CASE AUTH/3386/9/20 *NO BREACH OF THE CODE*

HEALTH PROFESSIONAL v GLAXOSMITHKLINE

Alleged promotion of low carbon inhalers to the public

An anonymous health professional complained about a website regarding low carbon inhalers produced by GlaxoSmithKline UK Limited.

The complainant stated that the wording on the website intended for the public was all in relation to discussions with the treating health professional about inhaler choice. The first statement underneath the 'what can you do section' read: 'Discuss with your nurse, doctor or pharmacist whether a low carbon inhaler is appropriate for you'. The complainant alleged that patients were thus being encouraged to speak to their health professionals about their treatments which might well result in a change to a specific treatment.

The complainant alleged that the webpage disparaged the use of a pressurised metered dose inhaler (pMDI) and was not fair and balanced. For example, there were big, emboldened headlines such as 'A high carbon MDI inhaler has a carbon footprint that is 18x higher than a low carbon DPI [dry powder inhaler] inhaler'. However, there was no balanced detail of some of the reasons why a pMDI might be preferred to a DPI by patients such as ability to use the devices or patient choice (eg spacer). The webpage was one-sided and did not take into account patient choice or other factors in choosing appropriate devices which could cause patients to lose control of their disease and drive patients to ask their health professionals for a specific device.

The complainant alleged that a lot of statements amounted to product claims as opposed to factual information, for instance, 'Do you think about your inhaler's carbon impact?'.

The complainant noted that there was no adverse event reporting box identified on the page.

The complainant noted that a statement, 'Use this decision aid with your doctor or nurse to choose the right inhaler for you', linked to a patient decision aid from the National Institute for Health and Care Excellence (NICE) and page 3 of which showed a GlaxoSmithKline Ellipta device amongst other inhalers. The complainant alleged that this was disguised promotion of a GlaxoSmithKline product.

The guide also discussed many of the important factors needed when choosing a device so it was not aligned to the content on the webpage itself which was heavily focused on carbon footprint and nothing else. In the complainant's view, the webpage could not be classed as disease awareness as there was no mention of symptoms etc but merely all around products (indirect mentions) and as GlaxoSmithKline had inhaler devices including a heavy interest in DPIs, the complainant was concerned as to whether the website was simply for promoting its products to patients.

The complainant alleged that the website was not appropriate for the general public, let alone patients, as it simply put a great deal of emphasis on being positive towards DPIs asking for patients to potentially get their inhaler changed.

The complainant noted that references/links at the bottom of the page took readers to other websites but there was no pop-up to let readers know they were going to another webpage. The complainant alleged that high standards had not been met on a website aimed at members of the public/patients.

The detailed response from GlaxoSmithKline is given below.

The Panel noted that the webpage included a link to a patient decision aid from the National Institute for Health and Care Excellence (NICE) and stated 'Use this decision aid with your doctor or nurse to choose the right inhaler for you'. A link to the inhaler decision aid user guide also appeared beneath followed by the statement 'Do not stop using your inhaler. Always talk to your doctor, nurse or pharmacist for advice about your inhaled medication' in capital letters in bold black font. Below this the webpage described the carbon footprint of pMDIs and DPIs. Near the bottom of the webpage it stated, in bold black font, 'MDIs/sprays may still be the appropriate option for some patients. Please consult your doctor, nurse or pharmacist to discuss which inhaler is best for you'.

The Panel noted that the website landing page provided by GlaxoSmithKline did not mention a specific prescription-only medicine and noted GlaxoSmithKline's submission that the website itself did not mention any specific inhaler or medicine. The Panel noted GlaxoSmithKline's submission that there were numerous low carbon inhalers available in the UK from a variety of manufacturers and included all inhalers that were not driven by propellant. The Panel noted that the NICE patient decision aid, to which users of the website were directed, included 10 different DPIs; two were manufactured by GlaxoSmithKline (Accuhaler and Ellipta) and the other eight were produced by other manufacturers. Six of these 10 DPIs (including Accuhaler and Ellipta) had a small picture of the device whilst the other four just listed the device name. The Panel further noted that the NICE decision aid in question listed 'That my inhaler has a low carbon footprint' as one of the five factors that patients should think about when discussing with their health professional which type of inhaler might be appropriate. The NICE patient decision aid also discussed other important factors needed when choosing a device. The accompanying NICE patient decision aid user guide explained that the decision aid was not an evaluation of the medicines and devices available; it did not provide guidance on the choice of medicine – this should be discussed and decided prior to using the aid.

The Panel noted that the website was aimed at members of the public; the header of the webpage stated 'This GSK site is intended for UK Members of the Public. The Panel considered that the reference to DPIs on the website and within the NICE decision aid could be to any one of a number of different inhalers available. In the Panel's view, the website in question did not promote prescription-only medicines to the general public nor did it encourage readers to ask their health professional for a specific prescription-only medicine. No breaches of the Code were ruled.

In the Panel's view, the website was non-promotional and thus it could not be disguised promotion. No breach of the Code was ruled.

The Panel noted the complainant's concern that the references/links at the bottom of the page took readers to other websites but there was no pop-up to let readers know they were going to another website. In the Panel's view, it was sufficiently clear from the description of the item coupled with the URL that each of the reference links took the reader to the relevant third party websites/documents. The Panel therefore ruled no breach of the Code.

In the Panel's view, as the material at issue was not intended specifically for patients taking a specific prescription-only medicine, a statement about reporting side-effects was not required. The Panel therefore ruled no breach of the Code. The Panel, however, noted GlaxoSmithKline's submission that the webpage included a link to 'Report an adverse event' at the bottom of the page which took users to a form to complete that went directly to the safety department.

The Panel noted its rulings above and considered that there was no evidence to show that GlaxoSmithKline had not maintained high standards. No breach of the Code was ruled including of Clause 2.

An anonymous health professional complained about a website, https://lowcarboninhalers.co.uk/public (ref NP-GB-RS-WCNT-190008 November 2019) produced by GlaxoSmithKline UK Limited.

COMPLAINT

The complainant noted that Clause 26.2 stated that statements must not be made for the purpose of encouraging members of the public to ask their health professional to prescribe a specific prescription-only medicine.

The complainant stated that the wording on the website intended for the public was all in relation to discussions with the treating health professional about inhaler choice. The first statement underneath the 'what can you do section' read: 'Discuss with your nurse, doctor or pharmacist whether a low carbon inhaler is appropriate for you'. The complainant alleged that patients were thus being encouraged to speak to their health professionals about their treatments which might well result in a change to a specific treatment.

The complainant stated that information given to patients/public should be factual but alleged that the content on the webpage disparaged the use of a pressurised metered dose inhaler (pMDI) and was not fair and balanced. For example, there were big, emboldened headlines such as 'A high carbon MDI inhaler has a carbon footprint that is 18x higher than a low carbon DPI [dry powder inhaler] inhaler'. However, there was no balanced detail of some of the reasons why a pMDI might be preferred to a DPI by patients such as ability to use the devices or patient choice (eg spacer). The complainant alleged that the entire webpage was one-sided and did not take into account patient choice or other factors in choosing appropriate devices which could cause patients to lose control of their disease and drive patients to ask their health professionals for a specific device.

The complainant alleged that a lot of statements amounted to product claims as opposed to factual information, for instance, 'Do you think about your inhaler's carbon impact?'. The complainant noted that Clause 26.2 also stated that information about prescription-only medicines, which was made available to the public either directly or indirectly, must be factual and presented in a balanced way.

The complainant noted that there was no adverse event reporting box identified on the page either as per Clause 26.3: 'Any material which relates to a medicine and which is 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 linked directly to the MHRA Yellow Card site]'.

The complainant noted that the webpage had a statement for the user which read 'Use this decision aid with your doctor or nurse to choose the right inhaler for you'. When this decision aid was clicked, it took the reader to a patient decision aid from the National Institute for Health and Care Excellence (NICE) and on page 3 of 14, an Ellipta device was shown amongst other inhalers which was a GlaxoSmithKline device. The complainant alleged that this was the disguised promotion of a GlaxoSmithKline product (as GlaxoSmithKline had linked to this decision aid), in breach of Clause 12.1.

The guide also discussed many of the important factors needed when choosing a device so it was not aligned to the content on the webpage itself which was heavily focused on carbon footprint and nothing else. In the complainant's view, the webpage could not be classed as disease awareness as there was no mention of symptoms etc but merely all around products (indirect mentions) and as GlaxoSmithKline had inhaler devices including a heavy interest in DPIs, the complainant was concerned as to whether the website was simply for promoting its products to patients. The complainant noted that the Code stated that companies could conduct disease awareness or public health campaigns provided that their purpose was to encourage members of the public to seek treatment for their symptoms while not promoting the use of a specific medicine.

The complainant did not consider that the website was appropriate for the general public, let alone patients, as it simply put a great deal of emphasis on being positive towards DPIs asking for patients to potentially get their inhaler changed.

The complainant alleged breaches of Clauses 26.1, 26.2, 26.3, 28.6 and 9.1. The complainant noted that references/links at the bottom of the page took readers to other websites but there was no pop-up to let readers know they were going to another webpage as per Clause 28.6. It should be made clear when a user was leaving any of the company's sites, or sites sponsored by the company, or was being directed to a site which was not that of the company. The complainant alleged that high standards had not been met on a website aimed at members of the public/patients.

When writing to GlaxoSmithKline, the Authority asked it to consider the requirements of Clauses 2, 9.1, 12.1, 26.1, 26.2, 26.3 and 28.6 of the Code.

RESPONSE

By way of background, GlaxoSmithKline explained that in April 2019, NICE published a new decision aid 'to encourage the use of greener inhalers'. This marked the first time that health professionals were encouraged to speak with patients about the carbon footprint of inhalers when considering their treatment options.

The decision aid followed the publication of the NHS Long Term Plan, in January 2019, which committed to reducing carbon emissions from inhalers. NHS England had previously committed to reducing its emissions by 34% by 2020 in response to updated targets set by the Montreal Protocol in 2017 and, as part of the long-term carbon reduction, ambitions for the UK set out in the Climate Change Act of 2008 (web link provided).

The NHS Sustainable Development Unit (SDU) first formally reported on the carbon footprint of the NHS in 2016 with a recognition that inhalers formed a significant part of emissions from the procurement of goods and services analysis (web link provided).

As part of the Environmental Audit Committee F-gas inquiry 2017/18, the SDU confirmed that MDIs made up approximately 3.5% of NHS emissions. In response, the government agreed that low global warming potential (GWP) inhalers should be promoted in the NHS (web link provided).

GlaxoSmithKline stated that it built the low carbon inhaler website in question in response to the urgent need to reduce carbon emissions in the NHS. The website was created to provide factual information for the public on the carbon footprint of the two broad categories of inhalers; pressurised metered dose inhalers (pMDIs) and dry powder inhalers (DPIs). pMDIs were the most commonly prescribed inhalers in the UK and were propelled by hydrofluorocarbons which were powerful greenhouse gases. According to NICE, pMDIs had estimated carbon footprints of 500g CO_2eq per dose, compared with 20g in DPIs. For context, the NICE decision aid analysis showed that six doses of an MDI had a higher carbon footprint than an average trip (nine miles) in a typical car.

The NHS Long Term Plan aimed for a shift to low carbon inhalers to deliver a 4% reduction in carbon footprint and this ambition had been supported by professional bodies and patient groups. For example, The British Thoracic Society (BTS) changed its asthma guidance to encourage all prescribers and patients to consider switching pMDIs to DPIs whenever they were likely to be equally effective. The patient organisation, the British Lung Foundation, advocated talking to a health professional if using an MDI to see if changing inhalers was suitable (web link provided).

GlaxoSmithKline considered that with the stated international, government and NHS ambitions, with change supported by the clinical and expert community, its website provided a helpful source of information and considerations for health professionals and patients.

There were numerous low carbon inhalers available in the UK from a variety of manufacturers and included all inhalers that were not driven by propellant. GlaxoSmithKline noted that the NICE decision aid, that was linked to from the website, included 10 different DPIs.

GlaxoSmithKline submitted that the website itself did not promote any prescription only medicine but provided accurate and factual information relating to the carbon footprint of the two categories of inhalers described above and advised readers to consult their health professionals to determine whether a low carbon inhaler was appropriate for them. This was in line with the

advice from NICE which listed 'That my inhaler has a low carbon footprint' as one of the five elements that should be considered when determining which type of inhaler might be appropriate. There was no information on the website related to efficacy, or which specific medicines were supplied in which specific inhalers, nor did the website advocate the use of a particular device. GlaxoSmithKline submitted that referring to a class of medicines which included multiple medicines had been found not in breach (Case AUTH/3308/2/20) and the website took one step further back and described only the two broad categories of inhalers.

GlaxoSmithKline stated that it took patient safety extremely seriously. The webpage was balanced and was mindful to advise patients not to stop using their inhalers, but to consult their health professionals about their inhaler choice and to remind them that a less green inhaler might still be the right option for some patients.

GlaxoSmithKline stated that it marketed both types of inhalers, pMDIs (Evohaler) and DPIs (Accuhaler and Ellipta) covering multiple products. Flixotide, Seretide, Serevent and Ventolin were available via both the Evohaler device and the Accuhaler and there were four different medicines available via the Ellipta device; Anoro, Incruse, Relvar and Trelegy. It should be recognised that many companies provided both pMDIs and DPIs and there were options for patients across all classes of medicine, both for prevention and for maintenance therapy. Market data showed, and as reported by the Environmental Audit Committee, that the UK had a higher proportion of prescribed pMDIs than comparable countries (weblink provided). In its evidence, the SDU went on to state that MDI error rates meant that clinical benefits could be achieved by the use of dry powder inhalers. As such, GlaxoSmithKline believed it was responsible to support the non-promotional education of health professionals and patients on the options available, in support of improved patient care in the NHS.

GlaxoSmithKline noted that the website was reviewed and certified as educational material for the public.

GlaxoSmithKline was pleased that the complainant acknowledged the website clearly directed users to discuss with their health professionals whether a low carbon inhaler was appropriate for them. Encouraging patients to discuss their treatment options with their health professionals was responsible and appropriate and ensured patients were given the most appropriate advice. The Guidelines on Disease Awareness Campaigns (DACs) from the Medicines and Healthcare products Regulatory Agency (MHRA) stated that 'DACs are concerned with providing information, promoting awareness or educating the public about health, diseases and their management' and 'the main objective for DACs is to encourage people to take appropriate steps, which may include seeking advice from appropriate healthcare professionals'. It was thus clear it was not just an acceptable practice for pharmaceutical companies to encourage the public to consult with their healthcare providers, but it was positively recommended. The website itself did not mention any specific inhaler or medicine but provided accurate and factual information relating to the carbon footprint of the two broad categories of inhalers, pMDIs and DPIs. During a consultation, a health professional and patient together might well decide to change treatment. Neither the website nor the associated link to the NICE decision tree advocated any specific medicine to be prescribed but made very clear that a number of factors should be considered when determining inhaler choice on a patient-by-patient basis.

GlaxoSmithKline refuted the alleged breaches of Clauses 26.1 and 26.2 as the website did not promote a specific prescription only medicine to the public, and all information was both factual and presented in a balanced way. Similarly, it did not raise unfounded hopes of success nor did

it mislead with respect to safety. Statements were not made to encourage the public to ask for a specific medicine.

GlaxoSmithKline submitted that it was clear that the website and webpage in question were about low carbon inhalers. They did not purport to be about the entire topic of inhalers, or to discuss why some people might prefer one inhaler over the other, but, in large black font, the page made it clear that 'MDIs/sprays may still be the appropriate option for some patients. Please consult your doctor, nurse or pharmacist to discuss which inhaler is best for you'.

The complainant provided no evidence that the 18x higher figure was not factual nor evidence that patients were losing control of their disease. Estimates of the difference between the carbon footprint of an MDI and DPI varied, but the NICE aid suggested it could be as high as 25 times (20g to 500g CO2e). GlaxoSmithKline used the 18 times figure as it was used in the BTS Environment and Lung Health publication and therefore might be best understood by health professionals.

GlaxoSmithKline stated that it took patient safety extremely seriously and repeatedly advised users to talk to their health professionals and had 'Do not stop using your inhaler. Always talk to your doctor, nurse or pharmacist for advice about your inhaled medication' in bold capital letters towards the top of the page.

GlaxoSmithKline submitted that it was not disparaging to provide negative information provided that it was capable of substantiation, which this was. The Government, NHS, NICE and BTS all recognised the need to reduce the country's carbon footprint and one way that GlaxoSmithKline could have a positive impact on that was to move to low carbon inhalers when clinically appropriate to do so. Providing the public with factual information about the comparative carbon footprints of the different categories of inhaler and advising them to discuss their choices of inhaler with their health professionals in accordance with NICE recommendations, was a responsible public health initiative. The Code allowed for the provision of accurate, factual, balanced information for the public as long as it did not promote a specific medicine.

GlaxoSmithKline noted that the complainant had provided no evidence that patients would ask their health professionals for a specific device as no specific devices were promoted. The two broad categories of devices were covered – the pMDIs (propellant driven metered dose inhalers (which had a higher carbon footprint than DPIs)) and DPIs (dry powder inhalers) – but no specific medicine or device was mentioned directly or indirectly. The webpage referred in general to DPIs with the headline 'There are many different shapes and types of low carbon inhalers, collectively known as DPIs (dry power inhalers[sic])' and provided thumbnail icons of different inhaler types marketed by different companies. Thus, the patient might ask for a 'greener inhaler' or a 'low carbon footprint inhaler' or 'a dry powder inhaler' but all of those descriptions applied to numerous different inhalers and therefore no specific medicine had been promoted. GlaxoSmithKline noted that many companies produced DPIs and there were 10 different named devices on the NICE patient decision aid.

GlaxoSmithKline refuted the alleged breach of Clause 26.2 as, in its view, the webpage provided factual and balanced information about broad categories of inhalers not specific prescription-only medicines.

GlaxoSmithKline stated that there were no product claims on the webpage. The example the complainant used, 'Do you think about your inhaler's carbon impact?', was a question related to

inhalers in general, not any specific product. GlaxoSmithKline agreed information about prescription-only medicines must be factual and presented in a balanced way and was confident the information provided about the carbon footprints of various different types of inhaler was both factual and balanced. The webpage did not relate to a specific prescription-only medicine but was important information relevant to all inhalers.

GlaxoSmithKline refuted the allegation of a breach of Clause 26.2 as the information was factual and presented in a balanced way.

With regard to the reporting of adverse events, GlaxoSmithKline stated that Clause 26.3 stated 'Any material which relates to **a** medicine and intended for patients taking **that** medicine must include…' (emphasis added). As the webpage did not relate to a particular medicine, and neither was it intended specifically for patients taking a particular medicine, the requirement to include the statement about the reporting of side-effects was not triggered. However, as GlaxoSmithKline took patient safety very seriously, and was always keen to encourage the reporting of adverse events, the webpage included a link to 'Report an adverse event' at the bottom of the page which took users to a form to complete that went directly to the safety department.

GlaxoSmithKline refuted an alleged breach of Clause 26.3 as the webpage at issue did not relate to a specific medicine.

With regard to allegation of disguised promotion, GlaxoSmithKline stated that when users clicked through to the NICE decision aid, page 3 had a table with thirteen different inhalers listed in it. Ten of those were DPIs, one of which was the Ellipta device. As with all the inhalers featured in the table, details of brand name, dosing, number of doses etc was omitted. This page did not promote Ellipta but was a balanced and factual table of inhalers commonly available in the UK. No special preference or highlighting was given to Ellipta and it was not given any undue prominence. As such, it was not promotional for Ellipta and so could not be disguised promotion. The decision aid was clearly branded as NICE – GlaxoSmithKline obtained permission from NICE to reference and to link to the aid. NICE stated in its press release of April 2018 'Cutting carbon emissions was good news for everyone, especially those with respiratory conditions'.

GlaxoSmithKline refuted the allegation of breach of Clause 12.1 as it was not promotional material. As such, it could not be disguised.

GlaxoSmithKline submitted that it was clear that the sole purpose of the website was to cover the issue of the carbon footprint of inhalers. It was called 'lowcarbon inhalers.co.uk'. The linked page provided useful further information for patients to help them with their health professionals make an informed decision about which inhaler they might like to try, and carbon footprint was one of the factors NICE listed as requiring consideration.

In GlaxoSmithKline's view, this information was within the scope of a public health campaign as climate change affected us all and gave rise to an enormous burden of respiratory disease. Just like manufacturers helped in the campaign to switch all MDIs to chlorofluorocarbon (CFC)-free MDIs in the early 1990s and provided information for patients and public as to why this was happening, so this campaign helped to take those next steps in reducing inhaler carbon footprint further where clinically appropriate and in consultation with a health professional. The page made clear the pMDIs usually had a higher carbon footprint than DPIs but it did not advocate

changing to any specific DPI of the numerous ones there were to choose from shown in the NICE patient decision aid. Promoting informed discussions with one's health profession sought to improve patient outcomes whilst trying to reduce the carbon footprint for the benefit of us all. This webpage was aligned with NICE guidance, the NHS Long Term Plan and the BTS, giving the public the basic facts about carbon emissions of their inhalers, suggesting they talk to their health professional about whether a low carbon inhaler would be appropriate for them. The webpage gave repeated clear guidance to consult with health professionals and that a pMDI might still be the appropriate option for some patients. Moreover, it linked directly to the NICE Decision Aid for patients which discussed further considerations of inhaler choice. The webpage also advocated correct inhaler usage (whatever inhaler was being used) and the NICE Decision Aid contained clear information on appropriate safe disposal and recycling.

GlaxoSmithKline stated that the complainant had provided no evidence of any promotion of medicines to the public. No medicines were mentioned directly or indirectly, there was no product branding and the webpage discussed DPIs in very general non-specific terms, including icons of most commonly used inhalers from different manufacturers to help patients recognise their current device.

GlaxoSmithKline denied breaches of Clauses 26.1 and 26.2.

With regard to the complainant's reference to Clause 28.6, GlaxoSmithKline noted that that clause mandated that it should be clear when a user was leaving a company site, but not that it must be via a pop-up. The four links provided had the full URL displayed after the title of the reference so it was clear that users were being directed to a non-GlaxoSmithKline site. Two were to NICE and both the references and the URLs made it clear they were NICE documents (ie they started with www.nice.org.uk/) and the NICE logo was clear at the top of the pdfs linked to. The third reference linked to a parliamentary report with a URL which started 'publications.parliament.uk' and the linked page had the famous portcullis logo and large title 'House of Commons Environmental Audit Committee', so readers could be in no doubt this was not a GlaxoSmithKline site. The final referenced link was to 'NHS Long Term Plan' and again the URL identified the NHS as the publisher and the landing page had a large NHS logo in the top left-hand corner. GlaxoSmithKline noted that the Panel had ruled no breach in comparable situations involving Twitter; Case AUTH/3162/2/19 where it was clear that the link took readers to the Heart Failure Society of America's webpage for Heart Failure Awareness Week even without a pop-up, and Case AUTH/3166/2/19 where the Panel considered that it would be clear to readers that a link was to the Independent Medicines and Medical Devices Safety (IMMDS) Review Twitter handle and not a pharmaceutical company site. Also, in Case AUTH/3308/2/20, the Panel noted that the list of references included the BTS/SIGN (Scottish Intercollegiate Guidelines Network) British Guideline on the Management of Asthma 2019. Available from: htt12s://www.britthoracic.org.uktguality-imwovemenVguidelines/asthma/ (Accessed September 2019). In the Panel's view, linking to a reference might be different to linking to a website, however, it was clear in that case that the link took readers to the BTS/SIGN guidelines.

GlaxoSmithKline refuted the alleged breach of Clause 28.6 as it was made clear when users were being directed to a site which was not that of the company by being explicit in the title of the references, the URL references and the linked pages had clear logos on the landing pages.

In summary, GlaxoSmithKline believed that, in response to the urgent need to reduce carbon emissions, with commitments from government, the NHS and professional bodies, it had provided a helpful and necessary educational website. GlaxoSmithKline, like all companies,

had a responsibility to reduce its carbon emissions and had a legitimate role to play in the solutions that government and the NHS proposed with regard to inhalers. GlaxoSmithKline was a member of the International Pharmaceutical Aerosol Consortium (IPAC) which was instrumental in moving from CFCs to hydrofluoroalkanes (HFAs) in inhalers which supported ambitious climate change targets in the 1990s and GlaxoSmithKline would work across industry to continue to take steps to reduce carbon emissions in the healthcare system.

In refuting the allegations of breaches of Clauses 12.1, 26.1, 26.2, 26.3 and 28.6, GlaxoSmithKline believed it had maintained high standards and thus it denied a breach of Clause 9.1.

GlaxoSmithKline stated that it took its obligations under the Code extremely seriously and considered information to the public and patient safety of the utmost importance. GlaxoSmithKline considered that the website in question provided relevant and valuable information for the public in a way that was compliant with the Code and therefore it denied a breach of Clause 2.

PANEL RULING

The Panel noted that there were differences between the pdf version of the material in question provided by the case preparation manager to GlaxoSmithKline when it was notified of the complaint and that provided by GlaxoSmithKline as part of its response. Each bore the same reference number. The Panel noted that the complainant had provided a link to the webpage in question from which it appeared that the case preparation manager had saved the relevant material and provided it to the company as a pdf. GlaxoSmithKline had not commented on the differences. The Panel noted that the differences included the layout, the omission of the heading 'The impact different inhalers have on the environment' from page 2 and the omission of the URL link within reference 7 from page 4 of the pdf provided by the case preparation manager to GlaxoSmithKline. The Panel noted the allegations and did not consider that these differences were such as to impact the Panel's rulings. Given that the complainant apparently provided a link to the webpage, the Panel decided to refer to the layout of the material as provided by GlaxoSmithKline.

The Panel noted GlaxoSmithKline's submission that it built the low carbon inhaler website in question in response to the urgent need to reduce carbon emissions in the NHS and that it provided factual information for the public on the carbon footprint of the two broad categories of inhalers; pressurised metered dose inhalers (pMDIs) and dry powder inhalers (DPIs); pMDIs were the most commonly prescribed inhalers in the UK and were propelled by hydrofluorocarbons which were powerful greenhouse gases.

The Panel noted that the website landing page was entitled '#LowCarbonInhalers' followed by 'How can your inhaler choices help to reduce your carbon footprint?'. The webpage noted that the UK government declared a 'climate emergency' on 1 May 2019 and asked 'Do you think about your inhaler's carbon impact?'. Readers were asked 'What can you do?'. Three answers, which were given equal prominence, included: discussing with their nurse, doctor or pharmacist whether a low carbon inhaler was appropriate for them; checking that they knew how to use their inhaler correctly to avoid medicine wastage; and returning their inhaler to any pharmacy for responsible disposal.

The Panel noted that the webpage then included a link to a patient decision aid from the National Institute for Health and Care Excellence (NICE) and stated 'Use this decision aid with your doctor or nurse to choose the right inhaler for you'. A link to the inhaler decision aid user guide also appeared beneath followed by the statement 'Do not stop using your inhaler. Always talk to your doctor, nurse or pharmacist for advice about your inhaled medication' in capital letters in bold black font. Below this the webpage described the carbon footprint of pMDIs and DPIs. The webpage included the prominent statement 'A high carbon MDI inhaler has a carbon footprint that is 18x higher than a low carbon DPI inhaler' accompanied by a large graphic illustrating this point. Near the bottom of the webpage it stated, in bold black font, 'MDIs/sprays may still be the appropriate option for some patients. Please consult your doctor, nurse or pharmacist to discuss which inhaler is best for you'.

The Panel noted that the website landing page provided by GlaxoSmithKline did not mention a specific prescription-only medicine and noted GlaxoSmithKline's submission that the website itself did not mention any specific inhaler or medicine. The Panel noted GlaxoSmithKline's submission that there were numerous low carbon inhalers available in the UK from a variety of manufacturers and included all inhalers that were not driven by propellant. The Panel noted that the NICE patient decision aid, to which users of the website were directed, included 10 different DPIs; two were manufactured by GlaxoSmithKline (Accuhaler and Ellipta) and the other eight were produced by other manufacturers. Six of these 10 DPIs (including Accuhaler and Ellipta) had a small picture of the device whilst the other four just listed the device name. The Panel further noted that the NICE decision aid in question listed 'That my inhaler has a low carbon footprint' as one of the five factors that patients should think about when discussing with their health professional which type of inhaler might be appropriate. The NICE patient decision aid also discussed other important factors needed when choosing a device. The accompanying NICE patient decision aid user guide explained that the decision aid was not an evaluation of the medicines and devices available; it did not provide guidance on the choice of medicine – this should be discussed and decided prior to using the aid.

The Panel noted that the website was aimed at members of the public; the header of the webpage stated 'This GSK site is intended for UK Members of the Public. Are you a Healthcare Professional? Visit our healthcare professional site'. The Panel considered that the reference to DPIs on the website and within the NICE decision aid could be to any one of a number of different inhalers available. In the Panel's view, the website in question did not promote prescription-only medicines to the general public nor did it encourage readers to ask their health professional for a specific prescription-only medicine. No breach of Clauses 26.1 and 26.2 were ruled.

In the Panel's view, the website was non-promotional and thus it could not be disguised promotion. No breach of Clause 12.1 was ruled.

The Panel noted that Clause 28.6 stated that it should be made clear when a user was leaving any of the company's sites, or sites sponsored by the company, or was being directed to a site which was not that of the company. The Panel noted the complainant's concern that the references/links at the bottom of the page took readers to other websites but there was no pop-up to let readers know they were going to another website. The Panel noted that there were eleven references listed on the webpage accessed via the link provided by the complainant which included four links to non-GlaxoSmithKline sites. The Panel noted GlaxoSmithKline's submission that the four links in question had the full URL displayed after the title of the reference so it was clear that users were being directed to a non-GlaxoSmithKline site. The

Panel noted that two links were to NICE documents and both the reference titles and the URLs referred to NICE. The third linked to a parliamentary report with a description that read 'EAC report-Progress on reducing F gases' followed by the URL which included 'publications.parliament.uk'. The fourth was entitled 'NHS Long Term Plan' and had an nhs.uk URL. The Panel noted that a fifth link to the article 'Which Inhalers are kindest to the environment' by the British Lung Foundation (2019) was included on the webpage provided by GlaxoSmithKline, this fifth link had a blf.org.uk URL. In the Panel's view, it was sufficiently clear from the description of the item coupled with the URL that each of the reference links took the reader to the relevant third party websites/documents. The Panel therefore ruled no breach of Clause 28.6.

The Panel noted that Clause 26.3 of the Code required a statement about reporting side-effects to be included on material which related to a medicine and was intended for patients taking that medicine. In the Panel's view, as the material at issue was not intended specifically for patients taking a specific prescription-only medicine, it was not required. The Panel therefore ruled no breach of Clause 26.3. The Panel, however, noted GlaxoSmithKline's submission that the webpage included a link to 'Report an adverse event' at the bottom of the page which took users to a form to complete that went directly to the safety department.

The Panel noted its rulings above and considered that there was no evidence to show that GlaxoSmithKline had not maintained high standards. No breach of Clause 9.1 was ruled.

Given its rulings above, the Panel ruled no breach of Clause 2.

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During the consideration of this case, the Panel noted that it accepted that certain differences may occur when material was made into a pdf versus how it might appear live on a website. The Panel was, nonetheless, concerned about the omission of the heading 'The impact different inhalers have on the environment' from the pdf version provided by the case preparation manager to GlaxoSmithKline and the differences between the two in the reference section including the differences in the URL address for the NHS Long Term Plan.

Complaint received **14 September 2020**

Case completed **19 February 2021**