CASE/0288/09/24 ***NO BREACH OF THE CODE***

COMPLAINANT v GSK

Allegations about a symposium at an international congress

CASE SUMMARY

This case was in relation to a symposium organised by GSK at an international congress in Austria. It was alleged that the titles of the symposia in the pdf version of the congress programme indirectly mentioned two GSK ICS/LABA products, along with the indications, and therefore prescribing information and an adverse event reporting statement should have been included in the programme.

The outcome under the 2021 Code was:

No Breach of Clause 2	**Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**
No Breach of Clause 5.1	**Requirement to maintain high standards**
No Breach of Clause 12.1	**Requirement to include up-to-date prescribing information**
No Breach of Clause 12.9	**Requirement that all promotional material must include the prominent adverse event statement**

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 GlaxoSmithKline UK Limited was received from a contactable complainant who described themselves as a health professional.

COMPLAINT

The complaint wording is reproduced below with some typographical errors corrected:

> "At the [named international congress] congress which took place in [Austria], GSK had organised a symposium on the 09th of September 2024 from 17:30pm-19:00pm. The title of the GSK symposium was - Finding the right balance: Choosing an ICS/LABA for your moderate asthma patients. There were 4 talks within this GSK symposium. UK HCPs were invited to these sessions and exposed to the advertising for the symposium in the congress programme booklet. One of the 4 talks was given by a UK HCP at 17.35pm and was titled - Why is timely assessment critical for ICS/LABA initiation in moderate asthma. The symposium and the individual sessions were named and advertised in the congress programme which was available to UK HCPs. GSK had 2

prominent ICS/LABA products - Seretide and Relvar. Considering the title of the symposium and the title of the talk from the UK speaker it was definitely an indirect mention of both Seretide and Relvar within the titles of the symposium and the UK HCP session, considering a drug class (ICS/LABA) and indication (asthma) were noted as the titles of the symposium and the UK speaker talk title. Prescribing information for Relvar and Seretide and adverse event reporting statements were not provided within the congress programme where these sessions were advertised. Thus it was a breach of clauses 12.1, 12.9, 5.1 and 2. It was concerning that GSK had not aligned with the code of practice guidance considering previous breaches at [named international congress]."

When writing to GSK, the PMCPA asked it to consider the requirements of Clauses 12.9, 12.1, 5.1 and 2 of the 2021 Code.

GSK'S RESPONSE

The response from GSK is reproduced below:

"Thank you for your letter dated 12th September 2024 in which you informed us that a healthcare professional raised concerns about a symposium at the 2024 [named international congress] in [Austria]. GSK is committed to following both the letter and the spirit of the ABPI Code of Practice and all other relevant regulations.

The anonymous complainant alleges that the symposium title 'Choosing an ICS/LABA for your moderate asthma patients' and session title 'Why is timely assessment critical for ICS/LABA initiation in moderate asthma' on the congress programme in question contains an indirect mention of GSK ICS/LABA (inhaled corticosteroid/long-acting beta-agonist) products Seretide (fluticasone propionate / salmeterol xinafoate) and Relvar (fluticasone furoate / vilanterol trifenatate). The complainant further alleges that '*considering a drug class (ICS/LABA) and indication (asthma) were noted as the titles', 'prescribing information for Relvar and Seretide and adverse event reporting statements were not provided within the congress programme where these sessions were advertised.'* The complainant has alleged breaches of Clauses 2, 5.1, 12.1 and 12.9 of the 2021 ABPI Code of Practice.

The Authority is not an investigatory body, and the burden of proof lies with the complainant. However, in this case they have provided no evidence for their assertions and rely of GSK having to determine which congress programme they refer to. There were three Congress programmes available; a printed version provided to delegates at the event, an online version and a pdf. From the nature of the complaint, we have assumed it to be the pdf as the printed version does not contain the titles of the presentations and the online version does contain both prescribing information and adverse event statement thus negating the complaint.

There are numerous 'ICS/LABA' combinations available from different companies. GSK markets three fixed dose combinations of ICS/LABA (Relvar, Seretide Accuhaler and Seretide Evohaler). There are also other ICS/LABA fixed dose combinations from competitor companies available from other companies.

Examples of other ICS/LABAs and their manufacturers include:

AstraZeneca's Symbicort metered dose inhaler (budesonide / formoterol fumarate dihydrate) and Symbicort Turbohaler;
Chiesi's Fostair metered dose inhaler (beclomethasone dipropionate / formoterol fumarate dihydrate) and Fostair NEXThaler;
Glenmark's Stalpex (salmeterol xinafoate / fluticasone propionate);
Lupin's Luforbec (beclometasone dipropionate / formoterol fumarate dihydrate);
Orion's Fobumix Easyhaler (budesonide / formoterol fumarate dihydrate) and Fusacomb Easyhaler (fluticasone propionate / salmeterol xinafoate);
Sandoz' AirFluSal Forspiro (fluticasone propionate / salmeterol xinafoate);
Teva's DuoResp Spiromax (budesonide / formoterol fumarate dihydrate);
Thornton's Fixkoh Airmaster (fluticasone propionate / salmeterol xinafoate);
Wockhardt's WockAIR (budesonide / formoterol fumarate dihydrate).

Thus, mentioning ICS/LABA in the symposium or session titles does not identify any specific GSK medicine and therefore does not require the inclusion of the prescribing information and adverse event statement. GSK has therefore complied with the requirements of the Code and denies breaches of Clauses 12.1 and 12.9.

Background
The [named international congress] is an annual meeting that brings together the world's respiratory experts to showcase all the latest advances in respiratory medicine and science. Attendees include a significant number of UK health professionals.

Asthma is a heterogeneous disease defined by the history of respiratory symptoms (e.g. wheeze, shortness of breath, chest tightness, and cough) that vary over time and in intensity, together with variable expiratory airflow limitation. Airflow limitation may later become persistent. ICS/LABAs are indicated in the regular treatment of patients with asthma who are not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short-acting beta agonist or already adequately controlled on both an inhaled corticosteroid and a long-acting beta agonist.

The [named international medical society] produced three Congress programmes for all delegates: one in print format, one pdf and one online. It listed all sessions taking place at the Congress including both those organised by the pharmaceutical industry and those that were not.

GSK believes the complainant is referring to [named session].

As outlined above, the title and description of the session do not identify any specific GSK product and therefore there is no requirement to supply prescribing information or the adverse event reporting statement. GSK involvement is made clear at the outset as required and alerts the audience that company products are likely to be discussed if the symposium is in a therapeutic area where the company have an interest.

In the online version of the programme, more information was provided to the reader and a specific product identified. As such, GSK classified it as promotional material and the prescribing information and adverse event statement were included.

GSK therefore refute the allegations of breaching Clauses 12.1, and 12.9.

While it is an established principle under the Code that it is possible to promote a product without mentioning its name, this would require some form of indirect reference, such as the product being the only one available in the class being mentioned, or having a unique feature that is mentioned, or by using branding that a health professional would associate with a particular medicine. None of these apply in the case of the programme in question in relation to Seretide or Relvar.

GSK's approach to the provision of Prescribing Information and the adverse event reporting statement on materials is to consider the content of each material, including direct and indirect references to specific products, to ensure that the correct Prescribing Information and the adverse event statement is provided.

The symposium itself was promotional. GSK is aware of the requirements of the ABPI Code of Practice and understand the importance of the inclusion of prescribing information and adverse event reporting information in promotional material. As demonstrated in the items attached, GSK ensured both the relevant prescribing information and adverse event reporting information were included in all GSK materials that identified a GSK product relating to the symposium. In accordance with GSK processes and the Code, all promotional materials in question were certified in final form by a signatory with over 6 years' experience who is [qualifications provided].

As such GSK has maintained high standards and have not brought discredit upon, or reduced confidence in, the pharmaceutical industry and refute the allegations of breaching Clauses 5.1 or 2.

Although no complaint was made about the content of the symposium or choice of speakers, as requested GSK has included the material presented at the symposium. GSK has also included the ePoster, printed invitation and email banner advertisement. These adverts were promotional and contained all the required information. There were no materials circulated after the event.

The rationale for why the speakers were chosen is listed below.
Speaker 1 is a Professor of Respiratory Medicine and a leading Consultant Physician. He is an academic with over 300 respiratory peer reviewed papers, on asthma, COPD and chronic cough.
Speaker 2 is a Professor of Clinical Pharmacology and Respiratory Medicine, and they have acted as the principal investigator in over 400 respiratory clinical trials.
Speaker 3 is an internationally recognised Consultant of Pulmonary Medicine with over 250 publications in the respiratory field.

Cases supportive of GSK's argument
Case AUTH/3308/2/20 similarly considered a complaint of prescribing information being needed because GSK had a 'triple therapy' product, despite there being other triple therapy products and combinations. The Appeal Board took the view 'that the reference to triple therapy could be any one of a number of different combinations of the three different inhalers available or one of the two available single fixed dose formulations available'. Prescribing information for Trelegy was therefore not needed and no breach was ruled.

GSK would also like to draw attention to the Panel and Appeal Board's decision in Case AUTH/2482/2/12. In that case, the complainant had alleged that Novo Nordisk had sent an email invitation to a meeting that mentioned 'modern insulins' but had not provided prescribing information for any insulin products. Novo Nordisk marketed three different insulin products and a further five were available from other companies at the time. The Panel ruling stated that 'The Panel did not consider that the email promoted any particular insulin and thus no prescribing information for insulin was required. No breach of Clause 4.1 [of the 2011 Code] was ruled. There was no disguised promotion of any insulin and no breach of Clause 12.1 [of the 2011 Code] was ruled.' The complainant appealed; however, the Appeal Board upheld the Panel's ruling and the appeal on these points was not successful.

GSK acknowledges that each case should be considered on its merits but believes that Case AUTH/3308/2/20 and Case AUTH/2482/2/12 are of particular relevance to this current case, due to the very similar natures of the complaints alleging indirect references to specific products where only classes of products are mentioned.

GSK would further like to draw attention to the Panel's rulings in Cases AUTH/1898/10/06 and AUTH/1900/10/06 which were separate complaints about a letter sent by Procter & Gamble to HCPs. Of particular interest in these cases was that even though the non-proprietary name (mesalazine) of a branded product that the company marketed had been used in a letter that had been sent by that company, the Panel did not view this as promotion of that company's product, because other mesalazine preparations were available from other companies. Consequently, prescribing information for Seretide and Relvar do not need to be provided and so GSK denies a breach of Clause 12.1.

Clauses 5.1 and 2
As GSK denies the complainant's allegations regarding the programme in question as detailed above, have followed all company policies and processes to ensure compliance with the Code including certification of all promotional materials, GSK firmly believes that high standards have been maintained and therefore deny a breach of Clause 5.1. Consequently, GSK does not believe that it has brought discredit upon, or reduced confidence in, the pharmaceutical industry, and deny a breach of Clause 2.

Summary
In summary, GSK takes its responsibilities of working within the letter and the spirit of the ABPI Code of Practice very seriously. The programme at issue did not identify a specific medicine and therefore did not trigger the need for prescribing information or adverse event statement as alleged. All materials that did identify both a specific medicine and its indication did include the obligatory elements and were certified appropriately. GSK strongly denies breaches of Clauses 2, 5.1, 12.1 and 12.9."

PANEL RULING

This case was in relation to a symposium organised by GSK at an international congress in Austria. The GSK symposium that was the subject of the complaint was a ninety-minute session titled "Finding the balance: Choosing an ICS/LABA for your moderate asthma patients". The symposium was made up of three talks provided by two UK health professionals and one Spanish health professional, followed by a panel discussion with Q&A.

One of the talks by a UK health professional was titled "Why is timely assessment critical for ICS/LABA initiation in moderate asthma?" The complainant alleged that the title of that talk and the title of the symposium were both an indirect mention of Seretide (fluticasone propionate / salmeterol xinafoate) and Relvar (fluticasone furoate / vilanterol trifenatate); two prominent, GSK ICS/LABA products. The complainant further alleged that the indirect mention of the drug name, together with the indication, meant that prescribing information and an adverse event reporting statement should have been provided within the congress programme.

The congress programme

The Panel noted that there were multiple versions and formats of the congress programmes and that the complainant did not specify which version of the programme their complaint concerned.

The Panel took account of GSK's submission that there were three versions of the congress programmes available to all delegates:

(a) a printed version provided to delegates at the congress,
(b) an online version, and
(c) a pdf version.

The complainant referred to a "congress programme booklet" rather than an online programme. The Panel therefore did not consider the online version of the programme to be the subject of the complaint.

GSK submitted that the allegations must relate to the pdf version of the programme because:

(a) the printed version did not contain titles of the presentations, and
(b) the online version *did* contain prescribing information and an adverse event statement.

Based on the complaint and response, and the materials provided by the parties, the Panel concluded that the allegations related to the pdf version of the programme and made its ruling on that basis. The pdf of the programme had been produced by the congress organisers and consisted of 502 pages, listing the title, time and location of all the sessions being held over the five day congress.

The Panel noted that GSK had commented on, and provided promotional material in relation to, the symposium. However, as the content and advertising of the symposium was not at issue, the Panel did not consider these as part of its ruling.

Was the pdf version of the programme promotional?

The complainant alleged that the congress programme booklet, which the Panel took to mean the pdf version of the programme, was promotional because it indirectly mentioned GSK products and so should have included prescribing information (Clause 12.1) and an adverse event reporting statement (Clause 12.9).

The key question for the Panel to address was whether the pdf version of the programme itself was promotional.

The Panel took account of the broad definition of promotion in Clause 1.17 of the Code, which referred to any activity which promotes the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines. The Panel noted it was an accepted principle under the Code that it was possible, given the broad definition of promotion, for material to be promotional without mentioning products by name.

The title of the symposium and the talk at issue were listed under Session 376 on page 403 of the pdf version of the programme, within a specific industry sessions section and clearly marked as being organised by GSK. The title of the symposium, and the title of one of the talks, referred to the drug class "ICS/LABA" and the indication "moderate asthma".

The Panel considered GSK's submission that the online version of the programme was classed as promotional because it mentioned specifically a GSK product and provided the reader with more information. For that reason, the prescribing information and adverse event reporting statement had been included on that version of the programme. However, GSK submitted that the pdf version of the programme (which was the subject of this complaint), only listed the title of the symposium, the speakers and the titles of their talks; it did not mention or identify any specific GSK product and therefore did not require prescribing information nor an adverse event reporting statement.

The Panel noted that the pdf version of the programme was produced by the congress organisers to provide an overview of the presentations that would be available to attendees. The programme did not solely focus on the symposium in question.

The Panel accepted that GSK had two dual therapy products at the time and reference to ICS/LABA could be any one of several different combinations of the different inhalers available or one of the two available single fixed dose formulations available.

The Panel concluded that the pdf programme was not promotional of any GSK product because:

1. There were other dual therapy products available and the reference to ICS/LABA did not refer to any specific GSK product.
2. The pdf version of the programme only referred to the title of the symposium and the talks that were part of it at page 403 of a 502 page congress programme. That was consistent with the way all other symposia were listed in that programme and the Panel did not consider it to be a promotional document.

Given the Panel's conclusion that the complaint related to the pdf version of the programme and that this version was not promotional, it followed that there was no requirement to include prescribing information nor an adverse event reporting statement. The Panel therefore ruled **no breach of Clauses 12.1 and 12.9**.

Given its rulings of no breach above and in the absence of any other allegations from the complainant, the Panel did not consider that GSK had failed to maintain high standards nor had it brought discredit upon the industry. The Panel therefore ruled **no breach of Clause 5.1 and Clause 2**.

Complaint received 10 September 2024

Case completed **7 August 2025**