

**CASE AUTH/3792/7/23**

**COMPLAINANT v GSK**

**Allegations regarding promotional GSK website**

**CASE SUMMARY**

This case was in relation to the promotion of GSK respiratory products on a GSK website.

The outcome under the 2021 Code was:

<b>Breach of Clause 6.1 (x2)</b>	<b>Providing misleading information</b>
<b>No Breach of Clause 2 (x4)</b>	<b>Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry</b>
<b>No Breach of Clause 5.1 (x4)</b>	<b>Requirement to maintain high standards at all times</b>
<b>No Breach of Clause 6.1</b>	<b>Requirement that information must not be misleading</b>
<b>No Breach of Clause 6.2 (x3)</b>	<b>Requirement that information must be capable of substantiation</b>
<b>No Breach of Clause 11.2 (x5)</b>	<b>Requirement that a medicine must be promoted in accordance with the terms of its marketing authorisation and must not be inconsistent with the particulars listed in its summary of product characteristics</b>

**This summary is not intended to be read in isolation.  
For full details, please see the full case report below.**

**FULL CASE REPORT**

A complaint about GSK UK Ltd was received from an anonymous, contactable complainant who described themselves as a health professional.

**COMPLAINT**

The complaint wording is reproduced below with typographical errors corrected:

“A promotional webpage for GSK respiratory products is non-compliant. The page can be accessed at [website link provided]. The page was in reference to COPD and mentioned 5 products. Trelegy, Anoro, Relvar, Incruse and Seretide Accuhaler. Relvar was available in two strengths and the 184/22 strength was not licensed for COPD. This was not made clear on the page (The page said Relvar only) so the assumption for any busy HCP incorrectly would be all strengths of Relvar were licensed for COPD which is a risk to

patient safety. This is misleading and so breached clauses 6.1, 6.2, 5.1 and 2. Although 5 products were mentioned on this promotional page and there was reference to COPD throughout the page, the actual licenses of all 5 products were much broader. For example, Trelegy was only licensed in maintenance treatment in adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) who are not adequately treated by a combination of an inhaled corticosteroid and a long-acting  $\beta$ 2-agonist or a combination of a long-acting  $\beta$ 2-agonist and a long-acting muscarinic antagonist. The other 4 products had precise indications too. To the intended reader of this webpage, the page would come across that the 5 products were all licensed for any COPD patient considering the repeated mentions of COPD throughout the page. When actually the products had very specific licenses. This was a breach of 11.2 (x5), 5.1 and 2 as the products had been promoted outside the licenced indication by not clarifying the actual indication anywhere on the page. Important to note there would be HCPs who would not have the understanding of the specific licensed indications without the actual licence being provided considering the range of different experiences of healthcare professionals involved in COPD management. On the page, there were 2 charts, underneath the title of Explore COPD medicine trends in England. However, these were misleading as the LAMA segment of the chart was actually also comprised of asthma data. This information was provided in small font in a the [sic] assumptions box underneath the chart which could only be read if clicked on. The box if clicked on, stated certain LAMA products can also be used for Asthma, opportunity is estimated only. This information about estimated opportunity should have been provided as part of the flow chart itself from the start of the chart. This was a breach of clauses 6.1, 6.2, 5.1 & 2. Further down the page towards the bottom, bar charts were presented underneath the header of, How do you compare to other health economies and the national average? However, these were misleading as the LAMA segment of the bar chart was actually also comprised of asthma data. This information was provided in the assumptions box underneath the chart in tiny text. The text stated Certain LAMA products can also be used for Asthma, opportunity is estimated only. This information about estimated opportunity should have been provided as part of the flow chart itself. This was a breach of clauses 6.1, 6.2, 5.1 & 2. Such modelling with assumptions and data which included asthma was not fair or balanced. The lack of licensed indications for the five GSK products was troubling. It is concerning that the compliance and medical team at GSK had allowed for this page to be published without ensuring it complied with the code.”

When writing to GSK, the Authority asked it to consider the requirements of Clauses: **Point 1:** 6.1, 6.2, 5.1 and 2; **Point 2:** 11.2 (x5), 5.1 and 2; **Point 3:** 6.1, 6.2, 5.1 and 2; **Point 4:** 6.1, 6.2, 5.1 and 2 of the Code as cited by the complainant.

## **GSK's RESPONSE**

The response from GSK is reproduced below:

“Thank you for your letter dated 5<sup>th</sup> July 2023 wherein you inform GSK that an anonymous complainant has raised concerns about a page on a GSK promotional website. GSK is committed to following both the letter and the spirit of the ABPI Code of Practice and all other relevant regulations and takes this complaint very seriously.

The allegations relate to the landing page of GSK's value.gsk website. Before addressing each of the allegations, GSK feels it is prudent to first provide the necessary background information on:

- COPD
- The purpose of the value.gsk website, and who its intended audience is.

## **Background Information**

### COPD

Chronic Obstructive Pulmonary Disease (COPD) is a heterogeneous lung condition characterized by chronic respiratory symptoms (dyspnea, cough, sputum production and/or exacerbations), abnormalities of the airways (bronchitis, bronchiolitis) and/or alveoli (emphysema) that cause persistent, often progressive, airflow obstruction.

Pharmacological therapy can reduce COPD symptoms, reduce the frequency and severity of exacerbations, and improve health status and exercise tolerance. Each pharmacological treatment regimen should be individualised and guided by the severity of symptoms, risk of exacerbations, side-effects, comorbidities, drug availability and cost, and the patient's response, preference, and ability to use various drug delivery devices. The heterogeneous nature of the condition means that there are a range of different treatment classes available, each designed for a different patient type; accordingly the licences of these classes of medicines vary.

### Value.gsk website

The website in question is value.gsk; the allegations relate to the landing page part of the site. The purpose of the website is to allow payer customers with responsibility for respiratory conditions to review the respiratory inhaler prescribing patterns in their local health economy, and view how this compares against other localities. It also allows them to utilise tools that highlight how they can run a medicines optimisation project, where they could run it, and the potential benefits from a cost and carbon perspective. As a result, the intended audience for this website is payers whose role involves medicines optimisation in COPD. Such individuals may be either healthcare professionals or Other Relevant Decision Makers (ORDMs). These individuals will be familiar with the therapy area of COPD, that it is a heterogeneous condition, and that there are different classes of medicines available to manage different patient phenotypes. Their role involves making management decisions at a population level, and thus the website is designed to support this purpose, rather than to support those making treatment decisions at an individual patient level.

In accordance with this intent, the website is used proactively by GSK in two ways. GSK's Regional Account Managers (promotional roles who work specifically with payer customers) can introduce the website to their payer customers, so that they can utilise it to support their work and have access to their latest prescribing data trends. It is also used as a destination for different digital activities, where certain email campaigns or QR codes at conferences/stand meetings/webinars will highlight that the site exists and provide a link to the website for people to access. These digital activities are only targeted at payer customers, and they make it clear, in advance, what the purpose of the website is.

Also consistent with this purpose is the search engine optimisation (SEO) description metadata approved for the website:

*'A portal for UK healthcare commissioners containing GSK product information, prescribing data and insights, benefits calculators and medicine optimisation planning tools. Explore where, why and how to do COPD medicines optimisation with Value.gsk'*

This would be the information visible to those who had organically found the website via a search engine, such that it would be clear to them at the outset, what the website's purpose and intended audience is. On entering the site, there is a clear overview of what the purpose of the website is:

*'Optimising COPD medicines can help you balance your clinical, cost and carbon priorities. Create an account and follow our step-by-step guide to identify, develop and deliver a bespoke COPD therapy optimisation project for your area. Our planning tools, customisable calculators and personalised prescribing trends allow you to predict the speed and impact of your project.'*

Users are required to register and create an account before being able to gain full access to all the aforementioned resources. Some content is available on the website prior to registering for an account and logging in, to give an idea of what kind of content will be available once registered. This includes class prescribing trends as well as data for prescribing trends by device type e.g. metered dose inhaler (MDI), or dry powder inhaler (DPI). This data is presented only by class; multiple options from multiple companies are available within each class and device type, therefore this information doesn't directly or indirectly promote any specific GSK medicines. However, the website, once logged in, does contain more information which is specific to GSK medicines. Therefore, it was important that GSK made this clear at the outset. GSK has done this in several ways. Firstly, on reaching the website a pop-up appears which requires the user to confirm that they are a UK healthcare professional and/or that they make decisions relevant to UK healthcare provision. The pop-up also states that the site is for *'Helping you with respiratory medicines optimisation'* and *'This site contains promotional information'*.

Secondly, at the very outset of the website it clearly states (after a prominent GSK logo) that *'This site contains promotional material'*. Additionally, to ensure full transparency, before a user decides to register for an account, GSK states in a clearly demarcated subsection, under the heading of *'Our respiratory products'* the following wording *'GSK respiratory products on this site include:'*. The five medicines that are contained in GSK's COPD portfolio are then listed by brand name. No claims are made here, no efficacy or safety data is provided, and there is no discussion on how these medicines can be used for patients with COPD. This is the first mention of any brand names, and the only mention (outside prescribing information links) of Relvar, Incruse and Seretide. Further down the webpage there is again reference to Trelegy and Anoro. However, no efficacy or safety data is provided, nor is there any discussion on how these medicines may be used to manage patients with COPD.

GSK accepts that the definition of promotion, as defined within clause 1.17, is broad, and recognises that it is widely accepted that the mention of a product in the context of a therapy area alone is likely to be viewed as promotion. In line with clause 8.1, the final

form of the website was certified as a promotional item. All requirements for promotional material, as set out in clause 12, were also met. Of note, the non-proprietary name of each brand was present immediately adjacent to the first display of each brand name (clause 12.3). As per clause 12.10, where required by the licensing authority an inverted black equilateral triangle was present. A clear, and prominent, direct, single click link to the relevant prescribing information was provided for each brand (clause 12.4). A clear prominent statement as to where the prescribing information could be found was present at the very top of the website (clause 12.6). The prescribing information provided for each of the products was fully compliant with clause 12.2. Of note, the authorised indication for each medicine was included, as was information relating to dosage. For Relvar specifically, the following statements were included in the prescribing information :

Under bold heading 'Indications': *COPD: 92/22 mcg only - Symptomatic treatment of adults with COPD with a FEV1<70% predicted normal (post-bronchodilator) and an exacerbation history despite regular bronchodilator therapy.*

Furthermore, under the bold heading 'Dosage and administration': *COPD: Adults ≥18 years: One inhalation once daily of 92/22 mcg. 184/22 mcg is not indicated in COPD.*

In summary, value.gsk is a promotional website intended for a payer audience whose role involves medicines optimisation in COPD and population level decision making. The website was fully reviewed and approved by a suitably qualified ABPI Signatory to ensure all relevant requirements of the ABPI Code of Practice were met.

### **Response to allegations within complaint**

As per your letter, there are four separate points within the complaint.

#### Point 2

The complainant has alleged that highlighting which GSK medicines are discussed within the website, within the wider context of information referring to the condition of COPD, without stating the exact indication of each individual medicine mentioned, gives the impression that each medicine is licensed for any COPD patient, and thus that they are being promoted outside of their licensed indications. They also state that it is important to note that there would be HCPs who would not have the understanding of the specific licensed indications without the actual licence being provided considering the range of different experiences of healthcare professionals involved in COPD management.

Clause 5.6 of the ABPI Code of Practice states '*Material should only be provided or made available to those groups of people whose need for or interest in it can reasonably be assumed. Material should be tailored to the audience to whom it is directed.*' As described above, the value.gsk website was designed for a payer audience whose role involves medicines optimisation in COPD. GSK's proactive use of the website is to such an audience only. Additionally, anyone arriving at the webpage organically via an internet search will also be aware of the purpose of the website, firstly via the search engine description metadata, secondly via the pop-up, and finally due to the introduction provided at the top of site. The intended audience in question would be familiar with the condition of COPD, including how patients are managed, due to their experience in creating local COPD guidelines, formularies, and optimisation programmes. Such an audience would be

aware that COPD is a heterogeneous condition, and that there are a range of medicine classes available to manage COPD, and that these have different licences and are approved to treat different cohorts of patients. The utility of value.gsk to this audience is to support population level management decisions, and not to provide information for those making prescribing decisions at an individual patient level.

Clause 6.1 requires that all information provided is accurate, balanced, unambiguous, and does not mislead either directly or by implication. Material must be sufficiently complete to enable recipients to form their own opinion of the therapeutic value of the medicine. As detailed above, the section of the website in question provides an overview of what tools, resources and information users will have access to if they create an account on value.gsk. It also refers broadly to the therapy area of COPD - the specialty within which the intended audience work. It is clear from the outset, and throughout, that the website contains promotional content. For full transparency, GSK lists which of its respiratory medicines the site will discuss, in a section that is clearly demarcated from other content. This is the first mention of GSK medicines, and the only mention of Relvar, Incruse and Seretide. At no point on this webpage is any efficacy or safety information discussed, neither is there any discussion of how these GSK medicines may be used when managing patients with COPD. There is no content on the website which suggests - and thus misleads, either directly or by implication, by distortion, exaggeration, or undue emphasis - that all the listed GSK medicines are each all licensed for use in any patient with COPD. Where one part of the website discusses NICE guideline recommendations for the LAMA/LABA class as a whole, it provides clarity that *'LAMA/LABAs are indicated as maintenance bronchodilator treatments to relieve symptoms in adult patients with COPD.'*

Users of the site who might have chosen to find out more about any of the listed GSK medicines could do so by accessing the prescribing information which contained the necessary particulars on licensed doses and indications. However, GSK strongly refutes the notion that mentioning, for transparency, the respiratory products that will be discussed on the site, in the context of content elsewhere on the webpage which refers more broadly to the therapy area of COPD, implies that all these medicines are licensed for all patients with COPD.

GSK notes that within Case AUTH/3541/7/21 (A health professional v Roche), there had been a similar allegation, that marketing authorisations for products were very specific and that only referring to therapy areas constituted off-licence promotion. In that case, the Panel considered that the statement in question was referring to Roche's portfolio and the therapy areas in which the products in its portfolio fell and was not referring to the indications of the products listed. GSK strongly believes that this is also the case here with the value.gsk website landing page. At no point is there any suggestion, either directly or indirectly, that all the GSK medicines mentioned are all licensed for all patients with COPD.

Furthermore, in the recently released PMCPA Social Media Guidance 2023 it states:

*'An indication or therapy area eg #obesity might constitute promotion of a product if it was used in combination with other language which could identify a specific product'*

We note the distinction here between 'indication' and 'therapy area'. As described above, GSK accepts that whilst the mention of a medicine in the broader context of a therapy

area makes that item promotional, it isn't the case that such a mention relays to a healthcare professional that the medicine must be licensed for all patients within that therapy area.

Clause 12 of the ABPI Code of Practice does not list, outside of the prescribing information, the indication statement as obligatory information which must be present on all materials which meet the definition of promotion. Notwithstanding the above, GSK agrees that in certain circumstances it is best practice to include the relevant indication statement for clarity; for example, where content discusses the use of specific medicines to manage patients, or discusses efficacy and safety data, or where its inclusion is required to avoid any confusion about how a medicine may be used. However, GSK does not believe that such conditions apply in this instance, as no information or discussion is present on how these specific medicines may be used to manage patients with COPD, and no efficacy or safety data is provided. The information is also suitably tailored to the intended audience – payers who specialise in COPD.

The complainant has alleged that there will be HCPs who view this website who do not have an understanding of the specific licensed indications within COPD, although the complainant has provided no evidence as to why those not involved in COPD treatment optimisation would choose to use this website to ascertain information on how to manage individual patients, given its purpose is clear from the outset. Nonetheless, GSK does not dispute that not all HCPs will be fully aware of what the licence of each available medicine in COPD is. However, GSK does believe it is disingenuous to suggest that a qualified HCP making management decisions in COPD would, based on the content of the landing page of value.gsk alone, without recourse to the PI or the SmPC as a minimum, believe that all the listed medicines can each be used to treat any patient with COPD. Indeed, the GMC's guidance Good Practice in Prescribing and Managing Medicines and Devices states, *inter alia*:

*'You are responsible for the prescriptions that you sign.'*

*'You are also accountable for your decisions and actions when supplying or administering medicines.'*

*'You must recognise and work within the limits of your competence.'*

*'You must maintain and develop your knowledge and skills that are relevant to your role and practice in: prescribing and managing medicines'*

*'In providing clinical care you must: prescribe medicine or treatment, including repeat prescriptions, only when you have adequate knowledge of the patient's health, and are satisfied that the medicine or treatment serve the patient's needs'*

*'If you are unsure about interactions or other aspects of prescribing and managing medicines, you should seek advice from experienced colleagues, including pharmacists, prescribing advisers and clinical pharmacologists.'*

Accordingly, professional standards of practice would dictate that given the limited information provided on the value.gsk website section in question, HCPs would need to seek out further information, for example via the provided prescribing information links, or the relevant SmPC, if they wanted to seek out the necessary information on indications and dosage particulars. The complainant has provided no evidence to corroborate why HCPs would not be acting in accordance with their mandated professional standards.

In conclusion, GSK refutes the allegation that it has promoted its COPD medicines outside of the terms of their marketing authorisations, and denies all breaches of clause 11.2. All the necessary information was provided in a clear and transparent manner, was not misleading, and was fully certified, and compliant with all the obligatory requirements of the ABPI Code of Practice. Therefore, GSK also denies breaches of clause 5.1 and clause 2.

#### Point 1

The complainant has stated that Relvar is available in two strengths and that the 184/22mcg strength is not licensed for COPD. They claim that this was not made clear on the page as it only refers to 'Relvar'. They allege that this would lead to any busy HCP incorrectly assuming that all strengths of Relvar were licensed for COPD which is a risk to patient safety.

GSK disagrees with the notion that an HCP who may be aware of the existence of two dosage strengths of Relvar - based on knowledge outside of that gleaned from this website - would as a result of the content of this website conclude that both these two dosage strengths can be used in COPD. Nowhere on the website has GSK specifically mentioned either the 92/22mcg dosage strength of Relvar or the 184/22mcg dosage strength of Relvar. As described above, for transparency, Relvar is simply listed as one of the GSK respiratory products which are discussed on the website – this, and the associated prescribing information link, are the only mentions of Relvar on the page in question. Beyond that, no further information, including efficacy or safety data, or information on how Relvar may be used to manage patients with COPD, is provided. At no point is there any suggestion, either directly or indirectly, that Relvar 184/22mcg is licensed for patients with COPD.

GSK accepts that the mention of a therapy area and product meets the broad definition of promotion, and thus the prescribing information for Relvar is provided. As already highlighted, prescribers have a professional duty to ensure they follow high standards when prescribing medicines to patients. Thus, if an HCP chooses to seek out further information about the licensed indications and dosage particulars for Relvar, this would be easily available to them via the prescribing information link. Additionally, as discussed above, the website is designed for payers who specialise in COPD optimisation decisions at a population level and are not, in that capacity, making prescribing decisions for individual patients. Such individuals would be aware of the importance of checking the relevant licensed indications and dosage particulars when creating guidelines, formularies, or optimisation programmes. Again, the complainant has provided no evidence to support their assertion that busy HCPs managing individual patients with COPD would use this landing page to inform their practice.

The limited information provided – Relvar is one of the medicines in GSK's COPD portfolio – is accurate and not unambiguous. GSK accepts that if asthma management was being discussed, and/or if the two dosage strengths of Relvar were highlighted on the website, then it would absolutely have needed to clearly state which dosages were licensed for which indication, and what those indications were. However, this was not the case, and therefore GSK strongly refutes the allegation that the information provided was misleading or insufficient. Relvar is a medicine within GSK's COPD portfolio, which GSK is able to substantiate with the SmPC. Beyond that no further claim or comparison is made.



Therefore, GSK refutes breaches of clauses 6.1 and 6.2. Accordingly, high standards were maintained and patient safety has not been compromised, as a result GSK also denies breaches of clause 5.1 and clause 2.

#### Points 3 and 4

To give visitors to the site an idea of the kind of data that would be available to them if they registered for an account, some example charts are provided on the landing page. These include national prescribing trends by class and by device type. Additionally, further down the site this same information is also provided at a more local level with the option for users to select a specific local health authority. This data is at a medicine class level, or device type level only. There is no data provided for specific brands of medicine, whether that be GSK medicines or those of other companies. The source of this data is clearly stated as GPrX Practice Prescribing data. Given the specialist nature of those this website is designed for, they will be familiar with this data source, and also more broadly viewing population level prescribing trends data.

Such data is of value to those making decisions at a population level and isn't intended for HCPs making individual patient level prescribing decisions. Such an audience would therefore be familiar with the fact that such data is always associated with certain assumptions and caveats - with it being designed to highlight potential trends and patterns, rather than give an exact answer to a specific question.

Some of the relevant assumptions are provided as part of the graphs themselves, whilst others are provided immediately below the graphical images in a clearly labelled section entitled 'Calculations and assumptions'. Therefore, all the relevant information is easily accessible all together in the same place, with no need for the user to have to scroll, link out to, or search other parts of the website to see it.

It was deemed important to include the statement 'LAMA products can also be used in Asthma, opportunity is estimated only' to ensure transparency, such that users could factor this in to how they interpreted the data. However, it was deemed sufficient to include this within the clearly labelled assumptions section immediately under the graph, versus as part of the graph itself, as many LAMA prescriptions are likely to be for patients with COPD. Long-acting muscarinic receptor antagonist (LAMA) medicines are a well-established class within COPD, with them being used both as a monotherapy for patients with less severe disease, and as an add on therapy for those with more severe disease who are also on an ICS/LABA combination inhaler. It is a commonly used class of medicine for COPD within primary care. Whilst in asthma its licensed role is reserved to that of an add on therapy in those with more severe asthma, with guidelines recommending that it is initiated under the direction of a specialist. Additionally, the majority of the LAMA therapies available in the UK are licensed only for COPD.

Therefore, the information provided is accurate, balanced, fair, objective, and unambiguous. It is not misleading as the assumption in question is transparently provided, and easily accessible, immediately below the graph. The assumption itself is also appropriate given the context of how LAMAs are prescribed across COPD and asthma. The information is sufficiently complete to enable the end audience to make their own judgements on its utility to their practice. All the information is appropriately referenced and can be substantiated. GSK therefore refutes breaches of clauses 6.1 and 6.2. High

standards have been maintained; thus, GSK also denies breaches of clause 5.1 and clause 2.

In conclusion, GSK strongly believes that the value.gsk website is fully compliant with both the letter and the spirit of the ABPI Code of Practice, and therefore refutes all the allegations made by the anonymous complainant.”

## PANEL RULING

The Panel noted the promotional webpage at issue was the landing page of the value.gsk website.

The Panel considered the layout and context of the page. The top banner included the location of prescribing information, the GSK logo, a declaration that the page was for UK healthcare professionals and that the site contained promotional material. Also included were tabs to “Log in”, “Register” and “Report adverse event”. The page title “Welcome to Value.GSK A breath of fresh air for COPD management” appeared below with the statement “We’re here to support you on your mission to do your best for your patients and your NHS” followed by a description explaining the purpose of the website and how to access the resources available and a call to action describing why, where and how to optimise for COPD medicines. Below was a section titled “Our respiratory products” listing the names of the five GSK respiratory products that were included on the site. These were Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol) Anora Ellipta (umeclidinium/vilanterol), Relvar Ellipta (fluticasone furoate/vilanterol), Incruse Ellipta (umeclidinium) and Seretide Accuhaler (salmeterol xinafoate/fluticasone propionate).

The remainder of the webpage was devoted to examples of the types of data available upon account registration. The first example illustrated COPD medicine prescribing data in England. Two charts were displayed showing prescribing data for COPD medicines based on class and device type. The chart titled “CLASSES” displayed prescribing data based on inhaled corticosteroids/long -acting beta2 agonists /long-acting muscarinic antagonists (ICH/LABA/LAMA), LAMA/LABA, LAMA. Below this chart appeared the statements:

“On average, 42% of medicine prescribing in England are on single inhaler triple therapy (SITT) medication.”

“Higher LAMA therapy prescribing we use as a proxy for higher multiple inhaler triple therapy prescribing.”

The chart titled “DEVICES” illustrated prescribing data based on metered-dose inhaler (MDT), dry powder inhaler (DPI) and fine mist inhaler (FMI). Below this chart appeared the statements:

“On average, 49% of medicine prescribing in England are on dry powder inhalers (DPI) devices.”

“Classes included in the device graph: LAMA, ICS/LABA/LAMA, LAMA/LABA, ICS/LABA.”

Below both charts was a drop-down box titled “calculations and assumptions” which when expanded stated:

“Class and Device Data: From GP Practice Prescribing data<sup>2</sup>

National average: Calculated for England, Scotland or Wales depending on health economy selection

NB. Certain LAMA products can also be used for Asthma, opportunity is estimated only.”

The second example illustrated COPD medicine prescribing data per health authority with two bar charts showing prescribing data for COPD medicines based on class and device type. The same classes of medicines and device types were illustrated. Below the “CLASSES” bar chart was a summary of the NICE COPD treatment guideline recommendations with a link to the NICE website and directly beneath this was a drop-down box labelled “calculations and assumptions” which when expanded stated:

“Class and Device Data: From GP Practice Prescribing data<sup>2</sup>

National average: Calculated for England, Scotland or Wales depending on health economy selection

Peer health economy selection: Selection of peers based on those peer health economies with lowest percentage of LAMA vs LABA/LAMA and ICS/LABA/LAMA

NB. Certain LAMA products can also be used for Asthma, opportunity is estimated only”

The statement “Classes included in device graph: LAMA, ICS/LABA/LAMA, LAMA/LABA, ICS/LABA” appeared below the “DEVICES” bar chart followed by a drop-down box labelled “calculations and assumptions” which when expanded contained the same information as above.

The Panel concluded that the purpose of the website was to support payers, whose roles involved medicines optimisation in COPD and was not for health professionals involved in making treatment decisions at an individual patient level. This was based on the following reasons:

- the search engine optimisation (SEO) description metadata stated that the value.gsk was a portal for UK healthcare commissioners containing GSK product information, prescribing data and insights, benefits calculators and medicine optimisation planning tools.
- on reaching the website users had to confirm they were a health professional and/or that they made decisions relevant to UK healthcare provision and to create an account in order to access information beyond that included on the face of the page or to use the benefits calculator and medicines optimisation tools.
- the landing page stated the website was for UK healthcare professionals and that its purpose was to aid the optimisation of COPD medicines to help balance clinical, cost and carbon priorities.
- there were no claims in relation to any of the GSK products listed on the page, nor was there efficacy or safety data.
- the webpage did not include any information on how these medicines may be used to manage patients with COPD.
- GSK’s submission that the website was proactively introduced by GSK’s Regional Account Managers to payer customers and that it was also used as a destination in digital activities targeted at payer customers.

While noting information specific to GSK’s medicines was available on the website for users who had logged in, the Panel accepted GSK’s submission that its products were listed on the landing page for transparency purposes. The mention of a therapy area and product met the broad definition of promotion and so links to prescribing information and other obligatory information were included.

### Points 1 and 2

The complainant alleged that the webpage was misleading as it was not made clear that the 184/22 strength of Relvar was not licensed in COPD, and a busy HCP may incorrectly assume that all strengths of Relvar were licensed for COPD. The complainant also alleged that the five GSK products mentioned on the webpage had been promoted outside of their marketing authorisation, as each product had a precise indication in relation to COPD and these were not listed. Viewers may misinterpret that these products were licensed for any COPD patient. This was important as there may be healthcare professionals (HCPs) who would not have the understanding of the specific licensed indications considering the range of different experiences of HCPs involved in COPD management.

The Panel noted that the value.gsk website was not a product website; it clearly stated at the outset that it was aimed at a health professional and/or a payer audience whose roles involved medicines optimisation to support population level management decisions. The Panel considered the inclusion of the names of the five GSK respiratory products on the webpage was for transparency purposes. In the Panel's view, it was unlikely that health professionals seeking product information to inform prescribing decisions at an individual patient level would access the website given its name and clearly stated purpose. Furthermore, any website users wanting information about the products listed could access the prescribing information via the links on the webpage or the product specific information included elsewhere on the website.

On balance, the Panel concluded that in relation to Relvar the webpage was not misleading and ruled **no breach of Clause 6.1**. The Panel did not consider that the reference to Relvar represented any information, claim or comparison that was incapable of substantiation and ruled **no breach of Clause 6.2**. Noting its comments above and its rulings the Panel did not consider that the complainant had established that GSK had failed to maintain high standards or that the webpage represented a risk to patient safety in relation to Relvar and accordingly it ruled **no breaches of Clauses 5.1 and 2**.

The Panel considered the impression created by the inclusion of the names of five GSK respiratory products on the webpage without referring to the specific indications of the products listed. The Panel did not consider that, in the particular circumstances of this case, that listing the product names in isolation suggested that each medicine would be licensed for all patients with COPD as alleged. Nor did the Panel consider that the complainant had established that the list of product names on the webpage constituted promotion outside of marketing authorisation. The Panel ruled **no breach of Clause 11.2** in relation to each medicine. Accordingly, the Panel did not consider that the complainant had established that GSK had failed to maintain high standards and ruled **no breaches of Clauses 5.1 and 2**.

### Points 3 and 4

The complainant alleged that the charts shown on the page were misleading as the LAMA segment of the charts included data for asthma, and this information was not made clear on the charts themselves.

GSK submitted it was sufficient to include the statement "LAMA products can also be used in Asthma, opportunity is estimated only" within the "calculations and assumptions" drop down section. The Panel noted that viewers would have to click on the drop-down function in order to become aware of this information. It was not clear to the Panel why it could not be provided as

an integral part of the charts. The Panel considered the information was highly pertinent to interpreting the charts and noted that the supplementary information to Clause 6.1 required material to be capable of standing alone with regards to accuracy and not rely on qualification by the use of footnotes. On balance, the Panel considered the omission of the information meant the charts created a misleading impression and it therefore ruled a **breach of Clause 6.1** in relation to the pie charts and a **breach of Clause 6.1** in relation the bar charts. The Panel did not consider that the complainant had established that the data could not be substantiated, as alleged and accordingly the Panel ruled **no breach of Clause 6.2** in relation to the pie charts and **no breach of Clause 6.2** in relation the bar charts. In the circumstances of the case, and given the breach ruled related to the use of a dropdown menu to access relevant information, the Panel considered that this matter was adequately covered in the ruling above and did not consider that GSK had failed to maintain high standards. The Panel ruled **no breaches of Clauses 5.1 and 2** in relation to the pie charts and **no breaches of Clauses 5.1 and 2** in relation to the bar charts.

**Complaint received**      **4 July 2023**

**Case completed**        **2 December 2024**