CASE AUTH/3424/11/20 *NO BREACH OF THE CODE*

ANONYMOUS v GLAXOSMITHKLINE

Online articles about asthma inhalers

An anonymous, non-contactable complainant who described themselves as a health professional complained about an article in GP online which detailed how switching asthma inhalers could help the NHS cut carbon emissions. Above the title of the article, it was stated in the top left-hand corner of the webpage 'Sponsored by GSK' and the company's corporate logo appeared in the top right-hand corner. GlaxoSmithKline UK marketed a number of inhalers for the treatment of asthma.

The complainant stated that from the initial statement at the top of the article, he/she was under the impression that GlaxoSmithKline had only sponsored the article. However, having read further it was clear that it had had greater involvement in being sole funders and initiators of the article. There was a statement at the very bottom of the article, in small text, that it had been initiated, funded and reviewed by GlaxoSmithKline and produced by a named party.

The complainant noted that the article contained a link to the webpage lowcarboninhalers.co.uk/ for health professionals which seemed to be heavily biased towards dry powder inhalers. The complainant noted that the webpage included headline claims such as 'A high carbon MDI inhaler has a carbon footprint that is 18x higher than a low carbon DPI inhaler'. There were also three statements as to what could be done next and the complainant was concerned that none of the three statements were referenced to guidance. There was heavy emphasis on promotion of GlaxoSmithKline dry powder inhaler brands but without any prescribing information. No adverse event reporting statement was on the page. The complainant stated that it was clear from the bottom of the webpage that GlaxoSmithKline wanted an action to move patients to dry powder devices and thus the statement: 'Will you now consider environmental factors when prescribing inhaled medication?'. This was supplemented by wording taken from the guidance issued by the British Thoracic Society (BTS) which referred to 'switching' in the first of three recommendations.

The complainant stated that, overall, it was one-sided promotion of the GlaxoSmithKline portfolio whilst disparaging pressurised metered dose inhalers. There was no mention of potential loss in control for a patient who was stable on an inhaler or potential wider issues such as review time for switching patients which did not provide fair and balanced content.

The detailed response from GlaxoSmithKline is given below.

The Panel noted GlaxoSmithKline's submission that the article 'How switching asthma inhalers can help the NHS cut carbon emissions' hosted on the independent website, gponline.com, was non-promotional. The Panel noted that above the title of the article, it

was stated in the top left-hand corner of the webpage 'Sponsored by GSK' and the company's corporate logo appeared in the top right-hand corner.

The Panel noted that within the article, below the second paragraph, there was a grey highlighted box with the prominent company logo and the text:

> **'Low carbon inhalers**
>
> **#LowCarbonInhalers is a campaign funded by GSK aiming to raise awareness about how inhaler choice can play a role in reducing carbon emissions. For more information visit https://lowcarboninhalers.co.uk/.'**

This grey highlighted box sat within a slightly larger grey outlined box at the bottom of which was the statement, in bold, black typeface, 'This article was initiated, funded and reviewed by GSK'. As noted by the complainant, 'Initiated, funded and reviewed by GSK' was also at the bottom of the article, below the references, in normal typeface.

The Panel disagreed with GlaxoSmithKline's submission that in this context the phrase 'sponsored by GSK', which appeared in the top left of the article, was routinely understood by readers to mean 'brought to you by', ie the company was responsible for the content. 'Sponsored by' was a vague term and a declaration of sponsorship should be unambiguous in relation to the nature of the company's involvement and influence over the material.

In the Panel's view, due to its position as described above, and that the grey outline box was relatively faint, it was unclear whether the statement 'This article was initiated, funded and reviewed by GSK' at the bottom of the outlined box referred to the linked article at https://lowcarboninhalers.co.uk, which appeared within the grey highlighted box immediately above, or to the article published on gponline.com.

In the Panel's view, the statement 'Initiated, funded and reviewed by GSK' should have appeared at the top of the article so that readers were aware of the nature of the company's involvement from the outset. It was not clear at the outset that the GP online article had been initiated by GlaxoSmithKline. The GlaxoSmithKline logo was insufficient in this regard.

The Panel ruled breaches of the Code including that GlaxoSmithKline had failed to maintain high standards. Both rulings were appealed by GlaxoSmithKline.

The Appeal Board noted that the article at issue comprised one-page, and the declaration of sponsorship appeared at the outset above the title and the nature of this sponsorship appeared after two paragraphs and again at the bottom of the page. There was no mention of who had written the article and this information would have been helpful. The Appeal Board considered that it might have been clearer if the extent of GlaxoSmithKline's involvement appeared at the outset above the title alongside the declaration of sponsorship; however in the context of the article in GP online, the Appeal Board did not consider that readers would be in any doubt that GlaxoSmithKline had sponsored the article. Further, it considered that, on the balance of probabilities, the company's involvement and influence over the material would be understood by the readers of GP online.

The Appeal Board ruled no breaches of the Code. The appeal on both points was successful.

In relation to the low carbon inhalers GlaxoSmithKline website, the Panel noted that the landing page, as provided by GlaxoSmithKline stated that it was intended for UK health professionals. The webpage included '#LowCarbonInhalers How can inhaler choices play a role in reducing carbon emissions?' and 'Learn which inhalers have a high carbon footprint to inform you when choosing an inhaler with your respiratory patient' followed by a prominent link to the NICE inhaler decision aid which according to GlaxoSmithKline provided further information on the factors patients and health professionals should consider before choosing a device. The Panel noted that the complainant did not make any allegations in relation to the content of, or the link to, the NICE decision aid. The complainant's concern was limited to whether statements in relation to the NICE decision aid on the website in question should have been referenced.

The Panel noted the complainant's allegation that the website overall was one sided promotion of the GlaxoSmithKline dry powder inhaler portfolio without any prescribing information or adverse event reporting statement. The Panel noted GlaxoSmithKline's submission that it built the website in response to the urgent need to reduce carbon emissions in the NHS. The website was created to provide factual information for health professionals on the carbon footprint of the two broad categories of inhalers; pressurised metered dose inhalers (pMDIs) and dry powder inhalers (DPIs).

The Panel noted GlaxoSmithKline's submission that it marketed both pMDIs (Evohaler) and DPIs (Accuhaler and Ellipta) covering multiple products and that many other companies provided both pMDIs and DPIs. The Panel further noted GlaxoSmithKline's submission that no specific GlaxoSmithKline medicines were mentioned directly or indirectly on the website.

In the Panel's view, the website in question described the carbon footprint of the two broad categories of inhalers, pMDIs and DPIs, and although GlaxoSmithKline marketed both these inhaler types, so did a number of other companies. The Panel did not consider that the complainant had established that the website promoted a specific GlaxoSmithKline medicine or device and therefore that prescribing information for any specific medicine or adverse event reporting statement was required. The Panel further noted GlaxoSmithKline's submission that the bottom of the webpage included an invitation to report adverse events if readers wished to do so. The Panel therefore ruled no breaches of the Code including that the website did not constitute disguised promotion as alleged.

The Panel noted that the website had a section titled 'HCP solutions – What can you do?' which included three statements that the complainant was concerned were not referenced to guidance. The Panel noted GlaxoSmithKline's submission that none of the information the complainant quoted referred to a published study and so did not require referencing under the Code and that all the information was substantiated by publications from national professional bodies, which were listed at the bottom of the website and could be provided upon request. The Panel had no evidence before it that the three statements in question were not capable of substantiation and thus it ruled no breach of the Code in that regard.

In relation to the allegation that there was no mention of potential loss in control for a patient who was stable on an inhaler or potential wider issues such as review time for switching patients which did not provide fair and balanced content, the Panel noted GlaxoSmithKline's submission that the website stated 'BTS [British Thoracic Society] encourages all prescribers and patients to consider switching pMDIs to DPIs whenever they are likely to be equally effective' which was to remind the health professional to consider efficacy/loss of control. The Panel further noted, as submitted by GlaxoSmithKline, that the webpage stated in bold font: 'MDIs however may still be the appropriate option for some patients and play an important role where there is clinical need and a DPI is not appropriate' and that this was included in the 'Recommendations' section as a recommendation from the BTS.

In the Panel's view, the complainant had not discharged his/her burden of proof to establish that the content of the website was not fair or balanced as alleged and no breach of the Code was ruled.

In relation to the allegation that the website disparaged metered dose inhalers, the Panel noted GlaxoSmithKline's submission that the website contained factual information regarding the relative carbon footprint of a category of products. The Panel further noted GlaxoSmithKline's submission that it manufactured and promoted both DPIs and pMDIs and that the majority of its sales by volume were from pMDIs. In the Panel's view, highlighting a particular attribute that one product had relative to another was not necessarily unacceptable provided that such information was accurate, balanced, fair, not misleading and otherwise complied with the Code. In the Panel's view, the complainant had not established that the website in question disparaged the medicines, products and activities of other pharmaceutical companies as alleged and no breach of the Code was ruled. The Panel ruled no breach of the Code as the website had been certified.

The Panel ruled no breach of the Code as it did not consider that the company had failed to maintain high standards in relation to the allegations about the low carbon inhalers website.

An anonymous, non-contactable complainant who described themselves as a health professional provided a link to, and complained about, an article in GP online which detailed how switching asthma inhalers could help the NHS cut carbon emissions (ref NP-GB-RS-ADVR-190001). Above the title of the article, it was stated in the top left-hand corner of the webpage 'Sponsored by GSK' and the company's corporate logo appeared in the top right-hand corner. GlaxoSmithKline UK marketed a number of inhalers for the treatment of asthma.

COMPLAINT

The complainant stated that from the initial statement at the top of the article, he/she was under the impression that GlaxoSmithKline had only sponsored the article. However, having read further it was clear that it had had greater involvement in being sole funders and initiators of the article. There was a statement at the very bottom of the article, in small text, that it had been initiated, funded and reviewed by GlaxoSmithKline and produced by a named third party. The complainant alleged a breach of Clauses 9.10 and 9.1 as he/she thought that GP online had funded and was the concept creator of the article from initial view.

The complainant noted that the well written article contained a link to the webpage lowcarboninhalers.co.uk/ for health professionals (ref NP-GB-RS-WCNT-190007) which seemed to be heavily biased towards dry powder inhalers and was not as well written as the article referred to above. The complainant noted that the middle of the webpage included headline claims such as 'A high carbon MDI inhaler has a carbon footprint that is 18x higher than a low carbon DPI inhaler'. There were also three statements as to what could be done next:

> Health professional solutions – What can you do?
>
> Local NHS can help the NHS reach their carbon targets by:
>
> 1 Making use of the NICE Decision aid and raising clinician awareness to its recent publication. This can assist in making appropriate inhaler choices, which include environmental considerations.
> 2 Championing change at a local level by advocating that low carbon DPIs are available for appropriate patients through local formularies.
> 3 Raising awareness for yourself and your colleagues on the environmental impact of inhalers.

The complainant was concerned that none of the three statements were referenced to guidance. It was clear from the page that there was heavy emphasis on promotion of GlaxoSmithKline dry powder inhaler brands but without any prescribing information. No adverse event reporting statement was on the page; at the bottom of the material it simply had NP-GB-RS-WCNT-190007 November 2019 and 'report adverse event' but without the specified wording. The complainant stated that it was clear from the bottom of the webpage that GlaxoSmithKline wanted an action to move patients to dry powder devices and thus the statement: 'Will you now consider environmental factors when prescribing inhaled medication?'. This was supplemented by wording taken from the guidance issued by the British Thoracic Society (BTS) which referred to 'switching' in the first of three recommendations.

The complainant stated that, overall, it was one-sided promotion of the GlaxoSmithKline portfolio whilst disparaging pressurised metered dose inhalers. There was no mention of potential loss in control for a patient who was stable on an inhaler or potential wider issues such as review time for switching patients which did not provide fair and balanced content. There were certain times it was appropriate to switch devices and certain times it was not but this webpage did not provide that view. The complainant alleged breaches of Clauses 14.1, 4.1, 12.1, 7.2, 7.4, 4.6, 8.1, 4.9 and 9.1.

When writing to GlaxoSmithKline the Authority asked it to bear in mind the requirements of Clauses 9.10 and 9.1 regarding the first article as cited by the complainant and Clauses 4.1, 4.6, 4.9, 7.2, 7.4, 8.1, 9.1, 12.1 and 14.1 of the Code regarding the low carbon inhalers website as cited by the complainant.

RESPONSE

GlaxoSmithKline submitted that the article for general practitioners hosted on www.gponline.com and the low carbon inhalers website were both intended to be informative and educational and were fully compliant with the Code.

By way of background, GlaxoSmithKline explained that in April 2020, the National Institute for Health and Care Excellence (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 a previous commitment of 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.

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.

As part of the Environmental Audit Committee F-gas inquiry 2017-18, the SDU confirmed that Metered Dose Inhalers (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.

GlaxoSmithKline stated that it built the website lowcarboninhalers.co.uk in response to the urgent need to reduce carbon emissions in the NHS. The website was created to provide factual information for health professionals 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 an estimated carbon footprint 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.

With the stated international, government and NHS ambitions, with support from the clinical and expert community for change, GlaxoSmithKline submitted that 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. (The NICE decision aid, that was linked to from the website, included ten different DPIs).

The website itself did not promote any prescription only medicine but provided accurate and factual information relating to the carbon footprint of the two different categories of inhalers

described above to inform health professionals on the guidance from national bodies and the resources available to aid decision making.

GlaxoSmithKline submitted that there was no information on the website which related to efficacy, or which specific medicines were supplied in which specific inhalers or which advocated the use of a particular device. Reference to a class of medicines which included multiple medicines had been deemed not to be promoting a specific product (eg Case AUTH/3308/2/20) and the website in question took one step further back and described only the two broad categories of inhalers.

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. GlaxoSmithKline noted 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 (link and copy 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.

With regard to the complainant's concern about the article on GP online, GlaxoSmithKline noted that he/she had acknowledged that it was clear at the outset that the company had sponsored the article. The article was headed 'Sponsored by GSK' plus a full colour GlaxoSmithKline logo. The type size of the sponsorship statement was larger than the text of the opening subheading and indeed, the complainant agreed he/she had seen 'the initial statement at top of article'. There was nothing in the sponsorship statement that implied GPOnline 'had funded and was the concept creator' and it would be an unusual scenario that a company would sponsor an article but not fund it.

GlaxoSmithKline noted that it was not uncommon for companies to sponsor articles in the GP press, and in this context the phrase' sponsored by' was routinely understood by readers to mean 'brought to you by' ie the company was responsible for the content. Indeed, Pulse the main competitor to GP had a section simply entitled 'sponsored' where companies placed their articles.

However, for the avoidance of doubt, within the first section of the article, there was a highlighted box with the GlaxoSmithKline logo and a clear statement in bold, black print that 'This article was initiated, funded and reviewed by GSK', to ensure readers could be in no doubt as to the involvement of GlaxoSmithKline. GlaxoSmithKline further noted that the complainant had acknowledged that that information was repeated at the end of the single page article.

The article clearly indicated it had been sponsored by GlaxoSmithKline at the outset, it was unambiguous and the involvement was clear. As such GlaxoSmithKline refuted the allegation of a breach of Clause 9.10.

GlaxoSmithKline submitted that the article had undergone review and certification to ensure the content met the requirements of the Code and was described by the complainant as a 'well

written article'. As such, GlaxoSmithKline refuted the allegation of not maintaining high standards, Clause 9.1.

With regard to the low carbon inhalers website, GlaxoSmithKline noted that the complainant had listed various claims without raising specific concerns relating to their content but was worried that they were not referenced. The Code did not mandate that all claims had to be referenced, only that they must be capable of substantiation. The only time the Code required references was when published studies were referred to. None of the information quoted by the complainant referred to a published study so did not require referencing. However, all the information was substantiated by publications from national professional bodies, which were listed in the references at the bottom of the website and copies of which were readily available from GlaxoSmithKline if requested by an interested party.

GlaxoSmithKline further noted that the complainant was concerned that 'There was no mention of potential loss in control for a patient who was stable on an inhaler or potential wider issues such as review time for switching patients which did not provide fair and balanced content'.

GlaxoSmithKline submitted that the website was intended to inform health professionals about carbon footprints of the different categories of inhalers, it was not intended as a complete guide on the clinical process of how to change patients' inhalers; there were plenty of alternative sources for that information. However, the website stated 'BTS encourages all prescribers and patients to consider switching pMDIs to DPIs whenever they are likely to be equally effective' which clearly reminded health professional to consider efficacy/loss of control, and a large statement in bold font 'MDIs however may still be the appropriate option for some patients and play an important role where there is clinical need and a DPI is not appropriate' and this was reiterated in the 'Recommendations' section of the website.

The link to the NICE decision aid also provided further information on the factors patients and health professionals should consider before choosing a device.

As such, GlaxoSmithKline refuted the allegations of breaches of Clauses 7.2 (misleading, unbalanced), and 7.4 (capable of substantiation).

With regard to the provision of prescribing information, GlaxoSmithKline noted that under Clause 4.1 it was only required on promotional materials. The website in question did not promote any specific medicine or medicines and neither did it promote a specific device. It did advocate for health professionals to consider carbon footprint when prescribing inhalers, and in line with national guidance and the body of scientific evidence it was clear non-propellant-driven inhalers had a smaller carbon footprint than standard pMDIs. There was no emphasis on any GlaxoSmithKline medicine or device. In fact, no specific GlaxoSmithKline medicines were mentioned directly or indirectly on the website. The website contained no product branding that would have identified specific products, and there was no emphasis on GlaxoSmithKline inhalers as the content applied to all inhalers equally. Therefore, as there was no promotion of specific medicines or specific inhaler devices, the website was non-promotional and so there was no requirement to provide prescribing information or a clear prominent statement as to where it could be found. As such, GlaxoSmithKline denied breaches of Clauses 4.1 and 4.6.

Similarly, GlaxoSmithKline noted that, as clearly set out in Clause 4.9, the adverse event statement only needed to appear on promotional materials. As the website did not promote any specific medicine or medicines, it was not promotional and so did not require an adverse event

statement. However, GlaxoSmithKline took patient safety extremely seriously and routinely offered easy ways to report adverse events on its websites even if not required by regulations, hence the invitation at the bottom of the website to report adverse events if readers wished to do so. As such, GlaxoSmithKline denied a breach of Clause 4.9.

GlaxoSmithKline noted the complainant's concern that the website was one-sided promotion of the company's inhalers whilst disparaging pMDIs but submitted that it manufactured and promoted both DPIs and pMDIs. GlaxoSmithKline noted that the majority of its sales by volume were from pMDIs (copy of sales data provided). The website did not promote specific medicines or devices but provided undisputed evidence that some types of inhalers had a lower carbon footprint than others and asked health professionals to consider that aspect in their prescribing – in line with NHS, NICE and BTS advice. All of the information on the website was accurate, factual and not misleading. Factual information regarding a particular attribute, in this case, the relative carbon footprint about a category of products made the information provided accurate, balanced and fair. As such, GlaxoSmithKline denied a breach of Clause 8.1.

GlaxoSmithKline reiterated that the website provided accurate and factual information relating to the carbon footprint of the two different categories of inhalers described above. There was no information on the website relating to which specific medicines were supplied in which specific inhalers or advocating the use of a particular device or medicine. Referring to a class of medicines which included multiple medicines had been found not to be promoting a particular product (eg Case AUTH/3308/2/20) and this website took one step further back and described only the two broad categories of inhalers. GlaxoSmithKline stated that it did not consider the page promotional and furthermore there was no promotion of a particular medicine therefore as such could not be disguised promotion. GlaxoSmithKline denied a breach of Clause 12.1.

GlaxoSmithKline noted that the complainant had provided no evidence for his/her allegation of a breach of Clause 14.1. Clause 14.1 required certification of promotional material in its final form prior to being issued. As the article on GPOnline and the website were both non-promotional items, there was no requirement to certify them under that clause. The website was, however, reviewed and certified in accordance with the Code and GlaxoSmithKline processes. GlaxoSmithKline certified such materials to ensure high standards as part of its internal governance processes. Certified copies of the materials were provided. GlaxoSmithKline refuted the allegation of breach of Clause 14.

In summary, GlaxoSmithKline believed that, in view of 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 in response, and sponsored an article highlighting this in a GP journal. 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 in regard to inhalers. GlaxoSmithKline was a member of the International Pharmaceutical Aerosol Consortium (IPAC) which was instrumental in moving from CFCs to HFAs in inhalers which supported ambitious climate change targets in the 1990s and the company 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 4.1, 4.6, 4.9, 7.2, 7.4, 8.1, 12.1 and 14.1 GlaxoSmithKline believed it had maintained high standards and refuted the alleged breach of Clause 9.1.

PANEL RULING

The Panel noted GlaxoSmithKline's submission that the article entitled 'How switching asthma inhalers can help the NHS cut carbon emissions' hosted on the independent website, gponline.com, was non-promotional. The Panel noted that above the title of the article, it was stated in the top left-hand corner of the webpage 'Sponsored by GSK' and the company's corporate logo appeared in the top right-hand corner.

The Panel noted that within the article, below the second paragraph, there was a grey highlighted box with the prominent company logo and the text:

> 'Low carbon inhalers
>
> #LowCarbonInhalers is a campaign funded by GSK aiming to raise awareness about how inhaler choice can play a role in reducing carbon emissions. For more information visit https://lowcarboninhalers.co.uk/.'

This grey highlighted box sat within a slightly larger grey outlined box at the bottom of which was the statement, in bold, black typeface, 'This article was initiated, funded and reviewed by GSK'. As noted by the complainant, 'Initiated, funded and reviewed by GSK' was also at the bottom of the article, below the references, in normal typeface.

The Panel noted that Clause 9.10 stated that material relating to medicines and their uses, whether promotional or not, and information relating to human health or diseases which is sponsored by a pharmaceutical company must clearly indicate that it had been sponsored by that company. The supplementary information to that clause stated that the declaration of sponsorship must be sufficiently prominent to ensure that readers of sponsored material were aware of it at the outset. The wording of the declaration must be unambiguous so that readers will immediately understand the extent of the company's involvement and influence over the material. The supplementary information stated that this was particularly important when companies were involved in the production of material which was circulated by an otherwise wholly independent party.

The Panel disagreed with GlaxoSmithKline's submission that in this context the phrase 'sponsored by GSK', which appeared in the top left of the article, was routinely understood by readers to mean 'brought to you by', ie the company was responsible for the content. 'Sponsored by' was a vague term and a declaration of sponsorship should be unambiguous in relation to the nature of the company's involvement and influence over the material.

In the Panel's view, due to its position as described above, and that the grey outline box was relatively faint, it was unclear whether the statement 'This article was initiated, funded and reviewed by GSK' at the bottom of the outlined box referred to the linked article at https://lowcarboninhalers.co.uk, which appeared within the grey highlighted box immediately above, or to the article published on gponline.com.

In the Panel's view, the statement 'Initiated, funded and reviewed by GSK' should have appeared at the top of the article so that readers were aware of the nature of the company's involvement from the outset. It was not clear at the outset that the GP online article had been initiated by GlaxoSmithKline. The GlaxoSmithKline logo was insufficient in this regard.

The Panel noted its comments above and considered that the requirements of Clause 9.10 had not been met and a breach of Clause 9.10 was ruled. GlaxoSmithKline had failed to maintain high standards in this regard and a breach of Clause 9.1 was ruled.

In relation to the low carbon inhalers GlaxoSmithKline website, the Panel noted that the landing page, as provided by GlaxoSmithKline in its response, stated that it was intended for UK health professionals. The webpage contained a prominent banner which stated: '#LowCarbonInhalers How can inhaler choices play a role in reducing carbon emissions?'. Near the top of the webpage it stated 'Learn which inhalers have a high carbon footprint to inform you when choosing an inhaler with your respiratory patient' followed by a prominent link inviting the reader to download the NICE inhaler decision aid which according to GlaxoSmithKline provided further information on the factors patients and health professionals should consider before choosing a device. The Panel noted that the complainant did not make any allegations in relation to the content of, or the link to, the NICE decision aid. The complainant's concern was limited to whether statements in relation to the NICE decision aid on the website in question should have been referenced.

The Panel noted the complainant's allegation that the website overall was one sided promotion of the GlaxoSmithKline dry powder inhaler portfolio without any prescribing information or adverse event reporting statement. The Panel noted GlaxoSmithKline's submission that it built the 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 health professionals on the carbon footprint of the two broad categories of inhalers; pressurised metered dose inhalers (pMDIs) and dry powder nhalers (DPIs).

The Panel noted GlaxoSmithKline's submission that it marketed both pMDIs (Evohaler) and DPIs (Accuhaler and Ellipta) covering multiple products and that many other companies provided both pMDIs and DPIs. The Panel further noted GlaxoSmithKline's submission that no specific GlaxoSmithKline medicines were mentioned directly or indirectly on the website; there was no information on the website relating to which specific medicines were supplied in which specific inhalers or advocating the use of a particular device or medicine. In the Panel's view, the website did not place any emphasis on any GlaxoSmithKline medicine or device as alleged.

In the Panel's view, the website in question described the carbon footprint of the two broad categories of inhalers, pMDIs and DPIs, and although GlaxoSmithKline marketed both these inhaler types, so did a number of other companies. The Panel did not consider that the complainant had established that the website promoted a specific GlaxoSmithKline medicine or device and therefore that prescribing information for any specific medicine or a prominent adverse event reporting statement was required. The Panel further noted GlaxoSmithKline's submission that the bottom of the webpage included an invitation to report adverse events if readers wished to do so. The Panel noted its comments above and therefore ruled no breach of Clauses 4.1, 4.6 and 4.9.

Noting its comments and rulings above, the Panel considered that the website did not constitute disguised promotion as alleged. No breach of Clause 12.1 was ruled.

The Panel noted that the website had a section titled 'HCP solutions – What can you do?' which included three statements that the complainant was concerned were not referenced to guidance. The Panel noted GlaxoSmithKline's submission that none of the information the complainant quoted referred to a published study and so did not require referencing under the

Code and that all the information was substantiated by publications from national professional bodies, which were listed in the references at the bottom of the website and could be provided upon request. The Panel had no evidence before it that the three statements in question were not capable of substantiation and thus it ruled no breach of Clause 7.4 in that regard.

In relation to the allegation that there was no mention of potential loss in control for a patient who was stable on an inhaler or potential wider issues such as review time for switching patients which did not provide fair and balanced content, the Panel noted GlaxoSmithKline's submission that the website stated 'BTS [British Thoracic Society] encourages all prescribers and patients to consider switching pMDIs to DPIs whenever they are likely to be equally effective' which was to remind the health professional to consider efficacy/loss of control. The Panel further noted, as submitted by GlaxoSmithKline, that the webpage stated in bold font: 'MDIs however may still be the appropriate option for some patients and play an important role where there is clinical need and a DPI is not appropriate' and that this was included in the 'Recommendations' section as a recommendation from the BTS.

In the Panel's view, the complainant had not discharged his/her burden of proof to establish that the content of the website was not fair or balanced as alleged and no breach of Clause 7.2 was ruled.

In relation to the allegation that the website disparaged metered dose inhalers, the Panel noted GlaxoSmithKline's submission that the website contained factual information regarding the relative carbon footprint of a category of products. The Panel further noted GlaxoSmithKline's submission that it manufactured and promoted both DPIs and pMDIs and that the majority of its sales by volume were from pMDIs. In the Panel's view, highlighting a particular attribute that one product had relative to another was not necessarily unacceptable provided that such information was accurate, balanced, fair, not misleading and otherwise complied with the Code. In the Panel's view, the complainant had not established that the website in question disparaged the medicines, products and activities of other pharmaceutical companies as alleged and no breach of Clause 8.1 was ruled.

The complainant alleged a breach of Clause 14.1 but provided no further detail in this regard. Clause 14.1 related to the certification of promotional material. The Panel noted its comments and rulings with regard to the website. The Panel further noted GlaxoSmithKline's submission that the website was non-promotional and had been reviewed and certified by a registered physician in accordance with the Code. The Panel noted its comments above and ruled no breach of Clause 14.1.

The Panel noted its comments and rulings above and consequently ruled no breach of Clause 9.1 in relation to the allegations about the low carbon inhalers website.

APPEAL FROM GLAXOSMITHKLINE

GlaxoSmithKline appealed the Panel's ruling that it had breached Clauses 9.10 and 9.1.

Summary position

GlaxoSmithKline submitted that the material at issue, an article in GP online, clearly indicated that it was sponsored by GlaxoSmithKline at the outset as required by the Code and readers would have been in no doubt as to the fact there was company involvement in this non-

promotional article. Further, the detail of the nature of the sponsorship was described twice; once within the article and once at the end. GlaxoSmithKline submitted that it had therefore not breached Clause 9.10.

Further, the Panel had found GlaxoSmithKline in breach of Clause 9.10 and then in breach of Clause 9.1 without providing any argumentation on the reasons why GlaxoSmithKline had failed to maintain high standards. GlaxoSmithKline submitted that it had at all times maintained high standards by providing transparency regarding the company's involvement and ensured compliance with the Code and that the Panel erred in concluding that a breach of Clause 9.10 automatically meant a breach of Clause 9.1.

Complaint and Ruling being appealed

The complainant had alleged that 'they were under the impression that Glaxo only sponsored this article' as they had thought that 'GP online had funded and were the concept creators of this article from initial view' and therefore GlaxoSmithKline had breached Clauses 9.10 and 9.1. The Panel agreed with the complainant and ruled that GlaxoSmithKline had indeed breached Clauses 9.10 and 9.1. GlaxoSmithKline was appealing both these rulings.

GlaxoSmithKline submitted that the rest of the complaint alleged breaches of a further nine clauses of the Code as the complainant had alleged that the linked website was disguised promotion, disparaged MDIs, was unbalanced, misleading and did not have the obligatory information for promotional materials. The Panel ruled no breach on all these points.

Clause 9.10 'Sponsored by' versus 'Initiated by'

GlaxoSmithKline noted that the Panel appeared to rule in breach of Clause 9.10 because 'it was not clear at the outset that the GP article had been initiated by GlaxoSmithKline.' (emphasis added). The Panel had misinterpreted the clause and its supplementary information to the extent that it had been unnecessarily restrictive in its interpretation of what the Code required. Clause 9.10 stated that 'Material relating to medicines and their uses, whether promotional or not, and information relating to human health or diseases which was sponsored by a pharmaceutical company must clearly indicate that it had been sponsored by that company.' (emphasis added). This article complied with this requirement by having 'Sponsored by GlaxoSmithKline' at the top left of the article and a prominent GlaxoSmithKline logo at the top right as noted by both the Panel and the complainant. Further, early within the article there was a highlighted box with the GlaxoSmithKline logo and a clear statement in bold, black print that 'This article was initiated, funded and reviewed by GlaxoSmithKline' and this information was repeated at the end of the single page article.

GlaxoSmithKline submitted that the term 'sponsorship' was broad and not defined in the applicable Code. It could range from payment to distribute an otherwise wholly independently authored article, to commissioning, reviewing, editing, printing and distributing material from a third party, to paying for stand space at a meeting, contributing to subsistence costs at the same, providing funds for clinical trials or for individuals to attend Congresses. All of these were routinely referred to as sponsorship yet the arrangements surrounding them could vary enormously.

GlaxoSmithKline submitted that Clause 9.10 required that the material 'must clearly indicate that it had been sponsored by that company'. The wording of the clause was very clear. Exactly

what this looked like or must contain was not defined in the Code, but it was not unreasonable to assume that a prominent logo and the statement Sponsored by GlaxoSmithKline' complied with the requirement to 'indicate that it had been sponsored' by the company.

Sponsorship needs to be clear at the outset, but details could come later

GlaxoSmithKline noted that the supplementary information to Clause 9.10 had two parts; the first stating that 'the declaration of sponsorship must be sufficiently prominent to ensure readers of sponsored material were aware of it at the outset'. In this context, GlaxoSmithKline again contended that it declared its sponsorship at the start of the article with its logo and sponsorship statement as outlined above. The complainant themselves indicated they were aware of the sponsorship at the top of the article; therefore it was reasonable to assume that the declaration was sufficiently prominent at the outset.

GlaxoSmithKline submitted that a second, separate paragraph in the supplementary information stated that the 'wording of the declaration must be unambiguous so that readers would immediately understand the extent of the company's involvement and influence over the material. This was particularly important when companies were involved in the production of material which was circulated by an otherwise wholly independent party, such as supplements to health professional journals'.

In this case, GlaxoSmithKline submitted that early within the article unambiguous wording of the declaration appeared making clear that GlaxoSmithKline initiated, funded and reviewed the article. This wording was repeated at the end of the article to further emphasise the point. In compliance with the supplementary information, GlaxoSmithKline argued that any reader on reading the detail provided would immediately be clear on the extent of GlaxoSmithKline's involvement in the article.

GlaxoSmithKline submitted that it had gone to great lengths to ensure that any reader of the article would know exactly its involvement in the production of the article. GlaxoSmithKline maintained that neither the Code nor the supplementary information required the detail to be provided at the outset. If that was the intention, the supplementary information could have made this clear by conjoining the requirements for a declaration to be provided both at the outset **and** for it to be detailed. GlaxoSmithKline's interpretation of the requirements was supported by examples of other sponsored articles in GP Online taking a similar approach where only the logo and 'sponsored by' appeared at the top of the article and further details appeared early in the article provided, and Case AUTH/2275/11/09 and Case AUTH/2849/6/16 details of which were discussed later in the appeal.

The wording of the declaration in bold, black font of a type size larger than the print in the article was unambiguous and clear such that readers would immediately understand the extent of the company's involvement and influence over the material ('This article was initiated, funded and reviewed by GlaxoSmithKline').

GlaxoSmithKline submitted that the Panel ruling stated that the declaration of sponsorship that appeared within the article was unclear whether it referred to the article itself or the 'linked article' described in the grey box above the statement. The content of the grey box in the article that was subject of this complaint was to provide further transparency to readers about company involvement in the non-promotional campaign to help reduce carbon emissions by considering inhaler choices as described by NICE, the British Thoracic Society and the NHS long term plan.

It had a prominent GlaxoSmithKline logo within it and explained that GlaxoSmithKline was funding the campaign and further information could be found at a dedicated website for which the URL was provided. To be clear, this was a website address and NOT 'an article' as the Panel stated within the ruling. It was this website that the complainant believed was promotional, misleading and disparaging and referred to as a 'page' or 'web page' in their complaint and did not refer to it as 'an article' indicating they had understood the difference between the information in the greyed out box and the statement detailing the nature of the sponsorship of the article.

GlaxoSmithKline submitted that the Panel also repeatedly referred to it as a website or webpage in their deliberations; 'In relation to the low carbon inhalers GlaxoSmithKline **website**, the Panel noted the landing page…', 'The **webpage** contained a prominent..', Near the top of the **webpage**…', '…on the **website** in question…', '…the **website** overall…' '…it built the **website**…', 'In the Panel's view the **website**…', 'The Panel did not consider that the complainant had established that the **website** promoted…', '…the Panel considered that the **website** did not constitute disguised promotion…' 'The Panel noted the **website** had a section…' '…no breach of Clause 9.1 in relation to the allegations about the low carbon inhalers **website**'.

Thus, it would appear it was also clear to the Panel that the greyed out box was describing and linking to a website. The text in the greyed out box invited readers 'For more information visit https://lowcarboninhalers.co.uk/' which was language used when directing people to a website, whereas the declaration clearly referred to 'This article', using the pronoun 'this', meaning the article in GP Online.

GlaxoSmithKline submitted that the confusion by the Panel was not something that the complainant made any reference to, but even if there were some lack of clarity due to the inclusion of the grey outlined box, the statement at the end of the article repeated the information 'Initiated, funded and reviewed by GlaxoSmithKline', again making clear GlaxoSmithKline's specific involvement. The complainant themselves commented that he/she had read the statement and from it, understood the detailed involvement of GlaxoSmithKline. As such, the complainant admitted he/she was aware of the sponsorship at the outset of the article and understood the detailed nature of that sponsorship once he/she had read that information.

Thus, GlaxoSmithKline submitted that the article complied with the Code by:

a) Clearly indicating that it was sponsored at the outset which was sufficiently prominent and
b) providing unambiguous wording on the nature of the sponsorship twice in the article itself.

<u>Examples of previous rulings supporting GlaxoSmithKline's position</u>

Case AUTH/2275/11/09

GlaxoSmithKline submitted that this case offered useful parallels with the current case (Case AUTH/3424/11/20). It concerned the sponsorship of a supplement, and 'The Panel noted that GlaxoSmithKline's corporate logo appeared on the bottom left hand corner of the front page above the statement "GSK has sponsored the production of this supplement; for details please

see the back cover page of the report". The corporate logo also appeared on the lower left hand corner of the back outside cover alongside the statement "GSK sponsorship has included payment for a medical writer, honoraria to the editorial board and payment to a public relations agency in respect of project management support"'. 'The Panel considered that GlaxoSmithKline's role in the production of the supplement had been made clear. Sufficient details appeared prominently on the front page with further explanation on the outside back cover.' and no breach of Clause 9.10 was ruled.

Case AUTH/2849/6/16

GlaxoSmithKline submitted that this case involved the sponsorship of a handbook. Lilly had initiated the production of the handbook but had outsourced the recent updating to a third party. 'Lilly Oncology' appeared in the bottom right hand corner of the front and back covers of the handbook and the back cover also referred to 'A Medical Education Goods and Services item by Lilly Oncology UK'. Page 3 included a note from the publisher which stated that Lilly's role as sponsor was limited to checking the factual accuracy of information on Lilly products and ensured compliance with the Code. 'The Panel noted the requirements of Clause 9.10 and considered that the statement on page 3 of the handbook that "Lilly's role as sponsor of this handbook, has been limited to checking the factual accuracy of information on Lilly products and ensuring compliance with the PMCPA Code of Practice for the Pharmaceutical Industry" should have more accurately reflected the extent of the company's involvement. Nonetheless, it was abundantly clear from the various references to Lilly on the front and back covers, pages 3 and 4 and all odd numbered pages that it was a Lilly-sponsored item and on balance, the Panel ruled no breach of Clause 9.10'. The complainants appealed, but the Appeal Board upheld the Panel's ruling; 'The Appeal Board noted the Panel's ruling above and agreed that it was abundantly clear in the handbook from the various references to Lilly on the front and back covers, pages 3 and 4 (all in red) and all odd numbered pages that it was a Lilly-sponsored item and the Appeal Board therefore upheld the Panel's ruling of no breach of the Clause 9.10'.

GlaxoSmithKline submitted that in both of these cases, one of which was upheld on appeal, the sign that the materials were sponsored by a pharmaceutical company was indicated at the outset with a logo with or without a statement saying the item was company sponsored. Further details of the nature of the sponsorship were found either on the back cover or on page three. And even though the actual statement did not accurately reflect the nature of the sponsorship in the Lilly case, it was considered that the fact it was sponsored was abundantly clear and a ruling of no breach of Clause 9.10 was upheld on appeal.

GlaxoSmithKline submitted that it accepted that each case needed to be assessed on its own merits, however, it had taken equal, if not greater, measures than the companies in those two cases to ensure that it was abundantly clear to any reader the extent of its involvement in the production of the article. Therefore, based on the principles outlined in both these rulings and on the wording of the Code and the supplementary information, GlaxoSmithKline strongly maintained it had not breached Clause 9.10 in these circumstances and as such appealed the ruling.

<u>Clause 9.1</u>

GlaxoSmithKline submitted that the complainant provided no evidence as to why he/she had alleged that GlaxoSmithKline had breached Clause 9.1 but appeared to simply add it on to the complaint. In fact, the complainant went as far as noting it was a well written article.

GlaxoSmithKline maintained it was not the purpose of Clause 9.1 to be a supplementary finding on the basis of having been found in breach of another clause, merely by default.

GlaxoSmithKline submitted that Clause 9.1 required that high standards must be maintained at all times and a breach was a recognition that processes and procedures had fallen below acceptable standards. Based on previous rulings, this had not been the case. Further, the examples provided in the supplementary information all related to the promotion of medicines whereas this article and the associated website were non-promotional. As found by the Panel, there was no disguised promotion nor health professionals mistakenly believing information provided about medicines was wholly independent when it was not, as the article and linked website did not promote specific medicines. In fact, there was no mention of any specific medicines directly or indirectly and the article and website did not place any emphasis on any GlaxoSmithKline medicine or device, as noted by the Panel.

GlaxoSmithKline submitted that the Panel gave no indication of the reasoning for its ruling of a breach of high standards, but in the sentence following the breach of Clause 9.10 stated that GlaxoSmithKline 'had failed to maintain high standards in this regard and a breach of Clause 9.1 was ruled'. It was difficult for GlaxoSmithKline to consider this anything other than a supplementary breach of Clause 9.1 as a result of breaching Clause 9.10 as no other breaches were ruled and there was no rationale from the Panel as to why it had considered high standards had not been maintained.

GlaxoSmithKline assured the Panel it took its responsibilities under the Code extremely seriously and in this case made every effort to comply with Code requirements, making sure its sponsorship was clearly indicated at the outset, and detailed information on the nature of that sponsorship within the article and again at the end. GlaxoSmithKline maintained it had been fully transparent about its involvement and the nature of its involvement and no reasonable reader would be in any doubt about its interest. There had been no attempt to hide company involvement; indeed GlaxoSmithKline was proud to be associated with this campaign that tackled an important issue that aimed to reduce the carbon footprint of the NHS.

All materials were subject to rigorous review by a registered physician and certified as non-promotional in accordance with GlaxoSmithKline policies and processes to ensure compliance with the Code.

GlaxoSmithKline submitted that it had maintained high standards.

COMMENTS FROM THE COMPLAINANT

The complainant became uncontactable so there could be no comments on the appeal.

APPEAL BOARD RULING

The Appeal Board noted that 'Sponsored by GSK' appeared in the top left-hand corner above the title of the article in GP online and the company's corporate logo appeared in the top right-hand corner. Below the second paragraph, there was a grey background highlighted box with the prominent company logo and the text:

> 'Low carbon inhalers

#LowCarbonInhalers is a campaign funded by GSK aiming to raise awareness about how inhaler choice can play a role in reducing carbon emissions. For more information visit https://lowcarboninhalers.co.uk/.'

This grey highlighted box sat within a slightly larger outlined box at the bottom of which was the statement, in bold, black typeface, 'This article was initiated, funded and reviewed by GSK'. The sentence 'Initiated, funded and reviewed by GSK' also appeared at the very end of the article, below the references, in normal typeface and was followed by the reference P-GB-S-ADVR-190001 and the date of preparation, July 2019.

The Appeal Board noted that Clause 9.10 stated that material relating to medicines and their uses, whether promotional or not, and information relating to human health or diseases which is sponsored by a pharmaceutical company must clearly indicate that it had been sponsored by that company. The supplementary information to that clause stated that the declaration of sponsorship must be sufficiently prominent to ensure that readers of sponsored material were aware of it at the outset. The wording of the declaration must be unambiguous so that readers would immediately understand the extent of the company's involvement and influence over the material. The supplementary information stated that this was particularly important when companies were involved in the production of material which was circulated by an otherwise wholly independent party.

The Appeal Board noted, from some of the examples provided by GlaxoSmithKline of sponsored articles in GP online, that the page arrangement of a 'Sponsored by [company]' declaration above the title with the company logo in the top right-hand corner, and further detail about that sponsorship appearing further down the webpage appeared to be one of the house style formats of the publication which some readers might be familiar with.

The Appeal Board noted that GlaxoSmithKline had cited a number of previous cases to support its submission. One of these was a GlaxoSmithKline case (Case AUTH/2275/11/09) which concerned sponsorship of a supplement in which the declaration of sponsorship appeared on the front page and referred to GlaxoSmithKline's sponsorship of the production of this supplement, and stated that further details of GlaxoSmithKline's involvement were on the back cover page. The Panel had ruled no breach of Clause 9.10. In another cited case (Case AUTH/2849/6/16) concerning Eli Lilly's sponsorship of an oncology handbook, 'Lilly Oncology' appeared on the front and back covers, and page 3 provided details of Lilly's involvement. Further reference to Lilly appeared on all odd numbered pages. The Panel had ruled no breach of Clause 9.10 which had been upheld on appeal.

The Appeal Board noted that there were a number of cases in which the declaration of sponsorship and the detail of the company's involvement had not been made clear at the outset where breaches of the Code, including Clause 9.10, had been ruled.

The Appeal Board noted that the article at issue comprised one-page, and the declaration of sponsorship appeared at the outset above the title and the nature of this sponsorship appeared after two paragraphs and again at the bottom of the page. There was no mention of who had written the article and this information would have been helpful. The Appeal Board considered that it might have been clearer if the extent of GlaxoSmithKline's involvement appeared at the outset above the title alongside the declaration of sponsorship; however in the context of the article in GP online, the Appeal Board did not consider that readers would be in any doubt that GlaxoSmithKline had sponsored the article. Further, it considered that, on the balance of

probabilities, the company's involvement and influence over the material would be understood by the readers of GP online.

The Appeal Board noted its comments above and ruled no breach of Clause 9.10. Consequently, the Appeal Board ruled no breach of Clause 9.1. The appeal on both points was successful.

Complaint received **13 November 2020**

Case completed **16 September 2021**