

ANONYMOUS, CONTACTABLE COMPLAINANT v CHIESI

Chiesi respiratory website

A contactable complainant who wished to remain anonymous and described him/herself as a member of the public raised concerns about Chiesi respiratory website (www.chiesirespiratory.co.uk).

The complainant stated that he/she was 'shocked' at the number of breaches of the Code within Chiesi's respiratory website. The complainant alleged that Chiesi was advertising prescription medicines to the public; it was completely unacceptable that one click on the patient or carer button revealed a full list of all respiratory products. The complainant stated that he/she was also concerned that including carers in that section was vague and needed further definition. There was not an adequate health professional self-declaration statement.

The complainant alleged that in the section looking at Fostair general resources, two of the video clips were out of date showing August 2018: 'Fostair an expert opinion ..' and 'The potential benefits of using a single inhaler for COPD to deliver triple therapy compared to separate inhalers ...'. The Fostair video included 'With Nexthaler they're not fiddling around, shaking and pulling things off, so that's really positive' which the complainant alleged implied other products were not good enough and was hence disparaging. The complainant further alleged that the sentence 'Nexthaler fits in with BTS guidelines and what we should be giving' was a strong unbalanced endorsement as many other products would fit that criteria and were not mentioned.

The complainant alleged that many of the other video resources were also out-of-date and that there were too many to list. A search for 'Fostair Chiesi' allegedly went straight to a product page with no health professional declaration which was advertising to the public.

The detailed response from Chiesi is given below.

The Panel noted that the Chiesi respiratory website landing page asked visitors to click on one of three links depending on whether they were a patient or carer of someone who had been prescribed a Chiesi Limited product for asthma or COPD, a registered UK healthcare professional or a member of the public, in order to access information tailored to the relevant audience.

The Panel noted Chiesi's submission that if individuals clicked and self-declared that they were a health professional, there were two prominent statements which made the intended audience clear. Firstly, the statement at the top of the page 'Intended for UK healthcare professionals' and secondly a paragraph beneath the page's heading 'Chiesi Limited respiratory website for UK healthcare professionals provides you with resources

and information to support you in the management of your respiratory patients'. Members of the public were directed to the Chiesi Limited company website.

The Panel noted Chiesi's submission that if individuals clicked on the link intended for patients or carers of someone who had been prescribed a Chiesi Limited product for asthma or COPD, they were directed to an area intended for them which was made clear by two statements. At the top of the page 'This website has been provided by Chiesi Limited to support patients, and carers of patients, who have been prescribed Chiesi respiratory products to help manage their asthma or chronic obstructive pulmonary disease (COPD)'. There was also a statement at the bottom of the same page 'If you are not a patient, or a carer of a patient, who has been prescribed a Chiesi respiratory product shown above and would like to find out more about Chiesi please visit www.chiesi.uk.com'.

In the Panel's view, the sections for each target audience were clearly separated and the intended audiences for each section identified and therefore no breach of the Code was ruled.

With regard to the allegation that it was completely unacceptable that one click on the patient/carer button took the visitor to a full list of all respiratory products and the reference to advertising prescription medicines to the public, the Panel noted that the patient/carer section of the website included Chiesi's respiratory products by brand name, followed by the non-proprietary name and an image of each. Chiesi's reason for choosing to include images of its respiratory products was to minimise any potential for confusion in accessing the appropriate information and met the needs of the patient/carer irrespective of the cognitive, literacy or visual requirements. The Panel noted that the text including the names of the products were not visible from the images. The Panel noted that in order to obtain further information on a particular product, including its indication, the reader had to select that product. The Panel noted that if a patient clicked on a specific product, at the top of the linked product page, it stated that your doctor, nurse or pharmacist has prescribed you the named product to help you manage the relevant condition. There was also a declaration at the bottom of the same product page which stated, 'This website has been provided by Chiesi Limited to support patients, and carers of patients, prescribed Chiesi respiratory products. If you have not been prescribed [the product selected] and are looking for information on another Chiesi respiratory product please visit our homepage'. A closely similar statement appeared at the bottom of the previous page which featured all products. The Panel did not consider that the webpage at issue promoted prescription only medicines to the public as alleged. The intended audience was made sufficiently clear and overall the page in question was not promotional. The Panel considered that the complainant had not established that the information provided on the patient/carer webpage was contrary to the requirements of the Code as alleged and no breach of the Code was ruled.

The Panel further noted Chiesi's submission that it had done a Google search using the term 'Fostair Chiesi' and clicked on the first three search results which related to its respiratory website (screenshots provided); all three led to a pop-up box which sought confirmation, by way of a self-declaration, that the proposed visitor was a health professional before being able to view the webpage. The Panel did not consider that the complainant had provided evidence to show that a Google search for 'Fostair Chiesi' took browsers straight to the product page without a health professional declaration and

therefore advertised prescription only medicines to the public as alleged. The Panel therefore ruled no breach of the Code.

The Panel noted its rulings of no breach of the Code in relation to both the Google search and the patient/carer webpage and did not consider that Chiesi had failed to maintain high standards or brought discredit to, or reduced confidence in, the industry in that regard and no breaches of the Code including Clause 2 were ruled.

The Panel considered that it was clear from both the homepage and patient/carer webpage that 'carer' referred to a carer of a patient prescribed a Chiesi Limited product for asthma or COPD and did not consider the use of the term 'carer' was vague as alleged; no breach of the Code was ruled in that regard.

The Panel noted the spreadsheet provided by Chiesi, which detailed all twenty-eight videos on the website, together with their dates of preparation and dates of approval/reapproval and noted that none of them appeared to be out-of-date as alleged. The Panel did not have the certificates for the videos other than the two above specifically identified by the complainant which Chiesi submitted had been approved in August 2018 and reapproved on 1 July 2020. The Panel considered that the complainant had not established that any of the videos on the website were out-of-date as alleged and therefore, based on the evidence before it, ruled no breach of the Code in relation to each video on the website.

The Panel noted Chiesi's submission that the speaker in the 'Fostair, an expert opinion' video was giving his/her expert opinion on the Nexthaler product in isolation and emphasised the positive aspects of its design when he/she stated 'With Nexthaler they're not fiddling around, shaking and pulling things off, so that's really positive'. The speaker's expert opinion, nonetheless, had to comply with the Code. The Panel disagreed with Chiesi's submission that there was no reference, express or implied, to other products. The Panel noted that according to the transcript provided by Chiesi, the video started by stating that 'At the moment the marketplace for both Asthma and COPD is really busy in terms of all the new options we've got. So when we're deciding what we need to use for patients, we have to consider the right medication in the right device for the right patient. The NEXThaler helps us because it gives us yet another option when we're treating patients and dealing with patients in offering them a device that not only delivers the medication they need but also gives them forms of feedback'. The video went on to refer to the importance of having options when treating patients and stated 'When it comes to teaching devices or using devices, a lot of the studies show us that both patients can't use them correctly and healthcare professionals can't use them correctly. The evidence for that seems to be that the more steps you have in terms of using the inhaler, the more complicated it becomes, the more likely people forget. So if you can keep it simple, then it works. When you're looking at the NEXThaler, what you've got is something that's simple to open that loads it. You've got feedback in terms of the delivery of the medication. You've got your dose counter. So it's simple for patients but it's also simple for the healthcare professionals who are the ones who are going to prescribe and to show the patients how to use it'.

The Panel considered that, on balance, within the context of the entire video, the statement at issue 'With Nexthaler they're not fiddling around, shaking and pulling things off, so that's really positive.' could be seen as comparative. There was an implication

that the absence of 'fiddling around, shaking and pulling things off' was a positive difference between Nexthaler and comparator products and that such other products might be more complicated to use affecting compliance. In that regard, the Panel considered that the statement in question was disparaging those alternative inhalers and a breach of the Code was ruled which was appealed by Chiesi.

The complainant had alleged that in the same video, the sentence 'Nexthaler fits in with BTS [British Thoracic Society] guidelines and what we should be giving' was a strong, unbalanced endorsement as many other products would fit that criteria and were not mentioned. The Panel noted Chiesi's submission that the speaker had given his/her expert opinion about the Nexthaler product and did not refer to other products or suggest in any way that they would not fit the criteria. The fact that he/she did not mention other products did not render the statement unbalanced. Further, the statement was made to encourage prescribing in line with the BTS Guidelines, and reference to Nexthaler was to let the audience know that it would be in line with the guidelines.

The Panel considered the full context in which the statement in question was made. The speaker/transcript stated 'Guidelines are always going to be important when we're considering what we're prescribing, so we'll have national guidance which will give us a range of options, but then we'll have our local and our area guidance, which is usually made up between primary and secondary care clinicians so that we're prescribing what's appropriate for patients, but also thinking about continuity for them. When we look at BTS guidelines for both asthma and we have the sign BTS ones for that, then the NEXThaler fits in with their guidance in terms of our prescribing and what we should be giving'. The Panel did not consider that the statement at issue 'Nexthaler fits in with BTS guidelines and what we should be giving' was an unbalanced endorsement as many other products which were not mentioned would fit that criteria as alleged. In the overall context of the video, it was clear that there were a range of options and in the opinion of the Panel, there was no implication that the BTS guidelines endorsed Nexthaler in preference to other products. The Panel did not consider the statement misleading as alleged and ruled no breach of the Code.

The Panel noted its rulings of no breaches of the Code in relation to material for health professionals and material for the public as set out above and therefore, in relation to its provision on the Internet, ruled no breach of the Code.

The Panel noted its comments and rulings above including a breach of the Code and considered that, on balance, Chiesi had failed to maintain high standards and a breach of the Code was ruled which was appealed by Chiesi. .

The Panel did not consider that the specific circumstances of this case warranted a ruling of a breach of Clause 2 which was a sign of particular censure and reserved for such use and no breach of Clause 2 was ruled.

The Appeal Board noted that the video discussed patient options and, according to Chiesi, the statement at issue 'With Nexthaler they're not fiddling around, shaking and pulling things off, so that's really positive' concerned one of many characteristics of an inhaler and this was a subjective assessment. The Appeal Board considered that, on balance, within the context of the entire video, the statement at issue could be seen as comparative to other inhalers, noting that the preceding sentence included '...they like

the ease with which it opens and closes and that loads it which makes it easier for them'. The Appeal Board considered there was a fine line between stating a positive feature of one medicine and disparaging another, which might not have that feature.

The Appeal Board noted the submission from Chiesi that if the statement at issue was considered to be comparative, then data from Voshaar *et al* provided for the appeal, and which was not before the Panel, substantiated it. In that study, asthma patients, previously naïve to dry powder inhalers, each used NEXThaler, Diskus and Turbuhaler and then were asked a series of questions. The two questions which Chiesi submitted which would substantiate the statement were 'Which inhaler did you find easiest to open, prepare, and set a dose with? (80.3% preferred NEXThaler) and 'OVERALL, which inhaler did you find easiest to use?' (74.2% preferred NEXThaler).

In addition, the Appeal Board noted that the language used by the speaker was different to the language used in Voshaar *et al*. Nonetheless, whilst the Appeal Board considered that the language used by the speaker was unfortunate, it did not consider that the statement in question disparaged the alternative inhalers as alleged and no breaches of the Code. The appeal on both points was successful.

A contactable complainant who wished to remain anonymous and described him/herself as a member of the public raised concerns about Chiesi Ltd's respiratory website (www.chiesirespiratory.co.uk).

Chiesi marketed a number of medicines for the treatment of asthma and chronic obstructive pulmonary disease (COPD).

COMPLAINT

The complainant stated that he/she was 'shocked' at the number of breaches of the Code within Chiesi's respiratory website. The complainant alleged that Chiesi was advertising prescription medicines to the public; it was completely unacceptable that one click on the patient or carer button revealed a full list of all respiratory products. The complainant stated that he/she was also concerned that including carers in that section was vague and needed further definition.

Moving through the health professional section, the complainant submitted that there was not an adequate health professional self-declaration statement ie 'Yes I am/No I am not' to ensure that non-health professionals did not access that section.

The complainant further noted that in the section looking at Fostair general resources (www.chiesirespiratory.co.uk/hcp/resources-for-hcps/), there were a number of video clips. The complainant alleged that two of the videos were out of date showing August 2018: 'Fostair an expert opinion' and 'The potential benefits of using a single inhaler for COPD to deliver triple therapy compared to separate inhalers'. With particular reference to the Fostair video, the complainant submitted that the sentence 'With Nexthaler they're not fiddling around, shaking and pulling things off, so that's really positive.' implied other products were not good enough and was hence disparaging. The complainant further alleged that the sentence 'Nexthaler fits in with BTS guidelines and what we should be giving' was a strong unbalanced endorsement as many other products would fit that criteria and were not mentioned.

The complainant submitted that many of the other video resources across the whole website were also out-of-date and that there were too many to list. The complainant also alleged that a Google search for 'Fostair Chiesi' went straight to a product page with no health professional declaration which was another route of advertising to the public. The complainant alleged breaches of Clauses 26.1, 28.1, 28.3 and 9.1.

When writing to Chiesi, the Authority asked it to consider the requirements of Clauses 9.1, 26.1, 28.1 and 28.3 as cited by the complainant. In addition, Clause 7.2 (with regard to the allegations about the content of the videos; alleged to be unbalanced and not up-to-date), Clause 8.1 (with regard to the alleged disparagement) and Clauses 2 and 9.1 (with regard to the alleged promotion of prescription only medicines to the public).

RESPONSE

Chiesi noted that the complainant had raised a number of concerns about how information was accessed on its respiratory website, ie that the website advertised prescription only medicines to the public via one click on the patient or carer button and that there was not an adequate health professional self-declaration statement to access the health professional section.

In that regard, Chiesi referred to the supplementary information to Clause 28.1 which stated that 'a pharmaceutical company website must provide information to the public as well as promotion to health professionals with the sections for each target audience clearly separated and the intended audience identified'. Chiesi noted that on its respiratory website individuals had access to three sections:

- 1 Information for patients or carers of someone who had been prescribed a Chiesi Limited product for asthma or COPD;
- 2 Information for UK registered health professionals; and
- 3 Information for the public.

Chiesi submitted that individuals entering the site were required to confirm which of the above categories they fell into before being able to access information specifically tailored to the relevant category.

If individuals self-declared that they were a patient/carer, then the website directed them to an area intended for patients and carers. Chiesi submitted that the intended audience for the patient/carer area was very clear as there were two clear statements to that effect. At the top of the page there was text which read: 'This website has been provided by Chiesi Limited to support patients, and carers of patients, who have been prescribed Chiesi respiratory products to help manage their asthma or chronic obstructive pulmonary disease (COPD)'. There was also a statement at the bottom of the same page which stated: 'If you are not a patient, or a carer of a patient, who has been prescribed a Chiesi respiratory product shown above and would like to find out more about Chiesi please visit www.chiesi.uk.com'. Chiesi submitted that these statements were important for two reasons: (i) they reminded patients/carers that they had chosen to enter the area of the website dedicated to them; and (ii) they helped browsing patients to sense check that they were in the right area of the website and assisted them in navigating to the appropriate information for the product(s) they had been prescribed.

Chiesi stated that within the patient/carer area, between the two statements described above, there were images of products in Chiesi's respiratory product portfolio. When developing

content for any material (digital or otherwise) it was important that, as well as abiding by the requirements of the Code, the information was displayed in an appropriate way for the intended audience. Chiesi stated that it had developed the patient area with this in mind, including images of the products in addition to brand names. This was to ensure that it had:

- A) minimised any potential for confusion in accessing the appropriate information for patients/carers given that Chiesi marketed entirely different products that had the same inhaler shapes (in the case of pressurised metered dose inhalers – pMDIs) or shared similar brand names because the medicine they contained was the same but the devices delivering the medicine were completely different to operate (Fostair was available in a pMDI and dry powder inhaler - DPI).
- B) met the needs of the patient/carer irrespective of the cognitive, literacy or visual requirements. For example, some patients were very visual (either due to eyesight constraints or literacy levels) and might only recognise their device. Therefore, not providing an image of their device would impede their ability to access the appropriate information. In this example, not providing an image might result in the patient having to trawl through other information and being exposed to information about products they were not prescribed.

When it made this decision, Chiesi submitted that it ensured that any mention of asthma and COPD was not immediately adjacent to the product names; this avoided products being linked to their intended use in a way which could be considered as advertising medicines to the public.

Once a patient identified the product which they had been prescribed and clicked on that specific product to confirm that they had been prescribed it, there were further declarations as to the intended audience. For example, if a patient clicked on Trimbow at the top of the page it stated: 'Your doctor, nurse or pharmacist has prescribed you a Trimbow inhaler for Chronic Obstructive Pulmonary Disease (COPD)'. There was also then a declaration at the bottom of the same page which stated, 'This website has been provided by Chiesi Limited to support patients, and carers of patients, prescribed Chiesi respiratory products. If you have not been prescribed Trimbow and are looking for information on another Chiesi respiratory product please visit our homepage'.

Chiesi stated that it also considered, in its decision, the advice provided by the Code and the MHRA Blue Guide that companies should provide information about a specific medicine to patients for whom the prescribing decision had already been made. In addition, Chiesi took into account the fact that there was no guidance provided for separation of information intended for patients/carers and the general public either in Clause 26 or in the supplementary information. Therefore, in previous cases the Panel had ruled according to the principle that all publicly accessible information for patients should also be suitable for the general public (eg including, but not limited to, Cases AUTH/3184/4/19 and AUTH/3252/10/19 – Chiesi stated that it reserved the right to refer to other cases which might be relevant in addressing the complaint).

Chiesi submitted that the proactive choice for individuals to self-declare that they were patients/carers, coupled with the prominent statements at the top and bottom of each page of the patient/carer areas of the respiratory website, clearly met the requirements of the Code.

In the case of health professionals accessing the site, Chiesi submitted that they would need to confirm that they were health professionals before being introduced to any promotional

information. In addition to this initial proactive decision (self-declaration) to click on the 'I am a healthcare professional' tab, two prominent statements made the intended audience clear. Firstly, there was a statement at the top of the page which read 'Intended for UK healthcare professionals'. There was also a paragraph at the top of the page which read, 'Chiesi Limited respiratory website for UK healthcare professionals provides you with resources and information to support you in the management of your respiratory patients'.

Chiesi again submitted that the proactive choice for individuals to self-declare that they were health professionals, coupled with the prominent statements when clicking through to the health professional area, clearly met the requirements of the Code.

Chiesi noted the complainant's concern that there was no definition of 'carer' but disagreed that there was any ambiguity as to the interpretation of the term. At the top of the webpage there was a clear statement as to the intended audience for the webpage: 'This website has been provided by Chiesi Limited to support patients, and carers of patients, who have been prescribed Chiesi respiratory products to help manage their asthma or chronic obstructive pulmonary disease (COPD)'. Chiesi considered that it was thus clear that 'carer' referred to a carer of a patient prescribed a Chiesi Limited product for asthma or COPD.

Chiesi further noted the Oxford Dictionary definition of 'carer' ie 'family member or paid help who regularly looks after a child or a sick elderly, or disabled person'. This definition was consistent with the definition which Chiesi had applied to a carer in this area of the website, namely a person who cared for a patient prescribed a Chiesi Limited product for asthma or COPD. For these reasons, Chiesi refuted the allegation that the term 'carer' was ambiguous and needed further definition.

Chiesi noted that the complainant had stated that there were two out-of-date videos on its respiratory website: 'Fostair an expert opinion' and 'The potential benefits of using a single inhaler for COPD to deliver triple therapy compared to single inhalers'. Transcripts of both videos were provided. Chiesi noted that the complainant also alleged that there were 'many other videos across the whole website which were also out of date'.

With regard to the two videos identified by the complainant, Chiesi submitted that they had been approved in August 2018 and both were reapproved on 1 July 2020. Chiesi attached the certificates for both of these re-approval materials.

Chiesi provided details of the signatories for each of the two videos. With regard to the complainant's allegation that 'many other videos across the whole website' were out-of-date, Chiesi provided a spreadsheet which detailed all videos on the website, together with their dates of preparation and dates of approval/reapproval as appropriate. Chiesi noted that there were twenty-eight videos on the website in question and submitted that none of them were out-of-date as alleged.

Chiesi noted the complainant's allegation that the sentence 'With Nexthaler they're not fiddling around, shaking and pulling things off, so that's really positive' in the 'Fostair, an expert opinion' video was disparaging as it implied that other products were not good enough. Chiesi stated that it did not understand how that was disparaging as there was no reference, express or implied, to other products and that the speaker had simply given his/her expert opinion on the Nexthaler product in isolation and emphasised the positive aspects of its design.

Chiesi noted that 'disparaging' was defined in the Oxford English Dictionary as: 'Expressing the opinion that something was of little worth; derogatory'. In that regard, Chiesi noted that there was no mention of any competitor product in the video and therefore the allegation that the words used were in some way disparaging could not be substantiated, otherwise it would not be possible to speak positively about a product in a market place which was occupied by competitor products.

Chiesi noted that, in the same video, the complainant had alleged that the sentence 'Nexthaler fits in with BTS guidelines and what we should be giving' was a strong, unbalanced endorsement as many other products would fit that criteria and were not mentioned. Once again, Chiesi noted that the speaker had given his/her expert opinion about the Nexthaler product (as was clear by the title of the video), and did not refer to other products or suggest in any way that they would not fit the criteria. The fact that he/she did not mention other products did not render the statement unbalanced. Further, the statement was made to encourage prescribing in line with the BTS Guidelines, and his/her reference to Nexthaler was to let the audience know that it would be in line with the guidelines.

Chiesi noted its comments above and submitted that the content of the video 'Fostair an expert opinion', was neither disparaging nor strong and unbalanced as alleged.

Chiesi noted that the complainant had submitted that a Google search for 'Fostair Chiesi' took browsers straight to the product page with no health professional declaration and suggested therefore that this was a '... another route of advertising to the public'.

In order to address this point, Chiesi Google searched using the term 'Fostair Chiesi' and then clicked on the first three search results which related to its respiratory website. Chiesi submitted that all three led to a Chiesi pop-up box seeking confirmation, by way of a self-declaration, that the proposed visitor was a health professional (UK-RES-2000248 and UK-RES-2000249). Accordingly, Chiesi denied that that was a route of advertising to the public, as the public could not access any promotional material intended for health professionals unless they self-declared that they were health professionals.

Chiesi noted its comments above and denied any breach of Clauses 2, 8.1, 9.1, 26.1, 28.1 or 28.2 of the Code.

PANEL RULING

The Panel noted that the Chiesi respiratory website landing page asked visitors to click on one of three specific links depending on whether they were a patient or carer of someone who had been prescribed a Chiesi Limited product for asthma or COPD, a registered UK healthcare professional or a member of the public, in order to access information tailored to the relevant audience.

The Panel noted Chiesi's submission that if individuals clicked and self-declared that they were a health professional, there were two prominent statements on the webpage they were directed to that made the intended audience clear. Firstly, there was a statement at the top of the page which read 'Intended for UK healthcare professionals' and secondly a paragraph beneath the page's heading which read, 'Chiesi Limited respiratory website for UK healthcare professionals provides you with resources and information to support you in the management of your respiratory patients'.

Members of the public were directed to the Chiesi Limited company website, www.chiesi.uk.com.

The Panel noted that Clause 28.1 and its supplementary information did not specifically mention material for patients who had been prescribed a specific medicine. The Panel noted, however, 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 Chiesi's submission that if individuals clicked on the link intended for patients or carers of someone who had been prescribed a Chiesi Limited product for asthma or COPD, they were directed to an area intended for them which was made clear by two statements. At the top of the page there was text which read: 'This website has been provided by Chiesi Limited to support patients, and carers of patients, who have been prescribed Chiesi respiratory products to help manage their asthma or chronic obstructive pulmonary disease (COPD)'. There was also a statement at the bottom of the same page which stated: 'If you are not a patient, or a carer of a patient, who has been prescribed a Chiesi respiratory product shown above and would like to find out more about Chiesi please visit www.chiesi.uk.com'.

The Panel noted that neither the Code nor its supplementary information required a health professional self-declaration statement as implied by the complainant to ensure that a non-health professional did not access health professional materials. The supplementary information to Clause 28.1 referred to sections for each target audience being clearly separated and the intended audience identified. Of course, companies could require a visitor to take a proactive step such as ticking a box to declare their professional status or otherwise but this was not a Code requirement. The Panel noted that as required by the supplementary information to Clause 28.1, the section that provided promotional information to health professionals and the sections that contained information for members of the public were clearly separated. In the Panel's view, the sections for each target audience were clearly separated and the intended audiences for each section identified and therefore no breach of Clause 28.1 was ruled.

The Panel noted the allegation that it was completely unacceptable that one click on the patient/carer button took the visitor to a full list of all respiratory products and the reference to advertising prescription medicines to the public. The Panel noted that the patient/carer section of the website included Chiesi's respiratory products by brand name, followed by the non-proprietary name and an image of each. The Panel noted Chiesi's reason for choosing to include images of its respiratory products: it minimised any potential for confusion in accessing the appropriate information and met the needs of the patient/carer irrespective of the cognitive, literacy or visual requirements. The Panel noted that the text including the names of the products were not visible from the images. The Panel noted that in order to obtain further information on a particular product, including its indication, the reader had to select that product. The Panel noted that if a patient clicked on a specific product, at the top of the linked product page, it stated that your doctor, nurse or pharmacist has prescribed you the named product to help you manage the relevant condition. There was also a declaration at the bottom of the same product page which stated, 'This website has been provided by Chiesi Limited to support patients, and carers of patients, prescribed Chiesi respiratory products. If you have not been prescribed [the product selected] and are looking for information on another Chiesi respiratory product please visit our homepage'. A closely similar statement appeared at the bottom of the

previous page which featured all products. The Panel did not consider that the webpage at issue promoted prescription only medicines to the public as alleged. In the Panel's view, the intended audience was made sufficiently clear and overall the page in question was not promotional. The Panel considered that the complainant had not established that the information provided on the patient/carer webpage was contrary to the requirements of Clause 26.1 as alleged and no breach of Clause 26.1 was ruled.

The Panel further noted Chiesi's submission that it had done a Google search using the term 'Fostair Chiesi' and clicked on the first three search results which related to its respiratory website (screenshots provided). According to Chiesi, all three led to a pop-up box which sought confirmation, by way of a self-declaration, that the proposed visitor was a health professional before being able to view the webpage. The Panel did not consider that the complainant had provided evidence to show that a Google search for 'Fostair Chiesi' took browsers straight to the product page without a health professional declaration and therefore advertised prescription only medicines to the public as alleged. The Panel therefore ruled no breach of Clause 26.1.

The Panel noted its rulings of no breach of Clause 26.1 in relation to both the Google search and the patient/carer webpage and did not consider that Chiesi had failed to maintain high standards or brought discredit to, or reduced confidence in, the industry in that regard and no breach of Clauses 9.1 and 2 were ruled.

The Panel noted the complainant's concern that including carers within the patient/carers section was vague and needed further definition. The Panel noted Chiesi's submission regarding the Oxford Dictionary definition of 'carer' and considered that it was clear from both the homepage and patient/carer webpage that 'carer' referred to a carer of a patient prescribed a Chiesi Limited product for asthma or COPD. The Panel therefore did not consider the use of the term 'carer' was vague as alleged and ruled no breach of Clause 9.1 in that regard.

The Panel noted the complainant's allegation that there were many videos across the respiratory website which were out-of-date and specifically referred to two videos, namely 'Fostair an expert opinion' and 'The potential benefits of using a single inhaler for COPD to deliver triple therapy compared to single inhalers' and, in this regard, referred to their date rather than content. The Panel noted Chiesi's submission that the two identified videos had been approved in August 2018 and reapproved on 1 July 2020.

The Panel further noted that a spreadsheet had been provided by Chiesi, which detailed all twenty-eight videos on the website, together with their dates of preparation and dates of approval/reapproval and noted that none of them appeared to be out-of-date as alleged. The Panel noted that it did not have before it the certificates for the videos other than the two above specifically identified by the complainant. The Panel considered that the complainant had not established that any of the videos on the website were out-of-date as alleged and therefore, based on the evidence before it, ruled no breach of Clause 7.2 in relation to each video on the website.

The Panel noted Chiesi's submission that the speaker in the 'Fostair, an expert opinion' video was giving her expert opinion on the Nexthaler product in isolation and emphasised the positive aspects of its design when he/she stated 'With Nexthaler they're not fiddling around, shaking and pulling things off, so that's really positive'. The Panel noted that the speaker's expert opinion nonetheless had to comply with the Code. The Panel disagreed with Chiesi's submission that there was no reference, express or implied, to other products. The Panel noted

that according to the transcript provided by Chiesi, the video started by stating that 'At the moment the marketplace for both Asthma and COPD is really busy in terms of all the new options we've got. So when we're deciding what we need to use for patients, we have to consider the right medication in the right device for the right patient. The NEXThaler helps us because it gives us yet another option when we're treating patients and dealing with patients in offering them a device that not only delivers the medication they need but also gives them forms of feedback'. The video went on to refer to the importance of having options when treating patients and stated 'When it comes to teaching devices or using devices, a lot of the studies show us that both patients can't use them correctly and healthcare professionals can't use them correctly. The evidence for that seems to be that the more steps you have in terms of using the inhaler, the more complicated it becomes, the more likely people forget. So if you can keep it simple, then it works. When you're looking at the NEXThaler, what you've got is something that's simple to open that loads it. You've got feedback in terms of the delivery of the medication. You've got your dose counter. So it's simple for patients but it's also simple for the healthcare professionals who are the ones who are going to prescribe and to show the patients how to use it'.

The Panel considered that, on balance, within the context of the entire video, the statement at issue 'With Nexthaler they're not fiddling around, shaking and pulling things off, so that's really positive.' could be seen as comparative. There was an implication that the absence of 'fiddling around, shaking and pulling things off' was a positive difference between Nexthaler and comparator products and that such other products might be more complicated to use affecting compliance. In that regard, the Panel considered that the statement in question was disparaging those alternative inhalers and a breach of Clause 8.1 was ruled.

The complainant had alleged that in the same video, the sentence 'Nexthaler fits in with BTS guidelines and what we should be giving' was a strong, unbalanced endorsement as many other products would fit that criteria and were not mentioned. The Panel noted Chiesi's submission that the speaker had given his/her expert opinion about the Nexthaler product and did not refer to other products or suggest in any way that they would not fit the criteria. The fact that he/she did not mention other products did not render the statement unbalanced. Further, the statement was made to encourage prescribing in line with the BTS Guidelines, and reference to Nexthaler was to let the audience know that it would be in line with the guidelines.

The Panel considered the full context in which the statement in question was made. The speaker/transcript stated 'Guidelines are always going to be important when we're considering what we're prescribing, so we'll have national guidance which will give us a **range of options**, but then we'll have our local and our area guidance, which is usually made up between primary and secondary care clinicians so that we're prescribing what's appropriate for patients, but also thinking about continuity for them. When we look at BTS guidelines for both asthma and we have the sign BTS ones for that, then the NEXThaler fits in with their guidance in terms of our prescribing and what we should be giving'. The Panel did not consider that the statement at issue 'Nexthaler fits in with BTS guidelines and what we should be giving' was an unbalanced endorsement as many other products which were not mentioned would fit that criteria as alleged. In the overall context of the video, it was clear that there were a range of options and in the opinion of the Panel, there was no implication that the BTS guidelines endorsed Nexthaler in preference to other products. The Panel did not consider the statement misleading as alleged and ruled no breach of Clause 7.2.

The Panel noted that the case preparation manager had raised Clause 28.3 which required that information about medicines covered by Clauses 28.1 and 28.2 which was provided on the Internet and which was intended for members of the public must comply with Clause 26.2. Chiesi, however, in its response summary denied a breach of Clause 28.2. In the Panel's view, Chiesi had, within its response, nonetheless responded in relation to the requirements of Clause 28.3 and therefore the Panel considered this matter under that clause. The Panel noted its rulings of no breaches of the Code in relation to material for health professionals and material for the public as set out above and therefore ruled no breach of Clause 28.3.

The Panel noted its comments and rulings above including a breach of Clause 8.1 and considered that, on balance, Chiesi had failed to maintain high standards and a breach of Clause 9.1 was ruled.

The Panel did not consider that the specific circumstances of this case warranted a ruling of a breach of Clause 2 which was a sign of particular censure and reserved for such use and no breach of Clause 2 was ruled.

APPEAL FROM CHIESI

Chiesi appealed the Panel ruling of a breach of Clauses 8.1 and 9.1 of the Code as follows.

Clause 8.1

Subjectivity

The Panel was concerned with the following extract of the video entitled 'Fostair, an expert opinion':

'When we show patients inhalers, we get really good feedback from them in terms of they like it because it feels right. So the NEXThaler is nice and chunky. So it's a really solid device. So they like that. They like the ease with which it opens and closes and that loads it, which makes it easier for them. So they're not fiddling around. Shaking pulling things off. So, that's really positive.'

Chiesi noted that the Panel had concluded that, in the context of the entire video, the statement could be seen as comparative and that there was an implication that the absence of 'fiddling around, shaking and pulling things off' was a positive difference between NEXThaler and comparator products and that such other products might be more complicated to use affecting compliance. Chiesi submitted that it respectfully disputed this conclusion as it did not consider that this video was comparative to any specific comparator product or device, either directly or indirectly. As the Panel itself identified, there was no direct mention of any competitor, or comparator product, in either the extract or the remainder of the video. Instead, the video was an expert clinical opinion based on the attributes of one single device in isolation, and therefore by definition could not be considered a comparison with competitor products or devices.

Chiesi submitted that even if, which was not accepted, the statement was comparative, this was highly subjective and it represented a significant extrapolation for the Panel to imply that this meant other products were 'complicated to use affecting compliance'.

Chiesi noted that Clause 8.1 stated: 'The medicines, products and activities of other pharmaceutical companies must not be disparaged', and the supplementary information to Clause 8.1 referred to '...critical references to another company's products...'. The clause however did not reference indirect comparison. Importantly in the video there was no reference at any point to either medicines, products or activities of any pharmaceutical company, and therefore Chiesi submitted that it could not be disparaging of any specific comparator or competitor when one was not specifically mentioned.

Chiesi submitted that the dictionary defined disparaging was: 'meant to belittle the value or importance of someone or something: serving or intended to disparage someone or something'. Similar to Clause 8.1, this referred to the requirement to reference 'something' or 'someone' in order to be able to be disparaging. In this situation neither a specific company, nor activity and/or material was referenced and therefore, by definition, it could not be considered as disparaging. The definition also required intent, and there was clearly no intent to disparage.

Chiesi submitted that Clause 1 allowed the promotion of medicines, and should an expert clinical opinion based on the attribute of one single device in isolation be considered to be comparative and/or disparaging, then this would have significant ramifications for the promotion of medicines across the industry and prevent promotion of the benefits of any medicine.

Substantiation

Chiesi noted that Clause 8.1 stated: 'Provided that ... critical references to another company's products were accurate, balanced, fair etc., and could be substantiated, they were acceptable under the Code'. The Panel did not question whether the statement in issue could be substantiated and there was no evidence that the Panel considered this.

Chiesi submitted that should the statement be considered to be comparative, something it disputed, the statement was capable of substantiation. Voshaar *et al* (2014), demonstrated that NEXThaler was superior to two other dry powder inhaler devices (Diskus and Turbohaler), in terms of the number of device failures ($p < 0.001$), time to set up ($p < 0.001$) and time to read the instructions for use ($p < 0.001$). In addition, the proportion of participants who completed a successful inhalation without any errors at all was significantly higher for NEXThaler ($p < 0.001$), and patients rated NEXThaler as the easiest to use and most preferred inhaler ($p < 0.001$).

Dismissiveness

Chiesi submitted that ease of administration was a large part of inhaler and health professional/patient choice, as well as impacting significantly on patient adherence and disease control. In the video in question the speaker, a national and reputable expert, provided his/her opinion regarding the benefits of the NEXThaler device in isolation, with no reference to competitor medicines or devices. In concluding that he/she was disparaging in his/her description of the NEXThaler the Panel had, in Chiesi's view, dismissed the relevance and importance of his/her expert opinion.

Consistency

Chiesi submitted that the ruling of a breach of Clause 8.1 was inconsistent with the decisions made by the Panel in a number of other similar cases described below and Chiesi welcomed the Appeal Board's review and comparison for reasons of consistency in approach and rulings.

- i) Case AUTH/2834/4/16: The Panel did not accept that a claim: 'Lustrate: simple and easy to administer' was a comparison. In the case report, mention was made of the fact there was no reference to a competitor product, Prostag DCS. It was also noteworthy that, in that case, the Panel stated that 'Readers would not necessarily interpret the claim as being that Lustrate was at least as simple and easy to administer as Prostag. The Panel ruled no breaches of the Code.' Chiesi submitted that it believed that this case was very similar in a number of ways to the discussion of the benefits of the NEXThaler device in isolation with no reference to any competitor medicines or devices in the current case.
- ii) Case AUTH/2822/2/16: The Panel did not accept that a claim 'superior reduction in clinically relevant bleeding vs well-controlled warfarin' was a comparison with other medicines within the class other than warfarin, and concluded that the claim did not imply a head-to-head comparison where one did not exist. Therefore, the Panel did not consider the claim had disparaged a specific competitor. Chiesi submitted that this was a relevant case, as similarly Chiesi did not imply a comparison with any competitor medicine or device.
- iii) Case AUTH/3364/6/20: The Appeal Board ruled that 'reference to distribution would not lead members of the public to consider that this related to imminent distribution' and that reference to 'potential vaccines' did not imply 'research success'. Again, Chiesi submitted this was a case worthy of consideration as the Appeal Board deemed the LinkedIn post to be factual, and did not consider that mention of facts in isolation (such as distribution or potential vaccines) could be automatically extrapolated to imply timings. Similarly, in the video in question, Chiesi did not believe that the mere mention of facts/benefits related to NEXThaler in isolation could be automatically implied as a comparison with any competitor medicine or device.

Chiesi submitted that as a general proposition, rulings under Clause 8.1 were made because of a specific derogatory or disparaging comparison against another medicine, product or activity. In the video in question, no competitor medicine, product or activity were either mentioned or belittled. Finally, Clause 8.1 and its supplementary information did not provide a great deal of guidance on the application of the clause in practice. Where circumstances left this open to interpretation any discretion should be exercised in the respondent's favour.

Clause 9.1

Chiesi submitted that if its appeal in respect of Clause 8.1 was successful then it must follow that its appeal against the ruling relating to Clause 9.1 would also succeed.

Proportionality

Chiesi submitted that only one issue was identified by the Panel as worthy of a breach during a review of the original complaint (out of a possible 10 breaches alleged), however the Panel still went on to rule that Chiesi did not maintain high standards on the basis of this single proposed breach. Chiesi submitted its appeal the ruling of a breach of Clause 9.1 on the grounds that:

- i) Chiesi did not consider that any competitors, whether directly or indirectly, had been disparaged within the video.

- ii) The complaint related to one statement made as part of a 5 min 34s video, and therefore did not proportionately relate to the content of the whole video being considered in breach of the Code.
- iii) The video in question was approved appropriately and remained within date.

Chiesi submitted that taking into account the single statement made within the content of an in-date video, and the fact that it had disputed that the statement was disparaging, it had maintained high standards and therefore that the Panel ruling of a breach of Clause 9.1 was disproportionate.

In summary, for the reasons stated above, Chiesi appealed against both Panel rulings in breach of Clauses 8.1 and 9.1.

COMMENT FROM THE COMPLAINANT

The complainant did not want to be involved in the appeal process.

APPEAL BOARD RULING

The Appeal Board noted that the supplementary information to Clause 8.1 stated that much pharmaceutical advertising contained comparisons with other products and, by the nature of advertising, such comparisons were usually made to show an advantage of the advertised product over its comparator. Provided that such critical references to another company's products were accurate, balanced, fair etc, and could be substantiated, they were acceptable under the Code.

The Appeal Board noted the submission from the Chiesi representatives at the appeal that the video at issue, entitled 'Fostair, an expert opinion', had been reviewed before it was published and if anything had been detected that it considered was not in line with the requirements of the Code, the relevant part would have been edited out.

The Appeal Board noted that the video discussed patient options and, according to Chiesi, the statement at issue 'With Nexthaler they're not fiddling around, shaking and pulling things off, so that's really positive' concerned one of many characteristics of an inhaler and this was a subjective assessment. The Appeal Board considered that, on balance, within the context of the entire video, the statement at issue could be seen as comparative to other inhalers, noting that the preceding sentence included '...they like the ease with which it opens and closes and that loads it which makes it easier for them'. The Appeal Board considered there was a fine line between stating a positive feature of one medicine and disparaging another, which might not have that feature.

The Appeal Board noted the submission from Chiesi that if the statement at issue was considered to be comparative, then data from Voshaar *et al* provided for the appeal, and which was not before the Panel, substantiated it. In that study, asthma patients, previously naïve to dry powder inhalers, each used NEXThaler, Diskus and Turbuhaler and then were asked a series of questions. The two questions which Chiesi submitted which would substantiate the statement were 'Which inhaler did you find easiest to open, prepare, and set a dose with?' (80.3% preferred NEXThaler) and 'OVERALL, which inhaler did you find easiest to use?' (74.2% preferred NEXThaler).

The Appeal Board noted its comments above and the data submitted for the appeal. The Appeal Board noted that the language used by the speaker was different to the language used in Voshaar *et al.* Nonetheless, whilst the Appeal Board considered that the language used by the speaker was unfortunate, it did not consider that the statement in question disparaged the alternative inhalers as alleged and no breach of Clause 8.1 was ruled. Consequently, the Appeal Board ruled also ruled no breach of Clause 9.1. The appeal on both points was successful.

Complaint received **23 October 2020**

Case completed **16 September 2021**