement to be included on material which related to a medicine and which was intended for patients taking that medicine. The Panel did not consider that the presentation was intended for patients taking a specific prescription only medicine and therefore ruled no breach of Clause 26.3.

The Panel, noting its comments above, considered that the sharing of the promotional presentation via social media would constitute the promotion of a Teva prescription only medicine to the public. The Panel noted that the complainant bore the burden of proof and had not established that it had been shared and thus the Panel ruled no breach of Clauses 9.9, 12.1, 26.2, 9.1 and 2.

The complainant alleged that an article (ref UK/RESP/17/0028au) on the website about using budesonide/formoterol 'as needed' to prevent asthma (link provided) was disguised promotion. The complainant stated that there was no prescribing information provided for DuoResp again considering the article was about budesonide/formoterol. It had a promotional intent and all promotional requirements had not been met and yet again it was an article that could be shared on social media. The complainant alleged that same breaches of the Code as with the video presentation above.

The Panel noted that the article at issue, also on the letstalkrespiratory.com website, was entitled 'Research roundup: Budesonide-formoterol used as needed to prevent asthma exacerbations: a trial reflecting real-world practice'. The Panel noted Teva's submission that the article referred to a scientific publication in the New England Journal of Medicine and as per other content of the website was non-promotional and was intended as non-promotional education as per the original paper and reflected the author's conclusions of the study and did not promote any product.

The Panel noted that the article stated 'The authors suggest that budesonide-formoterol taken as needed was superior to both as-needed SABA and maintenance budesonide plus as-needed SABA at reducing the risk of severe exacerbations. As such therapy with budesonide-formoterol taken when the patient perceived their symptoms to be worsening can avoid symptoms becoming severe enough to warrant further urgent care. The study extends previous finding regarding the use of reliever therapy to avoid asthma exacerbations, providing evidence from a study that reflects real-world clinical practice'.

The Panel noted Teva's submission regarding how health professionals and members of the public were directed to the relevant sections of the site including the use of the field force in relation to health professionals and its advertising on the health professional section of Teva's corporate website which in the Panel's view was promotional. The Panel further noted Teva's submission that all topics on the website were generated by the health professional led editorial board to ensure topics and subsequent contents were completely independent to Teva; Teva did, however, review and certify it to ensure consistency with the Code.

The Panel noted that whilst the presentation did not specifically mention DuoResp Spiromax, it referred to budesonide/formoterol and included, in the Panel's view, promotional claims for it. The Panel noted that a number of budesonide/formoterol combination inhalers were available on the market and DuoResp Spiromax was one of three budesonide/formoterol inhalers on the market. Nonetheless, the Panel considered that the website promoted budesonide/formoterol and Teva marketed this product, namely DuoResp Spiromax. In the Panel's view, noting its comments above regarding how health professionals were directed to it, and Teva's

involvement in its review, the article could not be considered anything other than promotional for Teva's medicine. The Panel considered that the article in question should have included DuoResp Spiromax prescribing information and a clear prominent statement of where it could be found and did not include either. The Panel therefore ruled a breach of Clauses 4.1 and 4.6. Clause 4.1 required the prescribing information listed in Clause 4.2 to be provided on all promotional material. Clause 4.2 listed the components of prescribing information. It was not possible to breach Clause 4.2 in this instance; failure to provide the required information would be a breach of Clause 4.1. The Panel therefore ruled no breach of Clause 4.2.

The Panel noted Teva's submission that there was the ability to report adverse events via the website at the bottom of all the relevant pages. The Panel, therefore, ruled no breach of Clause 4.9.

The Panel noted that Clause 26.3 required a side effect reporting statement to be included on material which related to a medicine and which was intended for patients taking that medicine. The Panel did not consider that the article was intended for patients taking a specific prescription only medicine and therefore ruled no breach of Clause 26.3.

The Panel noted the complainant's allegation that there was the option to share the article via Facebook, Twitter or LinkedIn. The Panel, noting its comments above, considered that the sharing of the promotional article via social media would constitute the promotion of a Teva prescription only medicine to the public. The Panel noted that the complainant bore the burden of proof and had not established that it had been shared and thus the Panel ruled no breach of Clauses 9.9, 12.1, 26.2, 9.1 and 2.

Complaint received **5 January 2021**

Case completed **2 December 2021**