NO BREACH OF THE CODE

Case AUTH/3204/6/19

ANONYMOUS PHARMACEUTIAL COMPANY EMPLOYEE V GLAXOSMITHKLINE

Alleged promotional information on company website

An anonymous individual, who described him/herself as a concerned health professional employed by Otsuka, complained in his/her private capacity that GlaxoSmithKline UK Limited's website promoted prescription only medicines to the public.

The complainant alleged that the GlaxoSmithKline website for members of the public had links to the various company products and included the brand name of the medicine, non-propriety name and the indication promoted to members of the public and encouraged them to ask for these medicines. The complainant referred to Nucala (mepolizumab) and stated that clicking the 'I am a patient' link provided, a pop-up asking for confirmation that the visitor was a patient. If the 'no' option was chosen, the visitor was directed to the patient information anyway instead of back to the page for the public.

The detailed response from GlaxoSmithKline is given below.

The Panel noted GlaxoSmithKline's submission that it operated two primary product websites intended for a UK audience that provided information about its prescription only products: the promotional GSKPro website for health professionals and the GlaxoSmithKline public website which was non-promotional and intended for patients and members of the public. Both websites were accessible via the company's corporate website. Readers were asked to confirm whether they were a UK health professional or member of the public and were taken to the GSKPro landing page if they confirmed that they were UK health professionals and to the GlaxoSmithKline public website landing page if they confirmed that they were a member of the public.

The Panel noted that the products section of the public site included a list of GlaxoSmithKline's products in alphabetical order by brand name and included the non-proprietary name of each; in order to obtain further information on a particular product including the indication, the reader had to select that product.

The Panel noted that the page of the website at issue was the Nucala page of the public website. This bore links to the SPC and patient information leaflet. It featured the indication beneath a subheading 'What is Nucala?', adjacent to a prominent photograph of the product. Subheadings of Safety information and Patient Information below appeared above links to the patient information leaflet and patient guides respectively. The latter linked to the patient information part of the site, as did a link on the left-hand side of the webpage in question. The Panel queried whether a prominent picture of the product in material aimed at the public was appropriate.

The Panel noted GlaxoSmithKline's submission that its public website provided a library resource in line with the provisions of the Code. The Panel noted GlaxoSmithKline's submission that each product page on the public site linked to the Electronic Medicines Compendium (eMC) website for the patient information leaflet (PIL) and summary of product characteristics (SPC), as well as the European or UK Public Assessment Reports (EPAR or UKPAR) where available, a factual introduction to the product, sections on safety information and patient information and, where relevant, links to third party websites related to the relevant disease area, such as NHS Choices and NHS Inform. This was confirmed by the copies of the information for Nucala provided to the Panel by GlaxoSmithKline.

The Panel further noted GlaxoSmithKline's submission that for certain products such as Nucala, the public website product page also included a separate section intended only for patients that had already been prescribed the product. These patient pages included further information including about the disease, its treatment and about Nucala that fairly reflected the current body of evidence about the product and its benefit risk profile. A screenshot of the patient information for Nucala was provided. The Panel noted that to access this information, patients had to select the 'I am a patient' link which asked the reader to confirm that they had been prescribed the medicine following consultation with a UK health professional before a new page opened. The Panel noted GlaxoSmithKline's submission that patient information was thus clearly separated and clearly marked for the target audience. The Panel noted that neither the content of the patient webpages nor the acceptability of a link to it were the subject of complaint.

The Panel's interpretation of the complaint was that according to the complainant, after clicking 'I am a patient' and when asked to confirm whether he/she had been prescribed the medicine, he/she selected 'no' but was, nonetheless, directed to the patient section. The Panel noted that the 'I am a patient' link stated for the 'No, go back' option 'Unfortunately we cannot display this GSK content if you are not a patient. You will be re-directed to the product page'. GlaxoSmithKline submitted that after selecting the 'No, go back' link, the user remained on the public webpage and was not redirected to the product page as intended. GlaxoSmithKline stated that this was a technical issue and not a Code issue; the issue had been corrected. The Panel considered that if its interpretation of the complaint was correct then the complainant's concern was potentially a Code issue in that members of the public were exposed to the information for patients who had been prescribed the product. It was potentially more than a technical issue as stated by GlaxoSmithKline. Given that it was not possible for the Panel to know how the link in question worked when accessed by the complainant and that there was insufficient evidence to establish what had occurred on the balance of probabilities, the Panel ruled no beach of the Code in relation to how the link in question worked.

Noting its comments above, in the Panel's view, the information about Nucala on the webpage for the public was not unacceptable in relation to the requirements of reference information as referred to in the supplementary information. The Panel ruled no breaches of the Code.

The Panel did not consider that GlaxoSmithKline had failed to maintain high standards in this regard and no breach of the Code was ruled. The Panel subsequently ruled no breach of the Code.

An anonymous individual, who described him/herself as a concerned health professional employed by Otsuka, complained in his/her private capacity that GlaxoSmithKline UK Limited's website promoted prescription only medicines to the public.

COMPLAINT

The complainant alleged that the GlaxoSmithKline website for members of the public had links to the various company products and contained the brand name of the medicine, non-proprietary name and the indication eg https://public.gsk.co.uk/products/nucala. The complainant alleged that this promoted to members of the public and encouraged them to ask for these medicines. If the 'I am a patient' link was clicked on the example provided, a pop-up appeared asking for confirmation that the visitor was a patient. If the 'no' option was chosen, the visitor was directed to the patient information anyway instead of back to the page for the public.

The complainant was very disappointed to see promotional information on the website, especially after the recent cases that had been published about company websites. When a case was published, the complainant hoped that other companies would review their own practice and learn from the mistakes of others. This appeared not to be the case.

When writing to GlaxoSmithKline, the Authority asked it to respond in relation to the requirements of Clauses 22.1, 22.2, 9.1 and 2.

RESPONSE

GlaxoSmithKline noted that Clauses 22.1 and 22.2 related to meetings and hospitality and concluded that these Clauses were stated in error and instead it considered Clauses 26.1 and 26.2 which related to information made available to the public.

GlaxoSmithKline stated that it operated two primary product websites intended for a UK audience that provided information about its prescription only products: the promotional GSKPro website for health professionals and the GlaxoSmithKline public website which was non-promotional and intended for patients and members of the public.

The public website was developed to provide adequate non-promotional information so that members of the public did not need to access material intended for health professionals on GSKPro unless they chose to declare themselves a health professional. The site was developed in accordance with Clause 28.1 and its supplementary information.

The GSKPro and the public websites operated on two separate URLs and were accessible via two separate links from the corporate website which clearly identified the intended audience. GSKPro was not password protected and so an 'overlay', which asked users to confirm whether they were a UK health professional or member of the public, sat on the website before the content was displayed. Users who confirmed that they were UK health professionals were taken to the GSKPro landing page. If users confirmed that they were a member of the public, they were taken to the GSK public website landing page. A screenshot of the overlay was

provided. Additionally, every page on the GSKPro website was headed 'For UK Healthcare Professionals'. This site contains promotional material' *and* 'Not a healthcare professional? Visit our Public site', with a link to the GSK public website. GlaxoSmithKline provided a screenshot of the Nucala (mepolizumab) product page on the GSKPro website compared with the Nucala product page on the public website.

GlaxoSmithKline stated that its public website provided a library resource in line with the provisions of Clauses 26.1 and 26.2 of the Code and related supplementary information. All content on the website was reference information about GlaxoSmithKline prescription only medicines which had a marketing authorization in the UK, as required by the Code.

Each product page on the public site linked to the Electronic Medicines Compendium (eMC) website for the patient information leaflet (PIL) and summary of product characteristics (SPC), as well as the European or UK Public Assessment Reports (EPAR or UKPAR) where available, a factual introduction to the product, sections on safety information and patient information and, where relevant, links to third party websites related to the relevant disease area, such as NHS Choices and NHS Inform. Clause 26.2 of the Code and its supplementary information additionally allowed for the provision of medicines guides and studies (published or not) but these had not been made available on the public website.

For certain products such as Nucala, the public website product page also included a separate section intended only for patients that had already been prescribed the product. These patient pages included further non-promotional information including about the disease, its treatment and about Nucala that fairly reflected the current body of evidence about the product and its benefit risk profile. A screenshot of the patient information for Nucala was provided. To access this information, patients had to select the 'I am a patient' link, which opened a new page. Patient information was thus clearly separated and clearly marked for the target audience, in compliance with the Blue Guide from the Medicines and Healthcare products Regulatory Agency (MHRA).

Further, as referred to by the complainant, after selecting the 'I am a patient' link, a pop-up appeared which asked users to reconfirm whether they were a patient (copy provided). When the public website was being developed, the company decided to institute this pop-up as a way of ensuring that the public could view patient information only if they chose to do so. Such a pop-up was not a Code requirement, nor a requirement of the MHRA Blue Guide. GlaxoSmithKline had fulfilled the requirements of the MHRA Blue Guide to clearly separate and mark the target audience.

GlaxoSmithKline noted that the complainant had referred to the Nucala public page of the public website and brought to its attention that after selecting the 'No, go back' link, the user remained on the public webpage and was not redirected to the product page as intended. GlaxoSmithKline stated that this was a technical issue and not a Code issue; the issue had been corrected. GlaxoSmithKline thanked the complainant for bringing this to its attention.

GlaxoSmithKline submitted that in compliance with Clauses 26.1, 26.2, 28.1, 28.3 and 28.5 of the Code and related supplementary information, all information on the public site was factual and presented in a balanced way, it did not raise unfounded hopes of successful treatment and side effects were stated so as not to mislead with respect to the safety of products. All content on the public website was presented in a non-promotional way - there were no brand colours or brand logos, no product claims, or any reference to promotional content or materials. No

statements were made for the purpose of encouraging members of the public to ask health professionals for a specific prescription only medicine.

Furthermore, all content on the public site was certified as non-promotional educational material, in accordance with Clause 14.3 of the Code. It had the appropriate adverse event reporting statements and, where required, carried black triangles, in accordance with Clause 26.3 of the Code and its supplementary information. There was also a clear indication when the user left the public website (eg when accessing links to third party websites described in above) by way of a 'pop-up' as required by Clause 28.6 of the Code. A screenshot of the pop-up was provided.

GlaxoSmithKline refuted the complainant's assertion that the information provided on its public website was promotional. Providing links to product reference materials such as the PIL and SPC, and providing the brand name, non-proprietary name and indication of a product did not amount to promotion nor did it encourage members of the public to ask a health professional for a particular product. To the contrary, this information was specifically required to be made available under the Code so that the public did not need to access material intended for health professionals on GSKPro. All information on the public website complied with the Code, and therefore GlaxoSmithKline denied any breach of Clauses 26.1, 26.2 or any other applicable clauses.

GlaxoSmithKline submitted that it had maintained high standards in the design and development of the public website and therefore it denied a breach of Clause 9.1.

GlaxoSmithKline noted that a ruling of breach of Clause 2 was a sign of particular censure, reserved for such circumstances. As GlaxoSmithKline denied any other breaches of the Code in respect of its public website, it respectfully submitted that its activities did not amount to a breach of Clause 2.

PANEL RULING

The Panel noted that GlaxoSmithKline had mistakenly been asked to respond to Clauses 22.1 and 22.2. The Panel noted that GlaxoSmithKline had responded in relation to the requirements of Clauses 26.1 and 26.2 and the Panel considered the allegations raised in relation to these Clauses.

The Panel noted that Clause 26.1 prohibited the promotion of prescription only medicines to the public. The Panel noted that Clause 26.2 permitted information about prescription only medicines to be supplied directly or indirectly to the public but such information must be factual, presented in a balanced way, must not raise unfounded hopes of successful treatment and must not encourage members of the public to ask their health professional to prescribe a specific prescription only medicine. The Panel noted that the supplementary information to Clause 26.2 set out the detailed requirements for reference information which was intended to provide a comprehensive library resource for members of the public giving information relating to prescription only medicines which had marketing authorizations. Reference information must represent fairly the current body of evidence relating to a medicine and its benefit/risk profile.

The Panel noted GlaxoSmithKline's submission that it operated two primary product websites intended for a UK audience that provided information about its prescription only products: the promotional GSKPro website for health professionals and the GlaxoSmithKline public website

which was non-promotional and intended for patients and members of the public. Both websites were accessible via the company's corporate website. Readers were asked to confirm whether they were a UK health professional or member of the public and were taken to the GSKPro landing page if they confirmed that they were UK health professionals and to the GlaxoSmithKline public website landing page if they confirmed that they were a member of the public.

The Panel noted that the products section of the public site included a list of GlaxoSmithKline's products in alphabetical order by brand name and included the non-proprietary name of each; in order to obtain further information on a particular product including the indication, the reader had to select that product.

The Panel noted that the page of the website at issue was the Nucala page of the public website. This bore links to the SPC and patient information leaflet. It featured the indication beneath a subheading 'What is Nucala?', adjacent to a prominent photograph of the product. Subheadings of Safety information and Patient Information below appeared above links to the patient information leaflet and patient guides respectively. The latter linked to the patient information part of the site, as did a link on the left-hand side of the webpage in question. The Panel queried whether a prominent picture of the product in material aimed at the public was appropriate.

The Panel noted GlaxoSmithKline's submission that its public website provided a library resource in line with the provisions of Clauses 26.1 and 26.2. The Panel noted GlaxoSmithKline's submission that each product page on the public site linked to the Electronic Medicines Compendium (eMC) website for the patient information leaflet (PIL) and summary of product characteristics (SPC), as well as the European or UK Public Assessment Reports (EPAR or UKPAR) where available, a factual introduction to the product, sections on safety information and patient information and, where relevant, links to third party websites related to the relevant disease area, such as NHS Choices and NHS Inform. This was confirmed by the copies of the information for Nucala provided to the Panel by GlaxoSmithKline.

The Panel further noted GlaxoSmithKline's submission that for certain products such as Nucala, the public website product page also included a separate section intended only for patients that had already been prescribed the product. These patient pages included further information including about the disease, its treatment and about Nucala that fairly reflected the current body of evidence about the product and its benefit risk profile. A screenshot of the patient information for Nucala was provided. The Panel noted that to access this information, patients had to select the 'I am a patient' link which asked the reader to confirm that they had been prescribed the medicine following consultation with a UK health professional before a new page opened. The Panel noted GlaxoSmithKline's submission that patient information was thus clearly separated and clearly marked for the target audience. The Panel noted that neither the content of the patient webpages nor the acceptability of a link to it were the subject of complaint.

The Panel's interpretation of the complaint was that according to the complainant, after clicking 'I am a patient' and when asked to confirm whether he/she had been prescribed the medicine, he/she selected 'no' but was, nonetheless, directed to the patient section. The Panel noted that the 'I am a patient' link stated for the 'No, go back' option 'Unfortunately we cannot display this GSK content if you are not a patient. You will be re-directed to the product page'. GlaxoSmithKline submitted that after selecting the 'No, go back' link, the user remained on the public webpage and was not redirected to the product page as intended. GlaxoSmithKline

stated that this was a technical issue and not a Code issue; the issue had been corrected. The Panel considered that if its interpretation of the complaint was correct then the complainant's concern was potentially a Code issue in that members of the public were exposed to the information for patients who had been prescribed the product. It was potentially more than a technical issue as stated by GlaxoSmithKline. Given that it was not possible for the Panel to know how the link in question worked when accessed by the complainant and that there was insufficient evidence to establish what had occurred on the balance of probabilities, the Panel ruled no beach of Clause 26.1 in relation to how the link in question worked.

Noting its comments above, in the Panel's view, the information about Nucala on the webpage for the public was not unacceptable in relation to the requirements of reference information as referred to in the supplementary information to Clause 26.2. The Panel ruled no breach of Clause 26.1 and 26.2.

The Panel did not consider that GlaxoSmithKline had failed to maintain high standards in this regard and no breach of Clause 9.1 was ruled. The Panel subsequently ruled no breach of Clause 2.

Complaint received **7 June 2019**

Case completed **27 April 2020**