CASE AUTH/3229/7/19

COMPLAINANT v GLAXOSMITHKLINE

Promotion of Relvar Ellipta

A complainant who described him/herself as a 'concerned UK health professional', complained about a two-page advertisement for Relvar Ellipta (fluticasone furoate/vilanterol) placed in the April 2019 edition of Pulse by GlaxoSmithKline UK Limited. Relvar Ellipta was a combination of an inhaled corticosteroid (ICS (fluticasone furoate)) and a long-acting beta$_2$ agonist (LABA (vilanterol)). Relvar Ellipta was indicated for, *inter alia*, the regular treatment of asthma in adults and adolescents aged 12 years and older where use of a combination medicine was appropriate in patients not adequately controlled with ICS and as needed inhaled short- acting beta$_2$ agonist (SABA) or patients adequately controlled on both ICS and LABA.

The first page of the advertisement featured the question 'Which ICS/LABA helps more patients improve asthma control?' all written in upper case with 'helps more' and 'asthma control' given particular prominence. The second page featured pack shots of the Relvar Ellipta devices and the claim 'Relvar Ellipta was superior to other ICS/LABAs (usual care) in helping more patients improve asthma control in everyday clinical practice in the Salford Lung Study' in small font. This was followed by a second paragraph 'The most commonly used ICS/LABAs were Seretide (fluticasone propionate/salmeterol), Symbicort [budesonide, formoterol fumarate dihydrate], Fostair [beclometasone dipropionate, formoterol fumarate dihydrate]. Data presented are from a subset of patients in the PEA [primary effectiveness analysis] population prescribed ICS/LABA at randomisation'. The claims were referenced to the Salford Lung Study and GlaxoSmithKline data on file.

The complainant noted the claim that Relvar was superior to other ICS/LABAs and that no statistics of any sort were placed on the advertisement. The complainant stated that none of the trials listed in the Relvar summary of product characteristics (SPC) were superiority trials and the SPC stated that 'No comparative studies versus salmeterol/FP [fluticasone propionate] or versus other ICS/LABA combinations have been conducted to appropriately compare the effects on asthma exacerbations' (Section 5.1).

The complainant noted there was no mention of this in the advertisement which instead solely focussed on real world evidence without giving any context of the other evidence – such as the licensed indication which was narrower than the patients in the Salford Lung Study. The advertisement stated that the data presented was from a subgroup of the Salford Lung Study but the primary endpoint was not mentioned. The complainant alleged that GlaxoSmithKline had promoted Relvar off-licence, the first statement made no mention of which patients were on treatment and what was claimed was not supported by current data; by implying it could improve all patients it exaggerated the use of the medicine and high standards had not been maintained.

The detailed response from GlaxoSmithKline is given below.

The Panel noted that Section 5.1 of the Relvar SPC stated that no comparative studies vs [Seretide] or vs other ICS/LABA combinations had been conducted to appropriately compare the effects on asthma exacerbations. This section of the SPC also included data from a 24 week study in adult and adolescent patients demonstrating an overall improvement in lung function for both Relvar and Seretide; the adjusted mean treatment difference between the groups was not statistically significant. For trough FEV1 the difference in the mean change from baseline between the Relvar group and the Seretide group was not statistically significant. The same section of the SPC referred to a randomised, double-blind 24 week non-inferiority study in adults and adolescents in which subjects randomised to Relvar maintained lung function comparable with those randomised to Seretide.

The Panel noted that the Salford Lung Study was in patients with asthma aged 18 or over whereas Relvar was licensed for patients aged over 12. This was not made clear in the advertisement. Nor was any information provided about the asthma control test. Although the advertisement referred to everyday clinical practice readers might expect that the differences described in the advertisement were also found in double-blind clinical trials. In the Panel's view readers would be interested in the results of the Salford Lung Study but it was important that sufficient information was given about the study. The context of claims was important. The Salford Lung Study was not included in the Relvar SPC. This was of course not necessarily a breach of the Code. The Code required that material was not inconsistent with the SPC. Results from studies not in the SPC must not contradict the SPC and should be presented in the context of the information within the SPC.

The Panel considered that the failure to set the results of the Salford Lung Study in the context of the study's limitations and other study data about Relvar meant that the advertisement was misleading and exaggerated the effects of Relvar and was a misleading comparison with other ICS/LABAs. Readers would assume that the study results applied to all those eligible to be prescribed Relvar and that was not so. The Panel ruled breaches of the Code. The Panel noted that statistics did not necessarily need to be included in material but it was important that readers were provided with sufficient information to enable them to form their own opinion of the therapeutic value of the medicine. Claims etc had to be capable of substantiation. In the Panel's view the overall misleading impression given by the advertisement could not be substantiated so a further breach was ruled.

The Panel noted that the first question 'Which ICS/LABA helps more patients improve asthma control?' which was the only claim on the first page of the advertisement did not mention which patients were on treatment. The Panel did not consider on balance that the absence of such detail meant that the promotion of Relvar was inconsistent with its SPC as alleged and ruled no breach of the Code.

The Panel ruled a breach as the advertisement did not maintain high standards.

A complainant who described him/herself as a concerned UK health professional, complained about a two-page advertisement for Relvar Ellipta (fluticasone furoate/vilanterol) placed in the April 2019 edition of Pulse by GlaxoSmithKline UK Limited. Relvar Ellipta was a combination of an inhaled corticosteroid (ICS (fluticasone furoate)) and a long-acting beta$_2$ agonist (LABA (vilanterol)). Relvar Ellipta was indicated for, *inter alia*, the regular treatment of asthma in adults

and adolescents aged 12 years and older where use of a combination medicine was appropriate in patients not adequately controlled with ICS and as needed inhaled short- acting beta$_2$ agonist (SABA) or patients adequately controlled on both ICS and LABA.

The first page of the advertisement featured the question 'Which ICS/LABA helps more patients improve asthma control?' all written in upper case with 'helps more' and 'asthma control' given particular prominence. The second page featured pack shots of the Relvar Ellipta devices and the claim 'Relvar Ellipta was superior to other ICS/LABAs (usual care) in helping more patients improve asthma control in everyday clinical practice in the Salford Lung Study' in small font. This was followed by a second paragraph 'The most commonly used ICS/LABAs were Seretide (fluticasone propionate/salmeterol), Symbicort [budesonide, formoterol fumarate dihydrate], Fostair [beclometasone dipropionate, formoterol fumarate dihydrate]. Data presented are from a subset of patients in the PEA [primary effectiveness analysis] population prescribed ICS/LABA at randomisation'. The claims were referenced to the Salford Lung Study and GlaxoSmithKline data on file.

COMPLAINT

The complainant noted the claim that Relvar was superior to other ICS/LABAs and that no statistics of any sort were placed on the advertisement. The complainant stated that none of the trials listed in the Relvar summary of product characteristics (SPC) were superiority trials and the SPC stated that 'No comparative studies versus salmeterol/FP [fluticasone propionate] or versus other ICS/LABA combinations have been conducted to appropriately compare the effects on asthma exacerbations' (Section 5.1).

The complainant noted there was no mention of this in the advertisement which instead solely focussed on real world evidence without giving any context of the other evidence – such as the licensed indication which was narrower than the patients in the Salford Lung Study. The advertisement stated that the data presented was from a subgroup of the Salford Lung Study but the primary endpoint was not mentioned. The complainant alleged that GlaxoSmithKline had promoted Relvar off-licence and asked for the following clauses to be considered:

Clause 3.2 – the first statement made no mention of which patients were on treatment;
Clauses 7.2, 7.3 and 7.4 – what was claimed was not supported by current data;
Clause 7.10 – by implying it could improve all patients it exaggerated the use of the medicine;
and Clause 9.1.

RESPONSE

GlaxoSmithKline submitted that its internal review had concluded that the advertisement could have provided further details of the Salford Lung Study to provide more context for the claim. The Salford Lung Study was a Phase 3b open-label, randomised, controlled, two-arm superiority trial conducted in the UK that included 4,233 patients (Woodcock *et al* 2017). The study was considered to be a landmark study due to its trial design. The impact of the study was reflected as one of the first studies of its kind to be published in The Lancet.

GlaxoSmithKline explained that traditional randomised controlled trials (RCTs) normally sought to control the characteristics of comparative patient populations through highly restrictive inclusion and exclusion criteria. This raised the concern of how applicable results from such trials were to real world clinical practice. The Salford Lung Study was conducted to understand

the effectiveness of Relvar compared with standard of care in everyday clinical practice under conditions more representative of patients seen in everyday clinical practice.

The criteria for inclusion were patients 'who were 18 years or older and had a documented diagnosis of symptomatic asthma made by a general practitioner. Patients had to be taking regular maintenance inhaler therapy with inhaled corticosteroids (ICS) alone or in combination with a long-acting β-agonist (LABA). Exclusion criteria were minimal, such as a recent history of life-threatening asthma, a history of chronic obstructive pulmonary disease (COPD), or concomitant life-threatening disease' (Woodcock *et al*). 90% of patients screened were randomised for inclusion in the study of which 20% were active smokers, 43% were overweight (BMI>30kg/m2) and 38% had comorbidities. These patients were typically excluded from traditional RCTs (Herland *et al* 2005).

In the Salford Lung Study the primary outcome measure was the asthma control test (ACT) score. The score consisted of 5 questions to determine the level of symptom control in asthma patients (Schatz *et al* 2006); A score of >20 indicated well-controlled asthma and a score of <20 indicated that patients did not have well controlled asthma.

Previous clinical trials had assessed the efficacy of asthma treatments primarily based on lung function. In particular, a double-blind, double-dummy design study summarised in the SPC compared Relvar with another ICS/LABA combination on a lung function endpoint, but found no significant difference. However, in clinical practice the focus was to assess asthma control which was multidimensional in nature. Measures of pulmonary function, symptoms, and quality of life often correlated poorly with one another and provided independent information about clinical status; lung function provided a point-in-time assessment and questionnaires assessed status over a given time period. The ACT score was developed to provide an easy and quickly administered tool to assess the multidimensional nature of asthma control in a busy clinical practice (Schatz *et al*). The open-label design of the Salford Lung Study also facilitated a comparison of the once-daily dosing of Relvar with the twice-daily dosing of the comparator ICS/LABA combination.

The design of the Salford Lung Study was to enable detection of superiority of Relvar vs usual care as described in Woodcock *et al* '2,906 patients (1,453 patients per treatment group) were required for the study to have 90% power to detect a relative improvement of 6% in the ACT score between the Relvar group and the usual care group, assuming a 50% response rate in the usual care group at 6 months. 4,036 patients were required in the total population (randomisation of 2,018 patients per treatment group)'. The total number of patients finally included in the study was 4,233.

In the Salford Lung Study, the primary endpoint was the percentage of patients at week 24 with either an ACT score of at least 20 or an increase in ACT score from baseline of at least 3 (termed responders). Patients in the primary effectiveness population (patients with uncontrolled asthma ie an ACT score of <20) were randomised to receive Relvar or usual care (which included ICS alone or ICS with LABA).

The primary endpoint was met 'At week 24, the odds of being a responder were higher for patients who initiated treatment with [Relvar] than for those on usual care (977 [71%] of 1,373 in the [Relvar] group vs 784 [56%] of 1,399 in the usual care group; odds ratio [OR] 2·00 [95% CI 1·70–2·34], p<0·0001)'. Relvar therefore demonstrated superiority in improving asthma control compared to usual care.

A prespecified subgroup analysis was conducted to compare the number of responders at week 24 in the group that had received Relvar vs the usual care group that received other ICS/LABAs. Woodcock *et al* stated 'In patients for whom the general practitioner had found an ICS/LABA combination to be indicated for usual therapy, the odds of being a responder were also higher for those in the [Relvar] group than for those in the usual care group at week 24 (637 [70%] responders and 271 [30%] non-responders vs 511 [56%] responders and 405 [44%] non-responders; OR 1·95 [95% CI 1·60–2·38])'.

The Salford Lung Study was a landmark, real world evidence study conducted in the UK; it included 4,233 patients and compared the treatment options of Relvar vs usual care under conditions far more representative of everyday clinical practice whilst maintaining the rigorous conditions of a randomised, controlled clinical trial. The primary endpoint was met and the results of the study conclusive in that, at week 24, Relvar was superior to other ICS/LABAs in achieving asthma control (based on the asthma control test). Therefore, the claim that Relvar was superior to other ICS/LABAs was factually correct however it could require additional context; it could be improved with further information, such as, statistical information. There was a website link provided which allowed health professionals to view the data on which the claim was based. GlaxoSmithKline thus acknowledged that the claim might fall short of the requirements of Clause 7.2.

GlaxoSmithKline stated that the primary endpoint of the Salford Lung Study was asthma control which was reflected in the claim contrary to the complainant's view that the primary endpoint was not mentioned. As explained above, a prespecified subgroup analysis was conducted to compare the number of responders at week 24 in the group that had received Relvar vs the usual care group that received other ICS/LABAs. It was acceptable to allow promotion of other study endpoints provided the primary endpoint was met. In the Salford Lung Study the primary endpoint was met adding a statement to make this point did not add any further context to the data presented; if the primary endpoint had not been met it would have been essential to include a statement to reflect this. The advertisement was clear in contextualising that 'the data presented are from a subset of patients in the PEA population prescribed ICS/LABA at randomisation'. Therefore, this was an accurate statement of the data, with regard to the endpoint.

The results of the comparison made between the groups receiving Relvar and participants in the usual care arm receiving ICS/LABA had been determined in the context of a randomised, controlled, superiority study with a robust statistical analysis plan aimed at controlling for differences between the groups and ensuring the trial was adequately powered to test the hypothesis of whether there was a difference between the two groups. The study design and results went through rigorous peer review before publication in The Lancet (Woodcock *et al*). The comparison was entirely appropriate as stated in the promotional claim. The comparison was fully qualified in the claim: 'Relvar Ellipta was superior to other ICS/LABAs (usual care) in helping more patients improve asthma control in everyday clinical practice in the Salford Lung Study'. The advertisement also included the most commonly used ICS/LABAs within the study: Seretide Symbicort and Fostair. The advertisement fulfilled the criteria for a permitted comparison and GlaxoSmithKline thus denied any breach of Clause 7.3.

GlaxoSmithKline submitted that the advertisement was clear that the material presented was based on the results of the Salford Lung Study. The advertisement was fully referenced to Woodcock *et al* which contained the published results of the Salford Lung Study. The claim was

based on a robust, randomised, controlled trial in which the primary endpoint was met and was further clearly substantiated by the statement that 'the data presented were from a subset of patients in the PEA population prescribed ICS/LABA at randomisation'. A website link allowed health professionals to view the data on which the advertisement was based. The alleged breach of Clause 7.4 was therefore unfounded as the claim could be substantiated. GlaxoSmithKline denied a breach of Clause 7.4.

GlaxoSmithKline submitted that the claim of superiority was appropriate as the Salford Lung Study was a superiority trial and the statistical analysis conducted enabled a claim of superiority to be made between the Relvar and the usual care groups. The advertisement did not contain an exaggerated or all-embracing claim and did not contain superlatives. The claims in the advertisement did not imply any special merit, quality or property. GlaxoSmithKline asserted that the claim fairly and accurately reflected the improvements in asthma control achieved in the Salford Lung Study and encouraged the rational use of Relvar Ellipta. The parameters of the claim were clearly identified. The advertisement encouraged the rational use of Relvar and did not exaggerate its properties.

The advertisement described asthma control specifically in the context of the ICS/LABA class. The use of ICS/LABA in the UK had been well defined by both The National Institute for Health and Care Excellence (NICE) and the British Thoracic Society (BTS) Asthma Guidelines. The licence of Relvar did not differ from other ICS/LABAs. The claim was specific in relating to asthma control in patients taking an ICS/LABA and was not generalizable to all asthma patients. GlaxoSmithKline denied a breach of Clause 7.10.

GlaxoSmithKline stated that Relvar Ellipta was indicated for the regular treatment of asthma in adults and adolescents aged 12 years and older where use of a combination medicinal product (long-acting beta2-agonist and inhaled corticosteroid) was appropriate:

- patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short acting beta2-agonists

- patients already adequately controlled on both inhaled corticosteroid and long-acting beta2-agonist.

Section 4.2 of the SPC stated that Relvar Ellipta 184/22 micrograms should be considered for adults and adolescents 12 years and over who required a higher dose of inhaled corticosteroid in combination with a long-acting beta2-agonist.

The Blue Guide issued by The Medicines and Healthcare products Regulatory Agency (MHRA) stated 'An advertisement may include statements not included in the SPC provided these can be substantiated and are not inconsistent with the SPC information' and went on to give the following example 'if the SPC makes no mention of any comparative study then a comparative claim would be permitted in advertising, provided it related to the licensed use of the product and was supported by robust evidence'.

GlaxoSmithKline noted that the complainant considered that no superiority trials were listed in the Relvar SPC. The Code and MHRA Blue Guide required that promotion was not inconsistent with the SPC and did not limit promotion to those trials listed in the SPC. The complainant pointed to an extract from Section 5.1 of the SPC to suggest that the advertisement was inconsistent with the SPC. This was not the case. The language that the claimant highlighted

related only to exacerbations. The primary endpoint for the Salford Lung Study was asthma control, the advertisement was about asthma control and made no mention of exacerbations. Reference to the part of Section 5.1 of the Relvar SPC which provided information on exacerbations was irrelevant. Asthma control and exacerbations were distinct measurements. The advertisement was based on the Salford Lung Study which measured the level of day to day asthma symptom control using the ACT score (Schatz *et al*). Asthma exacerbations were defined by BMJ best practice as: *'an acute or subacute* episode of progressive worsening of symptoms … Exacerbations are marked by decreases from baseline in objective measures of pulmonary function, such as peak expiratory flow rate and FEV1'. These episodes would normally require treatment such as a course of oral steroids or hospitalisation. In Case AUTH/2841/4/16 the Panel ruling made it clear that symptomatic control and exacerbations were two distinct entities. The SPC did not refer to comparative studies measuring asthma control (or their absence) and therefore promotional claims relating to asthma control based on the Salford Lung Study were not inconsistent with the Relvar SPC. Given that the promotion was within the licence, GlaxoSmithKline denied any breach of Clause 3.2 on this basis. GlaxoSmithKline noted the complainant's view that the advertisement 'solely focused on real world evidence without giving any context of the other evidence – such as the licensed indication which was narrower than the patients in the Salford Lung Study'. The complainant's statement lacked clarity on the nature of the allegation that was made. There were no other superiority studies that had compared Relvar with other treatments based on asthma control. The Salford Lung Study was a Phase 3b open-label, randomised, controlled, two-arm superiority trial that established the effectiveness of Relvar vs usual care under conditions designed to represent everyday clinical practice including 4,233 patients and using the asthma control test as a primary outcome measure (Woodcock *et al*).

GlaxoSmithKline noted that the complainant did not explain why he/she considered that the licensed indication was narrower than the patients in the Salford Lung Study. The Salford Lung Study asthma population on ICS/LABA was consistent with the European licence. Patients entering the study had had asthma diagnosed by a general practitioner, were at least 18 years of age and needed regular maintenance treatment with an ICS or ICS and LABA. The study protocol included a baseline asthma assessment and review where the physician was asked to assess the patient including forming their own judgement as to the adequacy of the patient's asthma control as though in normal clinical practice. GlaxoSmithKline therefore denied a breach of Clause 3.2.

The complainant stated that 'the first statement makes no mention of which patients are on treatment' as a basis for alleging a breach of Clause 3.2. The complainant's statement again lacked clarity and so it was difficult to understand as to what the complainant referred.

The advertisement described asthma control specifically in the context of the ICS/LABA class; it was published in Pulse magazine aimed at UK GPs and specifically referred to use of the ICS/LABA class in the UK which had been well defined by both NICE and the BTS Asthma Guidelines. The licence for Relvar did not differ from the licence of other ICS/LABAs. The indication was mentioned in the prescribing information. GSK denied a breach of Clause 3.2.

In conclusion, the complainant alleged breaches of Clauses 7.2, 7.3 and 7.4 on the basis that the claims were not supported by current data. GlaxoSmithKline asserted that the Salford Lung Study supported the claim of superior asthma control when prescribed Relvar Ellipta vs current ICS/LABA usual care. Having reviewed the advertisement, GlaxoSmithKline acknowledged that including further points of context would have clarified the claim and acknowledged a breach of

Clause 7.2. The company denied, however a breach of Clause 7.3 as this followed the criteria of a permitted comparison between Relvar and other ICS/LABAs that had been peer reviewed and published in the Lancet (Woodcock *et al*). As the claim was fully substantiable GlaxoSmithKline denied a breach of Clause 7.4.

As the Salford Lung Study was within the marketing authorization and was not inconsistent with the SPC, GlaxoSmithKline denied a breach of Clause 3.2.

Whilst GlaxoSmithKline acknowledged that the claim could be clarified with further context, it did not consider that the advertisement had not maintained the high standards expected of the pharmaceutical industry as described in Clause 9. GlaxoSmithKline therefore denied a breach of Clause 9.1.

PANEL RULING

The Panel noted that as stated in the introduction to the Constitution and Procedure the complainant had the burden of proving there was a breach of the Code on the balance of probabilities.

The Panel noted the comments about the Salford Lung Study. It was an open-label randomised, two-arm effectiveness trial in patients aged 18 or over assigned randomly to initiate treatment with a once daily inhaled combination of 100 or 200mcg of fluticasone furoate with 25mcg vilanterol (Relvar) or continuation of optimised usual care (ICS alone or in combination with a LABA) and followed up for 12 months. The primary endpoint was the percentage of patients who achieved an asthma control test (ACT) score of 20 or greater or an increase in ACT score from baseline of 3 or greater at 24 weeks (termed responders) in patients with a baseline ACT score less than 20. Baseline assessments were collected, including assessment of asthma control using the ACT, information on disease duration, smoking status, concomitant medical history, various questionaires relating to quality of life, work productivity, adherence, demographic information and information on concomitant medications. Patients were contacted by telephone at various time points and a study team member completed the ACT and assessed patients for adverse events or drug reactions. After 12 months a final assessment was done in person. There was no face-to-face contact with the study team between baseline and 12 month visits.

The ACT questions referred to the impact of asthma on work, school or home, frequency of shortness of breath, night time waking with symptoms, use of rescue medication and rating asthma control. All five questions related to the previous four weeks.

At week 24, the odds of being a responder were higher for patients who initiated treatment with Relvar than for those on usual care (odds ratio [OR] 2.00 [95% CI 1.70-2.34], $p<0.0001$). In patients for whom the general practitioner had found an ICS/LABA combination to be indicated for usual therapy, the odds of being a responder were also higher for those in the Relvar group than for those in the usual care group at week 24 (OR 1.95 [95% CI 1.60-2.38]). There was no statistically significant difference in the adjusted annual rate of severe exacerbations in patients initiated with Relvar vs those continuing usual care.

The authors of the Salford Lung Study described the study limitations as perceived weaknesses which might relate to the open-label design in routine care in the absence of regular face-to-face monitoring and the consequent potential for bias. A comparative effectiveness study required

careful interpretation. Any bias might be enhanced by choosing a soft primary outcome, the ACT score whereby patients could indicate improvement merely as a result of being switched to a novel treatment. However in the authors' view that the benefit was present for the entire 52 week duration of the study indicated that this was not so. The authors stated that the unblinded nature of the study was the likely reason for the large degree of modification of treatment during the first 3 months in the Relvar group and that this modification was not due to loss of asthma control but mainly due to patients choosing to return to a long-standing treatment. The study concluded that 'patients in general practice with a diagnosis of symptomatic asthma had improved asthma control from the introduction of a simple once-daily combination treatment of [Relvar] without having any additional risk of serious adverse events'.

The Panel noted that Section 5.1 of the Relvar SPC stated that no comparative studies vs salmeterol/FP or vs other ICS/LABA combinations had been conducted to appropriately compare the effects on asthma exacerbations. This section of the SPC also included data from a 24 week study in adult and adolescent patients demonstrating an overall improvement in lung function for both Relvar and Seretide; the adjusted mean treatment difference between the groups was not statistically significant. For trough FEV1 the difference in the mean change from baseline between the Relvar group and the Seretide group was not statistically significant. The same section of the SPC referred to a randomised, double-blind 24 week non-inferiority study in adults and adolescents in which subjects randomised to Relvar maintained lung function comparable with those randomised to Seretide.

The Panel noted that the Salford Lung Study was in asthma patients aged 18 or over whereas Relvar was licensed for patients aged over 12. This was not made clear in the advertisement. Nor was any information provided about the asthma control test. Although the advertisement referred to everyday clinical practice readers might expect that the differences described in the advertisement were also found in double-blind clinical trials. In the Panel's view readers would be interested in the results of the Salford Lung Study but it was important that sufficient information was given about the study. The context of claims was important. The Salford Lung Study was not included in the SPC for Relvar. This was of course not necessarily a breach of the Code. The Code required that material was not inconsistent with the SPC. Results from studies not in the SPC must not contradict the SPC and should be presented in the context of the information within the SPC.

The Panel considered that the failure to set the results of the Salford Lung Study in the context of the study's limitations and other study data about Relvar meant that the advertisement was misleading and exaggerated the effects of Relvar and was a misleading comparison with other ICS/LABAs. Readers would assume that the study results applied to all those eligible to be prescribed Relvar and that was not so. The Panel ruled a breach of Clause 7.2 as acknowledged by GlaxoSmithKline. The Panel also ruled a breach of Clauses 7.3 and 7.10. The Panel noted that statistics did not necessarily need to be included in material but it was important that readers were provided with sufficient information to enable them to form their own opinion of the therapeutic value of the medicine. Claims etc had to be capable of substantiation. In the Panel's view the overall misleading impression given by the advertisement could not be substantiated so a breach of Clause 7.4 of the Code was also ruled.

The Panel noted that the first question 'Which ICS/LABA helps more patients improve asthma control?' which was the only claim on the first page of the advertisement did not mention which patients were on treatment. The Panel did not consider on balance that the absence of such

detail meant that the promotion of Relvar was inconsistent with its SPC as alleged. The Panel therefore ruled no breach of Clause 3.2 of the Code.

The Panel considered that the advertisement did not maintain high standards and therefore ruled a breach of Clause 9.1 of the Code.

Complaint received **26 July 2019**

Case completed **9 December 2019**