CASE AUTH/3056/8/18

EX-REPRESENTATIVE v GLAXOSMITHKLINE

Activities of GlaxoSmithKline

An ex-representative of GlaxoSmithKline complained about GlaxoSmithKline's relationship with a named practice-based pharmacist and secondly about a claim in the digital sales aids for Relvar Ellipta (fluticasone furoate, vilanterol trifenatate), Anoro Ellipta (vilanterol trifenatate, umeclidinium bromide) and Trelegy Ellipta (fluticasone furoate, vilanterol trifenatate, umeclidinium bromide).

The detailed response from GlaxoSmithKline is given below.

1 GlaxoSmithKline's relationship with a practice-based pharmacist

The complainant alleged that a named pharmacist conducted a therapeutic review from a competitor product to Relvar and Incruse (umeclidinium bromide) without any initial input from GlaxoSmithKline. Having realised this, GlaxoSmithKline decided to use this to its advantage and initially had a 'Q and A' [question and answer] session at a national conference to show the success of what had been done.

The complainant stated that he/she attended a regional meeting along with representatives where the pharmacist in question did another 'Q and A' session and presented documents (copies provided). The complainant alleged that the objective was that representatives would ask health professionals if they needed support in carrying out a switch to a GlaxoSmithKline product. If the health professional replied yes, then the representative would email their contact details to a named senior representative who would contact the pharmacist in question who would then send over the documents to the health professionals. The senior representative in question kept a tracker of health professionals who had been contacted and submitted this higher up and had possibly received a higher rating of performance based on this piece of work. In the complainant's view this was supporting a switch/review to GlaxoSmithKline products.

The complainant stated that whilst there was no direct proof he/she queried if the pharmacist in question would have created a 'how to' document if he/she had not been contacted by GlaxoSmithKline. The complainant queried whether payments made to this pharmacist were in line with the time he/she spent for sharing his/her experience.

The Panel noted GlaxoSmithKline's submission that the pharmacist in question was contracted to speak at three internal meetings; the national sales conference in March 2017, a regional meeting in December 2017 and a respiratory leadership meeting in March 2018. The Panel noted the hourly rate and the number of hours the pharmacist was paid for. On the basis of the information before it, the Panel considered that there was no evidence to support the complainant's allegation that payments to this pharmacist for these meetings were not in line with the time spent for speaking at meetings and no breach was ruled.

The Panel noted that the documents provided by the complainant included a protocol for inhaler changes for patients with COPD. The protocol referred to the practice pharmacist identifying all listed COPD patients on Seretide Accuhaler 500/50mcg and Spriva Capsules 18mcg and excluding from the switch those patients who were unwell or unstable as identified from their records. All the other patients would have their Seretide accuhaler changed to Relvar Ellipta 92/22 and their Spiriva inhalation capsules changed to Incruse Ellipta. The Panel considered, as acknowledged by GlaxoSmithKline, that the reference to GlaxoSmithKline in the protocol gave the impression that GlaxoSmithKline was somehow involved in the protocol and the service.

The Panel noted GlaxoSmithKline's submission that following the national conference in March 2017, the pharmacist in question offered to be contacted by interested health professionals to share his/her positive experience of medicine optimisation. The Panel noted GlaxoSmithKline's submission that it did not pay this pharmacist to speak to other practice-based pharmacists on its behalf nor did it make any payments in respect of any aspect of his/her medicines optimisation activity.

The Panel noted that in August 2017 the pharmacist in question emailed the senior representative in question informing him/her that he/she had sent information to a named individual from a named area regarding inhaler switches. The email included the information sent as attachments, which were saved as 'GSK protocol for inhaler changes in COPD', 'GSK Seretide letter', 'GSK COPD letter, Seretide and Spiriva', and 'GSK Spiriva letter' and appeared to be the same documents as those provided by the complainant. The Panel noted that whilst it had concerns with regard to the misleading impression created by the attached documents and the lack of follow up by the representative to clarify the position, it did not consider that there was evidence to suggest that GlaxoSmithKline had initiated, contributed to or funded the documents in question as implied by the allegation that the 'how to' document would not exist had GlaxoSmithKline not contacted the pharmacist in question. No breach was ruled in this regard.

The Panel was concerned to note that GlaxoSmithKline knew about the content of the documents and that the pharmacist in question

was providing these to practices following 'referrals' from GlaxoSmithKline representatives, yet it took no action other than to decline to pay for the documents. The Panel further noted GlaxoSmithKline's submission that the pharmacist in question was asked by some representatives to share copies of his/her documents with other practices. GlaxoSmithKline acknowledged that it was not appropriate for the company to endorse or encourage the activity and the representatives in question should have taken the opportunity to reinforce GlaxoSmithKline's position on switch and to clarify the nature of GlaxoSmithKline's involvement with the pharmacist in question. The Panel considered that high standards had not been maintained in this regard, as acknowledged by the company, and a breach was ruled.

The Panel noted that although the pharmacist in question was not being paid to speak to interested peers, GlaxoSmithKline representatives were actively involved in the introduction of practices to him/her. The Panel noted that communication between the GlaxoSmithKline representatives and practices, for which GlaxoSmithKline was responsible, and communication between the pharmacist in question and the practices for which GlaxoSmithKline was potentially responsible for, might lead to a change to GlaxoSmithKline's medicines. The Panel noted that the Code did not prohibit a company from promoting a switch but did prohibit switch services paid for or facilitated directly or indirectly by a pharmaceutical company whereby a patient's medicine was simply changed to another.

The Panel noted that it could be argued that the provision of documents to practices, including template letters, via referrals from GlaxoSmithKline's representatives, went beyond promoting a switch. There was a fine line between simply promoting a switch and providing so much detailed information in that regard that the information facilitated a switch.

The Panel considered that there was insufficient evidence as to whether any change of medicine was as a result of a switch service or a therapy review or that the pharmacist in question or GlaxoSmithKline had actually assisted any health professional in implementing a change to a GlaxoSmithKline medicine. GlaxoSmithKline had made no payment in relation to any service. Taking all the circumstances into account the Panel decided that on balance there was insufficient evidence to show that overall GlaxoSmithKline arrangements facilitated a switch to its medicines as prohibited by the Code. The Panel ruled no breaches of the Code accordingly.

The Panel noted that the conversations between the representatives including the completion of the senior representative's tracker, together with the presentations by the pharmacist at both the national and regional meetings, would add to the impression that GlaxoSmithKline supported and endorsed the pharmacist's views and approaches and might be seen by representatives as instructions on how the product should be promoted. The Panel considered that the documents provided by the pharmacist in question to the 12 representatives at the regional meeting in December 2017, which could be seen as setting out GlaxoSmithKline's involvement in a switch service, in effect constituted briefing material. The Panel noted that GlaxoSmithKline made no submission with regard to any follow up with the 12 representatives confirming that it did not endorse this pharmacist's protocol or to remind the representatives of the company's position on switching. Whilst the Panel was concerned at the lack of clear guidance provided by the company, it did not consider, on the balance of probabilities, that the communications above advocated a course of action likely to be in breach of the Code and no breach was ruled.

The Panel noted that whilst GlaxoSmithKline had fallen short of the expected standards of documentation required by the Code in this instance as acknowledged by the company, the complainant had not established that this meant that there was a widespread lack of written communication and projects would disproportionately rely on verbal communication as alleged. The Panel considered that there was no evidence before it that the frequency of meetings between the pharmacist in question and GlaxoSmithKline representatives, prior to him speaking at national and regional meetings, were indicative of inappropriate verbal briefings for the meetings and no breach was ruled in this regard.

Although the Panel had some concerns about the overall arrangements and oversight by GlaxoSmithKline it did not consider that, on balance, the circumstances warranted a ruling of a breach of Clause 2, which was a sign of particular censure and reserved for such use, and ruled no breach accordingly.

2 Claim in digital sales aids for Relvar Ellipta, Anoro Ellipta and Trelegy Ellipta

The complainant stated that the digital sales aid for Relvar Ellipta, Anoro Ellipta and Trelegy Ellipta had a page that described the device as 'open, inhale and close.' This key message was contrary to the information provided in both the summary of product characteristics (SPC) and the patient information leaflet (PIL) which required more steps for the patient to benefit from the medication.

The Panel noted GlaxoSmithKline's submission that no Trelegy digital sales aids included any reference to open, inhale and close. The complainant had not provided any evidence to the contrary. The Panel, therefore, based on the very narrow allegation, ruled no breach with regard to the Trelegy sales aids.

The Panel noted that the Relvar Ellipta SPC stated under the method of administration that the step-by-step instructions should be followed. According to the Relvar SPC there were four steps.

The Panel accepted that as far as the device was concerned, it had to be opened by the patient, used for inhalation and closed by the patient. However,

to take the medicine correctly and, *inter alia*, for the dose to be effective the patient had to do more than simply open, inhale and close. The required steps were detailed in the Relvar and Incruse SPCs and PILs. It appeared from the material provided that, despite reading the PIL, some patients still made a critical error which was defined as an error most likely to result in no, or minimal, medication being inhaled.

In the Panel's view, the references to '…efficacy in 3 steps: patients simply Open Inhale Close' in the Relvar/Incruse digital sales aids (January 2018, May 2016, April 2017) and the Relvar asthma digital sales aids (May 2016, May 2017) were misleading and inconsistent with the Relvar SPC. Breaches of the Code were ruled.

On balance, the Panel considered that the Relvar Asthma digital sales aids (September 2017 and October 2017) which referred to 'With just 3 steps: patients simply Open Inhale Close' and the implication that it related to patient benefit from the medicine with just 3 steps, was misleading and inconsistent with the Relvar SPC and breaches of the Code were ruled.

The Panel noted that the current Relvar Ellipta digital sales aid (March 2018 ref UK/FFT/0004/18) did not refer to either '…efficacy in 3 steps: patients simply Open Inhale Close' or 'With just 3 steps: patients simply Open Inhale Close' as featured in previous Relvar digital sales aids. The current sales aid contained interactive Ellipta pages which referred to the mechanisms of the device rather than instructions on how patients should use the device; there were no claims regarding the number of steps required by the patient to benefit from the medicine and each page of the Interactive Ellipta section referred the user to the PIL for patient instructions. In the Panel's view, there was no evidence that the reference to open inhale close in the context of the Interactive Ellipta section was misleading or inconsistent with the SPC as alleged and no breaches were ruled.

Although there was no current digital sales aid for Anoro, previous versions (November 2016 and January 2017), used during the time-period in scope of the complaint, referred to open (with a 'click'), inhale and close beneath the statement 'delivered in a once-daily, easy-to-use Ellipta inhaler'. The Panel noted that the Anoro SPC and PIL referred to three steps when taking the medicine: first 'Prepare a dose' (including sliding the cover down until a click was heard); second 'How to inhale the medicinal product'; and third 'Close the inhaler'. Full details for how the patient was to perform each step were in the SPC and PIL. In the Panel's view, the page in question referred to the delivery of the medicine and there were no claims linking efficacy or patient benefit from the medicine to the 3 steps open, inhale and close. The Panel considered that in the circumstances and based on the narrow allegation the page in question was not misleading or inconsistent with the SPC and no breaches were ruled accordingly.

Noting its comments and rulings above, the Panel did not consider that GlaxoSmithKline had failed to maintain high standards and ruled no breach accordingly.

An ex-representative of GlaxoSmithKline complained about the activities of GlaxoSmithKline UK Limited. The complainant stated that whilst the complaint was specific in nature, there was a widespread culture within GlaxoSmithKline of 'having a conversation' as opposed to written communication. Whilst there were policies in place including 'write right', there was widespread lack of written communication and projects would disproportionately rely on verbal communication.

There were two matters raised by the complainant: the first related to GlaxoSmithKline's relationship with a practice-based pharmacist and the second related to a claim in the digital sales aids for Relvar Ellipta (fluticasone furoate, vilanterol trifenatate), Anoro Ellipta (vilanterol trifenatate, umeclidinium bromide) and Trelegy Ellipta (fluticasone furoate, vilanterol trifenatate, umeclidinium bromide).

Anoro Ellipta, Relvar Ellipta and Trelegy Ellipta were used in adults with chronic obstructive pulmonary disease (COPD). Relvar Ellipta was also used in adults and adolescents aged 12 years and older with asthma.

1 GlaxoSmithKline's relationship with a practice-based pharmacist

COMPLAINT

The complainant alleged that a named pharmacist conducted a therapeutic review from a competitor product to Relvar and Incruse (umeclidinium bromide) without any initial input from GlaxoSmithKline. Having realised what had happened, GlaxoSmithKline decided to use this to its advantage and initially had a 'Q and A' [question and answer] session at a national conference to show the success of what had been done.

The complainant stated that these Q and A sessions were a means of allowing a free flow of information without approved slides but in fact when the customer relationship management (CRM) database was looked at it could be found as preparation of the speaker, albeit it would not be mentioned in the notes.

The complainant stated that he/she attended a regional meeting along with representatives where the pharmacist in question did another 'Q and A' session and presented documents (copies provided). The complainant alleged that the objective was that representatives would ask health professionals if they needed support in carrying out a switch to a GlaxoSmithKline product. If the health professional replied yes, then the representative would email their contact details to a named senior representative who would contact the pharmacist in question who would then send over the documents to the health professionals. The senior representative in question kept a tracker of health professionals who had been

contacted and submitted this higher up and had possibly received a higher rating of performance based on this piece of work. In the complainant's view this was supporting a switch/review to GlaxoSmithKline products.

The complainant stated that whilst there was no direct proof he/she queried if the pharmacist in question would have created the 'how to' document if he/she had not been contacted by GlaxoSmithKline. The complainant suggested looking at payments made to this pharmacist as an 'internal' speaker to see if it was in line with the time he/she spent for sharing his/her experience. The complainant alleged a breach of Clause 19 of the Code.

In response to a request from the case preparation manager, the complainant explained that the CRM system was where meetings with health professionals were recorded. GlaxoSmithKline did not allow any free text so the notes would not contain information as to the true nature of the calls/meetings. The complainant stated that if one looked at the actual meeting dates with the pharmacist in question recorded in the system, one might spot a higher frequency of meetings prior to him/her speaking at regional and national meetings. The complainant stated that this would facilitate a verbal conversation of what the main messages would be, unless there was an email trail, and this tied into GlaxoSmithKline's culture of paying a health professional for an internal meeting with limited information of what was to be discussed. So, whilst in the regional meeting it was called a 'questions and answers' session, the first part of the meeting was in fact a presentation by the pharmacist in question where the documents in question were handed out.

When writing to GlaxoSmithKline, the Authority asked it to bear in mind the requirements of Clauses 2, 9.1, 15.9, 18.1, 19.1, 19.2 and 23.1 of the Code.

RESPONSE

GlaxoSmithKline submitted that it took the complaint extremely seriously and had conducted a thorough investigation in the time available to respond. It had conducted interviews with individuals named or implicated in the complaint.

GlaxoSmithKline asserted that it was not implementing a therapy review service in COPD and GlaxoSmithKline did not pay for or facilitate a switch service.

GlaxoSmithKline's commercial strategy for the Ellipta Medicines included promoting switch for patients already receiving treatment for COPD to Ellipta medicines if appropriate. GlaxoSmithKline did not support facilitation of switch programs, nor did GlaxoSmithKline advocate for healthcare practitioners to conduct switch programs without a clinical review and legitimate clinical rationale.

Background

GlaxoSmithKline submitted that it actively marketed a number of respiratory products for asthma and COPD. Four of those products, including Relvar and Incruse, were administered using GlaxoSmithKline's patented Ellipta inhaler. Relvar and Incruse were launched in 2014.

In 2017, a named healthcare organisation re-issued its COPD Management Plan, a set of guidelines intended to set out local recommendations for the management of COPD patients, including inhaler options available on the local formulary. These Guidelines advocated that treatment of COPD patients already established on inhaled medicines being changed (or optimised) to align to the recommended COPD treatment pathway. The Guidelines included examples of potential optimising inhalers, including Relvar.

The local Guidelines noted that the advantages of inhaler changes were optimising inhaler device, patient convenience and cost. As a result of these guidelines, clinical commissioning groups (CCGs) in the area started to adopt 'workplans' – these were plans outlining how respiratory medicines optimisation would be implemented in that CCG – for example, whether a full clinical review would be carried out or whether pharmacists, nurses or virtual technology would be deployed to identify optimisation opportunities.

Given the evolving external environment in the NHS and the increasingly important role of practice-based pharmacists with accountability for implementing medicines optimisation against aligned workplans in specific CCGs, GlaxoSmithKline sought to understand more about how optimisation was working in practice.

The NHS meaning of the word 'optimisation' was broad and was defined as looking at the value which medicines delivered, making sure they were clinically effective and cost effective, ensuring patients got the right choice of medicines, at the right time, and were engaged in the process by their clinical team.

GlaxoSmithKline understood that medicines optimisation, within the NHS, could be carried out by means of a simple switch (without clinical review). GlaxoSmithKline did not endorse this practice and prepared comprehensive briefing documents outlining that GlaxoSmithKline only supported medicines optimisation initiatives where they involved clinical review of patients.

A named CCG (which fell within the local guidelines) had a reputation for being an innovative CCG and adopting new medicines. It was therefore of interest to GlaxoSmithKline to understand how this CCG would implement these guidelines.

The pharmacist in question was working at this CCG in 2016. GlaxoSmithKline believed that he/she was self-employed and engaged on a consultancy basis by practices. He/she was engaged by the CCG Medicines Management Team to implement medicines optimisation initiatives in certain practices in the local area. GlaxoSmithKline understood that he/she implemented these initiatives in a variety of ways in consultation with the relevant practice, ranging from full clinical reviews to notes-based

reviews with follow-up support from community pharmacy.

The senior representative in question had been employed by GlaxoSmithKline for many years. This senior representative first became aware of the pharmacist in question in late 2016 during a routine call. This senior representative identified the pharmacist in question as a key emerging customer in his/her region and he/she continued to call on him/her during the ordinary course of his/her role as a representative.

A record from GlaxoSmithKline's CRM system, which showed the call log for GlaxoSmithKline's interactions with the pharmacist in question during the relevant period was provided. GlaxoSmithKline did not consider that the pattern of calls was unusual, considering this pharmacist was a key customer and strong advocate of GlaxoSmithKline medicines. GlaxoSmithKline submitted that the calls complied with the requirements of Clause 15.4 of the Code.

National Sales Conference March 2017

The objective of the annual National Sales Conference in March 2017 was to ensure that all representatives were clear on, and aligned to, GlaxoSmithKline's commercial strategy and structure for the following year. It was typical for GlaxoSmithKline sales conferences to include 'Voice of the Customer Sessions'. The pharmacist in question was identified as an appropriate customer to speak about his/her role as a practice-based pharmacist and his/her role in respiratory medicines optimisation. The session was presented as an interview style session, whereby a senior member of GlaxoSmithKline asked the pharmacist in question a series of certified questions that had been pre-agreed. The interview took place via live video link. The questions focussed on the role of a practice-based pharmacist and his/her role in medicines optimisation and not on the practical aspects of how he/she implemented optimisation.

The pharmacist in question was contracted for this activity in accordance with GlaxoSmithKline processes, with a written contract in place. Details of the hourly rate and number of hours the pharmacist was paid (including for his/her preparation time and actual presentation time) were provided.

The pharmacist in question was briefed for the meeting by a senior member of GlaxoSmithKline who was responsible for organising the 'voice of the customer' session at the conference. A copy of the hand-written briefing notes and confirmation emails as part of the briefing were provided. In the hand-written notes, the pharmacist in question's attention was drawn to the requirements of the Code, in particular the supplementary information to Clause 19.1 relating to Switch and Therapy Review Programmes.

GlaxoSmithKline submitted that clear guidance was provided at the National Conference defining the company's position on switch and what was acceptable within the Code.

Following the National Sales Conference in March, the pharmacist in question had offered to be contacted by other interested health professionals to share his/her positive experience of medicines optimisation. The senior representative in question created a tracker to support this. The pharmacist in question also made two offers for GlaxoSmithKline to commission (for a fee) a pack of the documents that he/she had used in his/her reviews that GlaxoSmithKline could share with other customers as an example of how optimisation could work. GlaxoSmithKline did not take up this offer.

Regional Sales Meeting – December 2017

The pharmacist in question was engaged by GlaxoSmithKline as a paid consultant on a second occasion to attend a regional sales meeting in December 2017. This meeting was organised by the first line sales manager and attended by 12 sales representatives from the region. It was a two-day business review meeting including an end-of-year celebration. Day 1 of the meeting included commercial strategy sessions and two 'voice of the customer' sessions. Day 2 comprised a performance review.

The pharmacist in question was engaged for an 'Ask the Expert' style session to talk about the local Guidelines on COPD management.

GlaxoSmithKline noted, with regret, that a detailed briefing for this meeting was not documented but understood that a verbal briefing was given by the senior representative in question. An account of the verbal briefing was provided. GlaxoSmithKline did not intend for any materials to be used for this session – this was supported by the pharmacist in question's contract in which it was noted that no materials were required and no audio-visual equipment was needed. However, GlaxoSmithKline understood that during the meeting the pharmacist in question produced hard copies of some of his/her medicines optimisation protocols and template letters, copies of which were provided by the complainant. GlaxoSmithKline understood that this had not been discussed or agreed with GlaxoSmithKline. During the investigation GlaxoSmithKline was told that, upon realising that these materials were being circulated to representatives, the first line sales manager collected the hard copy materials in from attendees and took them away to be destroyed. It was not clear how the complainant acquired a copy of the materials. The pharmacist in question was paid for his/her time, comprising 1 hour preparation and 1 hour speaking, based on a fair market rate (details provided).

Respiratory Leadership Team Meeting – March 2018

The pharmacist in question was engaged a third time in March 2018 to attend a Respiratory Leadership Team meeting. This was a monthly meeting which rotated around the UK and it was typical for these meetings to include a local customer for a 'voice of the customer' session. This meeting was not referenced in the complaint but for completeness GlaxoSmithKline provided the meeting agenda and a copy of the pharmacist in question's contract; he/

she was paid for his/her time, comprising 1 hour preparation and 1 hour speaking, based on a fair market rate (details provided).

Specifics of Complaint:

Clause 23.1 – Hiring of a Consultant

GlaxoSmithKline's engagement of external speakers was governed by an SOP which set out clear criteria for the selection and engagement of speakers. Representatives were trained on that policy.

GlaxoSmithKline strongly refuted the allegation that its hiring of the pharmacist in question constituted an inducement to recommend GlaxoSmithKline medicines. GlaxoSmithKline noted that:

- Payments made to this pharmacist related to legitimate services that were provided by him/her. He/she was paid a fair market value honorarium reflecting time actually spent attending and preparing for three GlaxoSmithKline internal meetings. In total over a period of 12 months he/she was paid for 6.25 hours – comprising 3.5 hours preparation and 2.75 hours speaking.
- GlaxoSmithKline did not pay this pharmacist to speak to other practice-based pharmacists on GlaxoSmithKline's behalf, or make any payments in respect of any aspect of his/her medicines optimisation activities or any other activity.

- A legitimate need for this pharmacist's services was identified in advance of requesting those services from him/her. GlaxoSmithKline noted further that on two of the three speaking engagements the pharmacist in question was not GlaxoSmithKline's first choice of speaker but in each case GlaxoSmithKline's first choice was not available. The pharmacist in question was considered to have the appropriate expertise to carry out the engagements.

- Written contracts were put in place with this pharmacist for each of his/her engagements in advance of the commencement of the services. The contracts specified the nature of the services and the basis for payment.

- A written record of GlaxoSmithKline's engagements with this pharmacist was contained in its health professional payment disclosure tracker.

- Importantly, no contracts or records existed in relation to this pharmacist's medicines optimisation activities because GlaxoSmithKline did not commission or fund those activities or the pharmacist's documents and made no payments in relation thereto.

Clause 15.9 – Detailed Briefing of Representatives

GlaxoSmithKline submitted it took training representatives very seriously and had a comprehensive training programme. The materials provided were certified.

GlaxoSmithKline referred to its SOP which set out GlaxoSmithKline's Approval Process for Promotional and Non-Promotional Material including GlaxoSmithKline's expectation that all training or briefing materials related to GlaxoSmithKline products and how they were to be promoted should be approved.

GlaxoSmithKline submitted it had comprehensive and detailed briefing documents for its representatives on promoting the Ellipta medicines. All briefing and training materials provided to representatives in connection with its commercialisation strategy for the Ellipta medicines were certified. Briefing materials drew the representatives' attention to relevant requirements of the Code and did not advocate any course of action which would be likely to lead to a breach of the Code.

GlaxoSmithKline had been asked to provide an account of all briefings related to 'the therapy review'. GlaxoSmithKline assumed this referred to the pharmacist in question's optimisation activities as GlaxoSmithKline was not conducting a therapy review service. As previously noted, this pharmacist's medicines optimisation activities did not constitute a therapy review service conceived or supported by GlaxoSmithKline. There were, therefore, no briefings (written or verbal) in relation to his/her optimisation activities.

GlaxoSmithKline noted that the complainant had provided copies of the pharmacist's documents. These documents were not produced or funded by GlaxoSmithKline and did not form part of any briefing material provided by GlaxoSmithKline to its representatives. GlaxoSmithKline's investigation ascertained that the pharmacist in question shared copies of these documents by email with a GlaxoSmithKline representative as an example of the sort of work he/she was undertaking. The names of the documents attached to this pharmacist's email contained references to GlaxoSmithKline. GlaxoSmithKline acknowledged that this created the misleading impression that the documents were created on behalf of GlaxoSmithKline. This was not so. A copy of the email was provided and GlaxoSmithKline drew attention to the final line which suggested that GlaxoSmithKline might wish to 'commission a pack for distribution'. The company's investigation found no evidence that it did so, and GlaxoSmithKline submitted that this offer validated that it was not involved in the creation of those documents.

GlaxoSmithKline ascertained that internal circulation of this pharmacist's documents were limited and the documents were not shared externally by GlaxoSmithKline.

GlaxoSmithKline acknowledged that the representatives in question should have taken the opportunity to correct and clarify the misleading impression caused by these documents and to make GlaxoSmithKline's position on switch, and the nature of GlaxoSmithKline's involvement with this pharmacist's activities, clear. GlaxoSmithKline regretted that it did not do so.

GlaxoSmithKline's investigation confirmed that this pharmacist also produced hard copies of his/her documents at the regional meeting in December 2017. GlaxoSmithKline understood that this had not been discussed or agreed with GlaxoSmithKline. During the investigation GlaxoSmithKline was told that, upon realising that these materials were being circulated to representatives, the first line sales manager collected the hard copy materials from attendees and took them away to be destroyed. It was not clear how the complainant acquired a copy.

GlaxoSmithKline asserted that it prepared detailed briefing materials which complied with the relevant requirements of the Code, in particular the certification requirements of Clause 14. GlaxoSmithKline did not believe that its briefing materials advocated any course of action which would be likely to lead to a breach of the Code. GlaxoSmithKline asserted that the pharmacist in question's documents were not training or briefing materials provided to representatives. GlaxoSmithKline therefore denied a breach of Clause 15.9.

Clause 18.1 – Prohibition on Inducements

GlaxoSmithKline strongly denied that any payments made to the pharmacist in question constituted an inducement to prescribe, supply, administer, recommend, buy or sell any GlaxoSmithKline medicine. The payments made to this pharmacist reflected a fair market value hourly rate for a *bona fide* service provided by him/her (namely speaking at internal meetings). His/her engagements met a pre-identified need as explained above.

Clause 19 – Medical and Educational Goods and Services

GlaxoSmithKline noted the requirements of the Code relating to medical education goods and services, and in particular the supplementary information relating to switch and therapy review programmes.

GlaxoSmithKline submitted it was not operating or facilitating a switch or therapy review service. The pharmacist in question's optimisation activities were carried out on behalf of the practices by whom he/she was engaged and were conceived and implemented independently of GlaxoSmithKline. GlaxoSmithKline noted that as of July 2018 it was providing a medicines goods and services COPD therapy review service that was fully compliant with the requirements of Clause 19 and was unrelated to the events outlined in the complaint.

GlaxoSmithKline submitted that its commercial strategy for the Ellipta Medicines included promoting switch from patients already receiving treatment for COPD to Ellipta Medicines if appropriate and in accordance with the requirements of the Code. GlaxoSmithKline did not support facilitation of switch programs, nor did GlaxoSmithKline advocate for health professionals to conduct switch programs without a clinical review and legitimate clinical rationale. GlaxoSmithKline had a clearly identified position on switch, which was articulated in the relevant briefing documents.

GlaxoSmithKline noted that the supplementary information relating to Clause 19.1 provided that 'it would be acceptable for a company to promote a simple switch from one product to another…' and submitted that its promotional campaign was not in breach of Clause 19.1.

GlaxoSmithKline understood that the pharmacist in question was engaged by the CCG to support the implementation of workplans in a number of practices. GlaxoSmithKline understood that this pharmacist did not adopt a 'one size fits all' approach to these activities but adapted optimisation activities to suit the requirements of the relevant practice. GlaxoSmithKline understood that a number of these included full clinical reviews and notes-based review.

GlaxoSmithKline noted the complainant's suggestion that the pharmacist in question prepared his/her protocol document, on GlaxoSmithKline's request, but the complainant had provided no evidence to support this suggestion. GlaxoSmithKline found no evidence that it commissioned or funded this pharmacist's documents.

Tracker

GlaxoSmithKline provided a copy of the tracker maintained by the senior representative in question. GlaxoSmithKline noted the complainant's assertion that the purpose of this tracker was to facilitate the sharing of documents used by the pharmacist in question in his/her optimisation programmes and stated that the complainant had not provided evidence to support this assertion.

At the relevant time, GlaxoSmithKline was working to understand and align to the NHS's focus on medicines optimisation. One element of GlaxoSmithKline's business strategy was to ask customers who had successfully carried out optimisation if they would be willing to share their positive experiences with other practices. The pharmacist in question was a strong advocate of the Ellipta medicines based on the patient outcomes he/she had seen and was keen to share his/her experiences with medicines optimisation with a network of peers.

A number of GlaxoSmithKline customers expressed an interest in engaging in this peer-to-peer dialogue. Contact details for these customers were (with their consent) passed on to the pharmacist in question and the tracker was established to record this and document any associated outcomes – such as whether other practices had implemented optimisation programmes. GlaxoSmithKline did not believe that any other representatives maintained similar trackers.

GlaxoSmithKline representatives became aware during 2017 that the pharmacist in question was sharing his/her documents with some practices who contacted him/her. GlaxoSmithKline noted, with regret, that those representatives continued to introduce practices to this pharmacist and, in some cases, the representatives asked this pharmacist to share copies of his/her documents with other practices. GlaxoSmithKline acknowledged that it

was not appropriate for GlaxoSmithKline to endorse or encourage this activity and representatives should have taken steps to reinforce GlaxoSmithKline's position on switch, and to clarify the nature of GlaxoSmithKline's involvement with the pharmacist in question.

GlaxoSmithKline submitted that it had not endorsed or briefed its representatives to partake in this activity and was taking appropriate corrective action. GlaxoSmithKline did not believe that the activities of the representatives amounted to facilitation of a switch service as contemplated by the Code.

GlaxoSmithKline noted that the supplementary information relating to Clause 19.1 provided that 'it would be acceptable for a company to promote a simple switch from one product to another but not to assist a health professional in implementing that switch, even if that such assistance was by means of a third party **such as a sponsored nurse or similar**. Such arrangements are seen as companies **in effect paying for prescriptions** and are unacceptable' (emphasis added by GlaxoSmithKline). GlaxoSmithKline noted the clear emphasis on funding of activities in the supplementary guidance.

GlaxoSmithKline also noted the Panel's consideration of similar issues in Case AUTH/2644/10/13, and the Panel's finding that there was no breach of the Code on the basis that Galen had not provided 'any service to effect or facilitate the switch. Any expense or effort …had to be borne by the health professional or PCO [primary care organisation]'. GlaxoSmithKline further noted that the Panel's ruling was upheld by the Appeal Board.

GlaxoSmithKline submitted that it did not actively assist any health professional to switch patients or provide or fund any service to effect or facilitate a switch in the practices listed in the tracker.

GlaxoSmithKline did not believe that connecting a network of like-minded health professionals to share experiences constituted direct or indirect facilitation of switch. GlaxoSmithKline noted, with regret, that its representatives acquiesced in the sharing of the pharmacist in question's documents, which gave advice on how to switch. Whilst GlaxoSmithKline did not condone this activity, GlaxoSmithKline submitted that it did not amount to facilitation of a switch service as defined by the Code, for reasons outlined above.

New Medicines Service

GlaxoSmithKline stated that the New Medicines Service was not a GlaxoSmithKline programme. GlaxoSmithKline understood the New Medicines Service to be an NHS-led initiative in which community-based pharmacists provided support to patients starting treatment on, or switching to, new medicines for a number of conditions, including asthma, COPD, diabetes and high blood pressure. GlaxoSmithKline submitted that no materials specific to this service were provided by it.

GlaxoSmithKline did make available inexpensive patient support items and training to pharmacists as part of GlaxoSmithKline's standard practice. Such items included placebo Ellipta devices, demonstration devices and support documents such as a leaflet instructing patients on how to use Ellipta devices. These items could be ordered by health professionals directly through GlaxoSmithKline's health professional-facing website or ordered by representatives on behalf of customers on request.

These items were made available to all customers and were not specific to, or conditional on, the provision of any switch or therapy review programme. GlaxoSmithKline representatives would have discussed the availability of these items when promoting Ellipta medicines. It would be usual practice for representatives to ensure that pharmacists known to be involved in optimisation activities had adequate supplies of these items and were trained to ensure patients were correctly shown how to use the Ellipta device. The senior representative in question was asked by the pharmacist in question to visit a local community pharmacy in this context to train the pharmacist on how to demonstrate the use of the Ellipta device in the ordinary course of his/her role.

GlaxoSmithKline submitted that these patient support items complied with the requirements of Clause 19.1 of the Code. GlaxoSmithKline acknowledged that the reference to GlaxoSmithKline's provision of these items in the pharmacist in question's documents created the misleading impression that GlaxoSmithKline was proactively involved in this pharmacist's activities, but this was not the case. GlaxoSmithKline denied any breach of Clause 19.1.

Clause 19.2

GlaxoSmithKline had not provided any grant, donation or benefit in kind to the pharmacist in question or any of the practices listed in the tracker. GlaxoSmithKline denied a breach of Clause 19.2.

Clause 9.1 – Maintaining High Standards

GlaxoSmithKline submitted that it endeavoured to maintain high standards at all times and in many cases, GlaxoSmithKline set its standards higher than the expectations of the Code.

GlaxoSmithKline noted, with regret, that the actions of a small number of its representatives in the region in question fell short of the high standards that GlaxoSmithKline expected. In particular:

- A more comprehensive written briefing relating to the regional meeting should have been kept.
- Representatives should not have encouraged the sharing of the pharmacist in question's documents and should have taken steps to reinforce GlaxoSmithKline's position on switch and clarify the nature of GlaxoSmithKline's involvement with this pharmacist's activities.

GlaxoSmithKline acknowledged, with regret, that it failed to maintain high standards pursuant to Clause 9.1 in these aspects. GlaxoSmithKline committed to taking the following steps to address these issues:

- Re-educate representatives on what constituted adequate briefing and documentation;
- Refresher Code training, with a particular emphasis on the promotion of switch and facilitation of switch services; and
- Repeat 'Write Right' training with a particular emphasis on how to catch, correct and clarify potentially misleading communications.

Communication Culture

Whilst GlaxoSmithKline noted, with regret, that it had fallen short of the expected standards of documentation required by the Code in an isolated instance identified as a result of this complaint, it strongly refuted the suggestion that this was reflective of a widespread cultural failing. GlaxoSmithKline maintained high standards of documentation, as evidenced by the materials supporting this response. The complainant referred to GlaxoSmithKline's 'Write Right' training. This was a training module given to all GlaxoSmithKline employees. Contrary to the complainant's assertion, this policy did not discourage the keeping of written records, but advocated taking care to ensure documentation was appropriate and aligned to GlaxoSmithKline values. The complete training was delivered live or by 'e-learning'.

Contrary to the complainant's assertion, this policy did not discourage the keeping of written records but advocated taking care to ensure documentation was appropriate and aligned to GlaxoSmithKline values.

GlaxoSmithKline provided a copy of the training curriculum that representatives followed and copies of relevant policies. The company drew attention to the section in which GlaxoSmithKline's expectations regarding briefing and documentation in connection with promotional meetings were set out.

GlaxoSmithKline stated it took pride in its core values of integrity, transparency, respect for people and patient focus, and encouraged employees to have regard to GlaxoSmithKline's values in all activities.

Clause 2

Based on its investigation, GlaxoSmithKline submitted that this was an isolated occurrence relating to a small group of representatives in one area and was not reflective of the high standards generally maintained by GlaxoSmithKline representatives.

GlaxoSmithKline did not accept that its activities or materials discredited or reduced confidence in the industry, compromised patient safety, constituted inducements to prescribe or involved unacceptable payments. GlaxoSmithKline noted, with regret, the shortcomings highlighted by this complaint and GlaxoSmithKline's subsequent investigation and had taken steps to reinforce that standards were maintained at all times.

GlaxoSmithKline respectfully submitted that its activities did not amount to a breach of Clause 2.

GlaxoSmithKline was disappointed to note that the complainant had chosen to raise their complaint directly with the PMCPA. GlaxoSmithKline strongly encouraged employees to raise concerns and had processes in place to provide a supportive environment in which these concerns could be raised, including anonymous 'speak up' channels. GlaxoSmithKline was extremely disappointed that the complainant chose to wait until leaving the organisation before raising his/her concerns.

In conclusion, GlaxoSmithKline denied breaches of Clauses 23.1, 15.9, 18.1, 19.1, 19.2 and Clause 2 but, as stated above, admitted a breach of Clause 9.1.

PANEL RULING

The Panel noted that Clause 23.1 stated, *inter alia*, that health professionals and other relevant decision makers may be used as consultants for services such as speaking at meetings where such participation involved remuneration and/or travel. The arrangements which covered these genuine consultancy or other services must, to the extent relevant to the particular arrangement, fulfil a number of criteria including that the hiring of the consultant to provide the relevant service must not be an inducement to prescribe, supply, administer, recommend, buy or sell any medicine and the compensation for the services must be reasonable and reflect the fair market value of the services provided. In this regard, token consultancy arrangements must not be used to justify compensating health professionals and other relevant decision makers.

Clause 18.1 stated that no gift, pecuniary advantage or benefit may be supplied, offered or promised to members of the health professions or to other relevant decision makers in connection with the promotion of medicines or as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine, subject to the provisions of Clauses 18.2 and 18.3. The supplementary information stated that any payment to an individual for an activity that was ruled in breach of Clause 23 was likely to be viewed as an unacceptable payment and thus in breach of Clause 18.1.

The Panel noted GlaxoSmithKline's submission that the pharmacist in question was contracted and paid to speak at three internal meetings; the national sales conference in March 2017, a regional meeting in December 2017 and a respiratory leadership meeting in March 2018. The Panel noted that in total over a period of 12 months the pharmacist in question was paid for 6.25 hours comprising 3.5 hours preparation and 2.75 hours speaking time (details of payments were provided). On the basis of the information before it, the Panel considered that there was no evidence to support the complainant's allegation that payments to this pharmacist for these meetings were not in line with the time spent for speaking at meetings and no breach of Clauses 23.1 and 18.1 were ruled.

The Panel noted that in 2017 some representatives would have attended two meetings where the pharmacist in question presented. The Panel noted

GlaxoSmithKline's submission that the national sales conference session in March 2017 was presented as a 30 minute interview during which the pharmacist in question was asked pre-approved questions. The output given for the session was that the audience understood the importance of the role of practice-based clinical pharmacists in medicines optimisation/switch decisions at GP level and the need for and difference Ellipta medicines could make to patients. The list of questions included advice as to how GlaxoSmithKline could add more value in its interaction with practice-based pharmacists to help further improve patient outcomes and make NHS savings, for example, through medicines optimisation/switching. Another of the prepared questions asked was 'Since you have been in role, what have you been working on in terms of medicines optimisation in respiratory? What results have you achieved and why do you think that is?'.

The Panel noted that the handwritten notes by a GlaxoSmithKline representative who briefed the pharmacist in question stated that the purpose of the session was the role of the practice-based pharmacist in respiratory medicine optimisation at GP practice level (including switching). The handwritten briefing further stated, 'Code on Switch/ page 29'. The Panel also noted GlaxoSmithKline's submission that clear guidance was provided at the conference defining its position on switch and what was acceptable within the Code. The 'GlaxoSmithKline believes that…' document (ref UK/RESP/0048/17a) defined switch as a change in preferred treatment options within a class of medicines, in appropriate patients, following clinical review. It stated that the Code allowed it to promote switching, where appropriate. However, it was not allowed to be involved in implementing a patient switch.

The Panel noted GlaxoSmithKline's submission that at the regional meeting in December 2017, the pharmacist in question provided hard copies of some of his/her medicines optimisation protocols and template letters to the 12 representatives attending the meeting without GlaxoSmithKline's permission. Copies of those documents were included in the complaint. GlaxoSmithKline further submitted that upon realising these materials were being circulated, the documents were collected by the first line sales manager to be destroyed. It was not clear to GlaxoSmithKline how the complainant acquired a copy of the materials. It was not clear to the Panel how long the attendees had the documents in their possession.

The Panel noted that the documents provided by the complainant included a protocol for inhaler changes for patients with COPD. The protocol referred to the practice pharmacist identifying all listed COPD patients on Seretide Accuhaler 500/50mcg and Spriva Capsules 18mcg and excluding from the switch those patients who were unwell or unstable as identified from their records. All the other patients would have their Seretide accuhaler changed to Relvar Ellipta 92/22 and their Spiriva inhalation capsules changed to Incruse Ellipta. The protocol stated that inhalation technique for all three devices was very similar so face-to-face training was not mandatory; the practice pharmacist would make the change on an electronic patient record system and the new inhaler(s) would be issued when the patient next requested a repeat of their former inhalers. The patient would be sent a letter informing them of the change, a GlaxoSmithKline leaflet explaining how to use the new Ellipta inhaler and a re-order form highlighting the new inhalers. The local community pharmacist would be asked to offer the new medicine service (NMS) to explain to patients how to use their new inhaler and to follow them up over the phone during the first month. The protocol further stated that 'GlaxoSmithKline will provide the community pharmacy with placebo devices and information leaflets and training to support the NMS intervention'. The protocol included sections headed 'Advantages for patients' and 'Advantages for the Practice'. The complainant also provided template letters to be sent to the patients and reports of switches in COPD patients at named medical centres. The Panel considered, as acknowledged by GlaxoSmithKline, that the reference to GlaxoSmithKline in the protocol gave the impression that GlaxoSmithKline was somehow involved in the protocol and the service. The Panel noted GlaxoSmithKline's submission that this was not so and the documents gave a misleading impression in that regard. GlaxoSmithKline acknowledged that it provided training to pharmacists and had patient support items which could be ordered by any health professional; it was not conditional on the provision of any switch or therapy review programme.

The Panel noted the requirements of Clause 19 and the supplementary information to Clause 19.1, Switch and Therapy Review Programmes which stated that Clauses 18.1 and 19.1 prohibited switch services paid for or facilitated directly or indirectly by a pharmaceutical company whereby a company's medicine was simply changed to another without any clinical assessment. It was acceptable for a company to promote a simple switch from one product to another but not to assist the health professional in implementing that switch even if assistance was by means of a third party such as a sponsored nurse or similar. A therapeutic review was different to a switch service: it aimed to ensure that patients received optimal treatment following a clinical assessment and was a legitimate activity for a pharmaceutical company to support and/or assist. Clause 19.2 stated that medical and educational goods and services in the form of donations, grants and benefits in kind to institutions, organisations and associations that were comprised of health professionals and/or, *inter alia*, provided healthcare were only allowed if they complied with Clause 19.1, were documented and kept on record by the company and did not constitute an inducement to, *inter alia*, prescribe.

The complainant alleged that GlaxoSmithKline was supporting a switch to GlaxoSmithKline medicines because at the Q and A session at the regional meeting in December 2017, the pharmacist in question presented the documents referred to above, the objective being that representatives would ask health professionals if they needed support in

carrying out a switch to a GlaxoSmithKline product. If the answer was yes, the representative would email the health professional's contact details to the senior representative in question who would pass them to the pharmacist in question to send the documents. The senior representative in question kept a tracker of which health professionals had been contacted.

The Panel noted GlaxoSmithKline's submission that following the national conference in March 2017, the pharmacist in question offered to be contacted by interested health professionals to share his/her positive experience of medicine optimisation. The Panel noted GlaxoSmithKline's submission that it did not pay this pharmacist to speak to other practice-based pharmacists on its behalf nor did it make any payments in respect of any aspect of his/her medicines optimisation activity. The Panel noted GlaxoSmithKline's submission that one element of its business strategy was to ask customers who had successfully carried out optimisation if they would be willing to share their positive experiences with other practices.

The Panel noted that in August 2017 the pharmacist in question emailed the senior representative in question informing him/her that he/she had sent information to a named individual from a named area regarding inhaler switches. The email further stated 'Attached is the info I am sending to practices for your information…'. The names of the documents attached were 'GSK protocol for inhaler changes in COPD', 'GSK Seretide letter', 'GSK COPD letter, Seretide and Spiriva' and 'GSK Spiriva letter' and appeared to be the same as those documents provided by the complainant. The Panel considered that this created the misleading impression that the documents were created on behalf of GlaxoSmithKline, as acknowledged by the company, which submitted that it had declined to commission a pack of the documents for use. The Panel noted that whilst it had concerns with regard to the misleading impression created by the documents and the lack of follow up by the representative to clarify the position, it did not consider that there was evidence to suggest that GlaxoSmithKline had initiated, contributed to or funded the documents in question as implied by the allegation that the 'how to' document would not exist had GlaxoSmithKline not contacted the pharmacist in question. No breach of Clause 9.1 was ruled in this regard.

The Panel was concerned to note that GlaxoSmithKline knew about the content of the documents and that the pharmacist in question was providing these to practices following 'referrals' from GlaxoSmithKline representatives, yet it took no action other than to decline to pay for the documents. The Panel further noted GlaxoSmithKline's submission that the pharmacist in question was asked by some representatives to share copies of his/her documents with other practices. GlaxoSmithKline acknowledged that it was not appropriate for the company to endorse or encourage the activity and the representatives in question should have taken the opportunity to reinforce GlaxoSmithKline's position on switch and to clarify the nature of GlaxoSmithKline's involvement with the pharmacist in question. The Panel considered that high standards had not been maintained in this regard, as acknowledged by the company, and a breach of Clause 9.1 was ruled.

The Panel recognised that NHS colleagues would talk to each other but was, nonetheless, concerned that contact details of health professionals had been provided to the pharmacist in question by GlaxoSmithKline representatives. Follow-up of his/her interaction with those health professionals and outcomes were also tracked by the company. The tracker listed the GlaxoSmithKline representatives, the account interested, the date the contact was passed on, whether contact had been made with the pharmacist in question, Seretide numbers, 'Tio' numbers and 'relevant' information. It appeared from the tracker that in one practice, Tiotropium was changed to Incruse after a practice-based pharmacist ran 'lists' and 'letters' were sent out by the practice manager. The tracker did not specifically record any contact by the pharmacist in question with this practice in relation to this change, however, the Panel noted GlaxoSmithKline's submission that the tracker in question was established to record details of customers contacts passed on to this pharmacist and any associated outcomes such as whether practices had implemented optimisation programmes. A different practice listed on the tracker featured a note that contact was made with the pharmacist in question and it led to the practice employing a practice-based pharmacist to look at COPD and asthma and the pharmacist was currently being trained for optimisation.

The Panel noted that although the pharmacist in question was not being paid to speak to interested peers, GlaxoSmithKline representatives were actively involved in the introduction of practices to him/her. The Panel noted that communication between the GlaxoSmithKline representatives and practices, for which GlaxoSmithKline was responsible, and communication between the pharmacist in question and the practices for which GlaxoSmithKline was potentially responsible for, might lead to a change to GlaxoSmithKline's medicines. The Panel noted that the Code did not prohibit a company from promoting a switch but did prohibit switch services paid for or facilitated directly or indirectly by a pharmaceutical company whereby a patient's medicine was simply changed to another.

The Panel noted that it could be argued that the provision of the pharmacist in question's documents to practices, including template letters, via referrals from GlaxoSmithKline's representatives, went beyond promoting a switch. There was a fine line between simply promoting a switch and providing so much detailed information in that regard that the information facilitated a switch.

The Panel considered that there was insufficient evidence as to whether any change of medicine was as a result of a switch service or a therapy review or that the pharmacist in question or GlaxoSmithKline had actually assisted any health professional in implementing a change to a GlaxoSmithKline

medicine. GlaxoSmithKline had made no payment in relation to any service. Taking all the circumstances into account the Panel decided that on balance there was insufficient evidence to show that overall GlaxoSmithKline arrangements facilitated a switch to its medicines as prohibited by Clause 19.1. The Panel ruled no breach of Clause 19.1 and thus no breach of Clause 18.1. In addition, the Panel did not consider that there was an allegation of a breach of Clause 19.2 and no breach was ruled accordingly.

The Panel noted that Clause 15.9 required, *inter alia*, that companies must prepare detailed briefing material for medical representatives on the technical aspects of each medicine which they will promote. The supplementary information referred to both the training material and instructions about how a product should be promoted. Briefing material must comply with the relevant requirements of the Code and, in particular, was subject to the certification requirements of Clause 14 and must not advocate, either directly or indirectly, any course of action which would be likely to lead to a breach of the Code.

The Panel noted that the conversations between the representatives including the completion of the senior representative's tracker, together with the presentations by the pharmacist in question at both the national and regional meetings, would add to the impression that GlaxoSmithKline supported and endorsed this pharmacist's views and approaches and might be seen by representatives as instructions on how the product should be promoted. The Panel considered that the documents provided by the pharmacist in question to the 12 representatives at the regional meeting in December 2017, which could be seen as setting out GlaxoSmithKline's involvement in a switch service, in effect constituted briefing material. The Panel noted that GlaxoSmithKline made no submission with regard to any follow up with the 12 representatives confirming that it did not endorse this pharmacist's protocol or to remind the representatives of the company's position on switching. Whilst the Panel was concerned at the lack of clear guidance provided by the company, it did not consider, on the balance of probabilities, that the communications above advocated a course of action likely to be in breach of the Code. No breach of Clause 15.9 was ruled.

The Panel noted that whilst GlaxoSmithKline had fallen short of the expected standards of documentation required by the Code in this instance as acknowledged by the company, the complainant had not established that this meant that there was a widespread lack of written communication and projects would disproportionately rely on verbal communication as alleged. The Panel considered that there was no evidence before it that the frequency of meetings between the pharmacist in question and GlaxoSmithKline representatives, prior to him speaking at national and regional meetings, were indicative of inappropriate verbal briefings for the meetings and no breach of Clause 9.1 was ruled in this regard.

Although the Panel had some concerns about the overall arrangements and oversight by GlaxoSmithKline, noting its ruling of a breach of Clause 9.1 above, it did not consider that, on balance, the circumstances warranted a ruling of a breach of Clause 2, which was a sign of particular censure and reserved for such use, and ruled no breach accordingly.

2 Claim in digital sales aids for Relvar Ellipta, Anoro Ellipta and Trelegy Ellipta

COMPLAINT

The complainant stated that the digital sales aid that representatives used for Relvar Ellipta, Anoro Ellipta and Trelegy Ellipta had a page that described the device as 'open, inhale and close.' This was a key message for the Ellipta portfolio and had been since 2016. The complainant stated that this was contrary to the information provided in both the summary of product characteristics (SPC) and the patient information leaflet (PIL) which required more steps for the patient to benefit from the medication.

When writing to GlaxoSmithKline, the Authority asked it to bear in mind the requirements of Clauses 3.2, 7.2 and 9.1 of the Code.

RESPONSE

GlaxoSmithKline submitted that digital detail aids were amended and re-certified as promotional campaigns developed over time. GlaxoSmithKline stated that the time point in question was not clear from the complainant, so it had reviewed the digital sales aids which the therapy representatives currently used for two of the three products. There was no current Anoro digital sales aid as representatives no longer actively promoted it.

For the Trelegy digital sales aid, the statement 'Open, Inhale and close' was not used at all. Similarly, the Relvar digital sales aid did not have a page which described the device as open, inhale and close as alleged by the complainant. However, there was a digitally interactive section of the digital sales aid headed 'Interactive Ellipta' which was designed for therapy representatives to initiate discussions concerning the mechanism and internal workings of the device. At the bottom of the screen in this section there were four digital 'buttons' labelled: open, look inside, inhale and close. These were not claims regarding the Ellipta device but functional digital 'buttons' which when touched allowed the health professional to show these four specific features of the device. The button labelled, 'Look inside' showed the internal structure of the device, something not normally visible to the health professional unless they actively dismantled it and so allowed them to view the mechanistic details of the device in more detail.

The interactive digital section of the digital sales aid also allowed the health professional to look at the device in a 3D setting as by placing their finger on the digital image they were able move it in all directions and rotate the model accordingly. The briefing instructions to the therapy representatives for this section of the interactive digital sales aid

even stated that, 'If appropriate you may wish to give your iPad to the HCP to allow them to use the interactive Ellipta Device'.

This interactive section of the digital sales aid also had the following statement at the bottom of the screen: 'For patient Instructions, refer to the Patient Information leaflet' so as to ensure that there was no confusion between the mechanistic workings of the device and the instructions for patient use of the device. In addition, GlaxoSmithKline also provided a tear-off pad for representatives to use with health professionals which gave detailed instructions as to how to use the Ellipta device as well as a photograph of the Ellipta device demonstration kit which health professionals might use with their patients on an individual basis enabling them to be able to competently demonstrate these GlaxoSmithKline medicines.

This interactive section of the digital sales aid was only 4 of 9 pages, all of which had in the heading 'After reading the PIL' (Patient Information Leaflet).

In summary, GlaxoSmithKline denied any breach of the Code.

In response to a request for further information, GlaxoSmithKline noted that Trelegy was only promoted after it received a marketing authorisation in November 2017 and submitted that no digital sales aid used since that date included any reference to 'open, inhale and close'.

With respect to Relvar and Anoro, GlaxoSmithKline had ascertained that certain versions of its digital sales aids as used by the representatives from 2016 to date contained references to 'open, inhale and close' (copies of relevant pages provided).

GlaxoSmithKline submitted it made certain core claims in relation to its Ellipta medicines. One of those core claims related to ease of use of the device, as had been clinically evaluated in patients with both asthma and COPD. The Ellipta device was a single-step breath-activated inhaler featuring a cover that was opened by the patient to simultaneously reveal the mouthpiece and automatically load a single dose of medication (Collison *et al* 2018). This distinguished the inhaler from other devices, in which an additional loading step was required, in that simply opening the inhaler rendered it ready for use. Grant *et al* (2015) stated that 'There are three principal operating steps to administer a dose: open, inhale, close'. In addition, Grant stated 'The inhaler is operated through three simple steps: 1) opening the mouthpiece cover fully; 2) inhaling the dose; and 3) closing the mouthpiece cover'. Additional evidence to support the claim was reported by Svedsater *et al* (2013) in an ease of use study. Several participants spontaneously reported on the straightforwardness and intuitiveness of the use of the dry powder inhaler (DPI), describing the few steps required eg 'open and inhale, that's it: not much to it'.

GlaxoSmithKline noted that the Panel had previously considered a claim that the Ellipta device was 'straightforward to use' and found that the claim was not misleading and was substantiable (Case AUTH/2701/2/14).

The pages of the materials that include references to 'Open, Inhale, Close' were included under the heading 'Ease of Use' in each of the relevant materials.

GlaxoSmithKline noted that the 'open, inhale, close' language was reviewed by the PMCPA in Case AUTH/2933/2/17 which concerned Chiesi's use of the 'open, inhale, close' claim in relation to Fostair NEXThaler and the Panel ruled a breach of the Code because the claim was inconsistent with the SPC and the PIL for Fostair. This was on the basis that the SPC and PIL for Fostair in fact included four steps. GlaxoSmithKline asserted that this case could be distinguished from Case AUTH/2933/17 in that the SPCs and PILs for each of the relevant GlaxoSmithKline Ellipta products contained only three steps. The SPCs for all three Ellipta products presented the step-by-step instructions on how to use the inhaler under distinct headings. Each heading then had more detail below it. The same was true of the PILs for each of the Ellipta products. There were three substantive steps for use of the Ellipta inhaler on a daily basis. The first step was headed 'Prepare a dose' the second 'Inhale your medicine' and the third 'Close the inhaler'. Under the first heading 'Prepare a dose', the only instruction was 'slide down the cover until you hear a click. Your medicine is now ready to be inhaled'. In other words, the only step to preparing the device is to open it. GlaxoSmithKline acknowledged that in the 'Instructions for Use' section of the SPC for Relvar and Trelegy, these three steps were in fact labelled steps 2, 3 and 4. This was because step 1 was an instruction to the patient to read all the following information before commencing. This was to avoid patients opening and closing the device without inhaling the medicine, as by doing so the dose would be lost. GlaxoSmithKline did not consider that this cautionary note constituted an additional step to using the device on a day to day basis, and therefore did not believe that this created an inconsistency with the materials.

GlaxoSmithKline noted that the materials in question were intended for use with health professionals and were not intended to provide instructions to patients on how to use the Ellipta device. GlaxoSmithKline made available a number of patient support materials, including a tear-off pad for representatives to use with health professionals which gave detailed instructions as to how to use the Ellipta device as well as an Ellipta device demonstration kit which a health professional might use with their patients on an individual basis enabling them to be able to competently demonstrate the medicines. GlaxoSmithKline therefore submitted that the claim was not inconsistent with the licences for the Ellipta medicines and so not in breach of Clause 3. The claim was accurate and unambiguous and therefore not in breach of Clause 7.2. GlaxoSmithKline submitted it had therefore maintained high standards in the promotion of its medicines and was not in breach of Clause 9.1.

PANEL RULING

The Panel noted the allegation that the Relvar, Anoro and Trelegy digital sales aids contained a page that described the device as 'open, inhale and close', which had been a key message for the Ellipta portfolio since 2016 and was contrary to the SPC and patient information leaflet (PIL) which described more steps in order for the patient to benefit from the medication.

The Panel noted GlaxoSmithKline's initial submission that the time point in question was not clear from the complaint and therefore it provided the currently used Relvar and Trelegy digital sales aids; there was no current sales aid for Anoro as it was no longer promoted.

The Panel noted GlaxoSmithKline's submission that the current Trelegy digital sales aid did not use the statement 'open, inhale and close'. The current Relvar digital sales aid, however, featured an 'Interactive Ellipta' section which contained four digital buttons labelled: open, look inside, inhale and close, which GlaxoSmithKline submitted were not claims regarding the device, but functional buttons to show specific features of the device.

In the Panel's view, it was clear that the complaint covered material used from 2016 onwards. The Panel was concerned that it was only after a request for further information that GlaxoSmithKline submitted that certain versions of its Anoro and Relvar digital sales aids since 2016 had contained references to open, inhale and close and subsequently provided the relevant pages.

The Panel noted GlaxoSmithKline's submission that no Trelegy digital sales aids included any reference to open, inhale and close. The complainant had not provided any evidence to the contrary. The Panel, therefore, based on the very narrow allegation, ruled no breach of Clauses 3.2 and 7.2 with regard to the Trelegy sales aids used since the product received a marketing authorisation in November 2017.

The Panel noted that the Relvar Ellipta SPC stated under the method of administration that the step-by-step instructions should be followed. According to the Relvar SPC, the first step required the patient to read the information on how to use the device to avoid losing a dose by opening and closing the inhaler without inhaling. The second step was about how to prepare a dose and involved opening the cover and sliding it down until a click was heard. The third step covered how to inhale the medicine and stated that before inhaling, the patient should hold the inhaler away from their mouth and breathe out as far as comfortable. The patient was warned not to block the air-vents with their fingers and to take a long, steady, deep breath in holding the breath for as long as possible (at least 3-4 seconds) and then remove the inhaler from the mouth and breathe out slowly and gently. The fourth step involved closing the inhaler and rinsing the mouth to reduce the risk of developing a sore mouth or throat as a side-effect.

The Panel noted that the Relvar/Incruse January 2018 digital sales aid stated 'Incruse & Relvar delivers 24 hours of continuous efficacy in 3 steps: patients simply Open Inhale Close'. The May 2016 and April 2017 Relvar/Incruse digital sales aids stated 'Incruse in combination with Relvar delivers 24 hours of continuous efficacy in 3 steps: patients simply Open Inhale Close'. The Relvar Asthma digital sales aids (May 2016 and May 2017) stated 'Relvar delivers 24 hours of continuous efficacy in 3 steps: patients simply Open Inhale Close'. The Panel accepted that as far as the device was concerned, it had to be opened by the patient, used for inhalation and closed by the patient. However, to take the medicine correctly and, *inter alia*, for the dose to be effective the patient had to do more than simply open, inhale and close. The required steps were detailed in the Relvar and Incruse SPCs and PILs. It appeared from the material provided that, despite reading the PIL, some patients still made a critical error which was defined as an error most likely to result in no, or minimal, medication being inhaled. In the Panel's view it was important that the step-by-step instructions were followed, and this was highlighted in the Relvar SPC, to obtain the full benefit of the medicine.

In the Panel's view, the references to '…efficacy in 3 steps: patients simply Open Inhale Close' in the Relvar/Incruse digital sales aids (January 2018, May 2016, April 2017) and the Relvar asthma digital sales aids (May 2016, May 2017) were misleading and inconsistent with the Relvar SPC. A breach of Clauses 3.2 and 7.2 were ruled.

The Relvar Asthma digital sales aids (September 2017 and October 2017) stated 'With just 3 steps: patients simply Open Inhale Close' which appeared on a page titled 'The Ellipta inhaler is easy-to-use'. The Panel noted that there was no reference to 'efficacy in 3 steps'. The Panel considered that the reference to 'With just 3 steps: patients simply Open Inhale Close' in the context of a further claim on the page which stated 'Fewer patients using Ellipta made a critical error compared with other commonly used inhalers after reading the patient information leaflet….' where a critical error was defined as an error most likely to result in no, or minimal, medication being inhaled, implied that the page was referring to the patient needing to perform 3 steps to receive benefit from the medicine. As noted above, the Relvar SPC featured four steps and each of the steps had a number of instructions. The 'How to inhale the medicine' section included an instruction to hold the inhaler away from your mouth and breathe out as far as was comfortable and another to take one long, steady, deep breath in and hold it for as long as possible (at least 3-4 seconds) before removing the inhaler from the mouth and breathing out slowly and gently.

The Panel accepted that as far as the device was concerned, it had to be opened by the patient, used for inhalation and closed by the patient. However, to take the medicine correctly and, *inter alia*, for the dose to be effective, the patient had to do more than simply open, inhale and close.

On balance, the Panel considered that the Relvar Asthma digital sales aids (September 2017 and October 2017) which referred to 'With just 3

steps: patients simply Open Inhale Close' and the implication that it related to patient benefit from the medicine with just 3 steps, was misleading and inconsistent with the Relvar SPC and a breach of Clauses 3.2 and 7.2 were ruled.

The Panel noted that the current Relvar Ellipta digital sales aid (March 2018 ref UK/FFT/0004/18) had been adapted from previous versions and did not refer to either '…efficacy in 3 steps: patients simply Open Inhale Close' or 'With just 3 steps: patients simply Open Inhale Close' as featured in previous Relvar digital sales aids. The current sales aid contained a section headed 'Interactive Ellipta' which GlaxoSmithKline submitted was designed to initiate discussions concerning the mechanism and internal workings of the device. The Panel noted that this page contained four interactive tabs labelled 'Open', 'Look inside', 'Inhale' and 'Close'; each linked to an image of the device at that stage. Below the tabs was the statement 'For patient instructions, refer to the Patient Information Leaflet' and the Panel noted GlaxoSmithKline's submission that this statement was to prevent confusion between the mechanistic workings of the device and the instructions for patient use of the device. The Panel noted that some pages in the digital sales aid contained the claim 'easy to use' with a link to the Interactive Ellipta pages. The accompanying briefing document stated that the objective of the interactive pages in question was to show the health professional how the Ellipta device was used. The briefing further stated, 'if appropriate you may wish to give your iPad to the HCP to allow them to use the interactive Ellipta device' and to use this as an opportunity to offer, *inter alia*, placebo devices. The briefing gave a proposed probing question which asked 'How do you think the Ellipta inhaler device compares to others you currently prescribe?'. The Panel noted GlaxoSmithKline's submission that there was a separate leavepiece which gave detailed instructions on patient use of the device. In the Panel's view, the interactive Ellipta pages, which could be accessed via pages citing 'easy to use' constituted product claims regarding the device. The Panel considered that the pages in question referred to the mechanisms of the device rather than instructions on how patients should use the device; there were no claims regarding the number of steps required by the patient to benefit from the medicine and each page of the Interactive Ellipta section referred the user to the PIL for patient instructions. In the Panel's view, there was no evidence that the reference to open inhale close in the context of the Interactive Ellipta section was misleading or inconsistent with the SPC as alleged and no breach of Clauses 3.2 and 7.2 were ruled.

Although there was no current digital sales aid for Anoro, previous versions (November 2016 and January 2017), used during the time-period in scope of the complaint, referred to open (with a 'click'), inhale and close beneath the statement 'delivered in a once-daily, easy-to-use Ellipta inhaler'. The Panel had requested that GlaxoSmithKline provide the sections of the digital sales aids which referred to open, inhale, close. The Panel was provided with a single page and therefore reviewed the page in isolation and not within the context of the entire digital sales aid. The Panel noted that the Anoro SPC and PIL referred to three steps when taking the medicine: first 'Prepare a dose' (including sliding the cover down until a click was heard); second 'How to inhale the medicinal product'; and third 'Close the inhaler'. Full details for how the patient was to perform each step were in the SPC and PIL. In the Panel's view, the page in question referred to the delivery of the medicine and there were no claims linking efficacy or patient benefit from the medicine to the 3 steps open, inhale and close. The Panel considered that in the circumstances and based on the narrow allegation the page in question was not misleading or inconsistent with the SPC and no breach of Clauses 7.2 and 3.2 were ruled accordingly.

Noting its comments and rulings above, the Panel did not consider that GlaxoSmithKline had failed to maintain high standards and ruled no breach of Clause 9.1.

Complaint received **31 July 2018**

Case completed **11 March 2019**