CASE AUTH/3194/4/19 *NO BREACH OF THE CODE*

ANONYMOUS v GLAXOSMITHKLINE

Sponsored therapy review service

An anonymous contactable group, which described itself as consisting of GPs, NHS leaders, pharmacists, NHS patients and current staff from a named third party providing therapy review services, complained about a number of therapy review services provided by that third party on behalf of a number of pharmaceutical companies, including GlaxoSmithKline UK Limited. The GlaxoSmithKline service at issue was related to chronic obstructive pulmonary disease (COPD).

GlaxoSmithKline marketed a number of medicines for COPD including Serevent (salmeterol), Seretide (salmeterol/fluticasone propionate), Trelegy Ellipta (fluticasone furoate, vilanterol trifenatate, umeclidinium bromide) and Relvar Ellipta (fluticasone furoate, vilanterol trifenatate).

The complainants stated that a therapy review service sponsored by a pharmaceutical company would, in the majority of cases, lead to an increase in prescribing of that pharmaceutical company's medicines; a fact widely known and accepted within the healthcare industry. It also followed that a therapy review service programme which did not demonstrate an increase in prescribing of the product of the sponsoring company would not lead to ongoing financial investment from the sponsoring company.

In order to remain profitable, the named third party service provider had to retain pharmaceutical companies as clients by providing them with a 'return on investment' when it delivered therapy review services. It did this by coaching its pharmacists on what it called 'client value' which was a guise for 'return on investment'. The complainant stated that the named third party service provider had historically done this verbally, being careful not to put anything in writing. Like most untoward activities however the truth was eventually exposed.

There was now written proof that the named third party service provider linked its therapy review services to the products of the sponsoring pharmaceutical company. This was commercial bias.

The complainants stated that their complaint was based on an internal email sent by a very senior employee at the named third party service provider to the entire clinical team dated 14 August 2018. The complainants alleged that within the email there were several links made between pharmaceutical company product and therapy review service which was totally unacceptable and represented clear breaches of the Code.

The complainants stated that regardless of whether some of the services referred to were currently 'live' or not, the confidence and integrity of the pharmaceutical companies involved, along with the Code had already been breached by the sending of the email.

The complainants referred to a number of companies and used the example of linking some named products to some named companies as implying that other therapy reviews listed where no product was mentioned had a clear and obvious link to client product/therapy priorities. There was a number of cross referrals within the letter of complaint.

The email read as follows with regard to the involvement of GlaxoSmithKline:

> **'The GlaxoSmithKline COPD service continues to be universally welcomed by our NHS customers and we are current taking bookings at scale across the country with projects rolling out in [named areas and number of practices] along with bookings from some of the biggest practices in England. We expect this work to build significantly for all regions with days hitting 100 plus over the coming months. Additional COPD training is already booked in for September.'**

Another extract from the email (final paragraph), provided to GlaxoSmithKline was as follows:

> **'As the business evolves a constant challenge will be to transition and integrate client product/therapy priorities into our internal resource and schedules. The addition of new client such as [three named companies including GlaxoSmithKline] also add in the additional challenge of new clinical training. Whilst not every aspect will run exactly to plan the list above illustrates clearly that our reputation as the […] continues to grow and that our objectives of expansion and diversification are on track.'**

The complainants noted the wording of the final paragraph of the email and submitted that it was not Code compliant for an 'independent' clinical service provider to email its pharmacists about integrating client product/therapy priorities into its internal resources and schedules. The complainants alleged that this was an attempt to influence the pharmacists and set the expectation for client product where there should be no link at all. The wording implied that the therapy reviews named in the email had a clear and obvious link to 'client product/therapy priorities'.

As the therapy review from GlaxoSmithKline was referred to within the email, a breach of Clause 2 was alleged.

By operating in this way, the therapy review services were misleading, deceptive and unlawful. The services were not transparent to either those who used them or to patients who had their notes accessed and medicines altered without their consent or knowledge of this bias.

The complainants stated that the matter was being reported to the NHS Counter Fraud Authority. The activities would soon be highlighted in the pharmaceutical and mainstream media as it was in the public interest. The public needed to know that GPs were being misled into signing up to 'independent' reviews and that patients had had their treatments changed by the named third party service provider which had a hidden agenda to provide a return on investment to the pharmaceutical companies which paid

its wages in order for it to make a profit as a business. The NHS and the public needed protecting from this.

The detailed response from GlaxoSmithKline is given below.

The Panel noted that before considering each individual case, there were general points relevant to the therapy review services and the email in question which in its view were relevant to all of the cases and these are given below. Each individual case would be considered on its own merits.

In the Panel's view, the overall impression of the email was such that in the view of the author the therapy services carried out by the third party were inextricably linked to the products of the sponsoring companies. It was extremely concerning that in places the email linked the service to particular products or only offered the service in practices where the formulary did not preclude the company's product. This and the reminder regarding developing the business including the phrase 'integrate client product/therapy priorities' could link company products to a therapy review service. Even where a particular product was not mentioned by name it was extremely likely that the company's product would be linked to the relevant therapy review, as understandably many of the recipients might see integrating client product/therapy priorities as increased prescribing of the company's medicines. The important consideration for the Panel was the effect and influence of the email in question in relation to all the other arrangements for each therapy review.

The Panel noted its comments with regard to the impression of the entire email but noted that the email did not refer to a specific GlaxoSmithKline medicine nor link the GlaxoSmithKline therapy review service to a specific medicine.

The Panel noted GlaxoSmithKline's submission that the COPD therapy review service was offered only to local health economies (LHEs) with the greatest unmet patient need and how these were identified. Requests from other LHE or practices were also considered.

These details were included in the methodology statement which included information about formulary screening to ensure that the review service did not inadvertently cause a switch to a GlaxoSmithKline medicine based on its sole availability within a particular therapeutic class. The process to be followed was that in any LHE where a GlaxoSmithKline medicine was the sole choice within a therapeutic class (or where GlaxoSmithKline single inhaler therapy was available with no other triple therapy options via any combination of inhalers), the review service would not be offered. In any LHE where GlaxoSmithKline was aware of an NHS led programme of switching to any single GlaxoSmithKline therapy, the review service would not be offered,

The Panel noted the arrangements for the therapy review service as set out below. Including GlaxoSmithKline's requirements for reviewing the local guidelines and formulary to ensure that a therapy review service could be undertaken and the criteria applied.

The Panel noted GlaxoSmithKline's submission that there was no expectation or requirement for a GlaxoSmithKline product to be on the formulary.

The Panel further noted GlaxoSmithKline's submission that it periodically requested and received a summary of the number of clinics delivered, number of patients seen per clinic, number of pharmacological and non-pharmacological interventions, and the number of patients moved between therapeutic classes as a result of the therapy review service. GlaxoSmithKline submitted that it looked at the data sets to determine efficiency of the service in terms of cancellations, numbers of patients seen and number of clinics held and that the data also demonstrated that there was unmet need as illustrated by, for example, the patients who had not previously received symptom scores or needed referral for pulmonary rehabilitation. GlaxoSmithKline did not undertake any sub-analysis of this data and did not ask for or receive data on numbers of patients moving to GlaxoSmithKline products as a result of the therapy review service. GlaxoSmithKline stated that by measuring only these outputs, it demonstrated its commitment to the patient benefit derived from the service, rather than direct commercial gain to the company. The Panel noted the example report provided by GlaxoSmithKline which showed the management of patients by medicine class before and after the named third party service provider pharmacist led clinic; this report appeared to show*, inter alia*, that after the clinic there was an increase in the number of patients on a combined LAMA/LABA (from 192 to 694) and on closed triple therapy (from 162 to 884). The Panel noted that GlaxoSmithKline was not the only company to market a combined LAMA/LABA or a closed triple therapy medicine.

Whilst the Panel had concerns including about how the email portrayed the named third party service provider therapy services and its effects on the named third party service provider pharmacists and other staff, it nonetheless noted that the complainant bore the burden of proof. On the balance of probabilities, it was not unreasonable that some, if not all, of the named third party service provider pharmacists would associate the GlaxoSmithKline therapy review with GlaxoSmithKline products particularly based on the email at issue. However, taking all the circumstances into account including the Panel's view that GlaxoSmithKline's written arrangements for the review did not appear to amount to a switch to GlaxoSmithKline medicines, the Panel did not consider that the complainant had established, on the balance of probabilities, that the email demonstrated that the arrangements for the COPD therapy review supported by GlaxoSmithKline were such that they failed to meet the requirements for medical and educational goods and services in the Code. Nor had the complainants provided evidence that the therapy review constituted disguised promotion. The Panel therefore ruled no breaches of the Code.

In the Panel's view, GlaxoSmithKline had been let down by its third-party agency. The Panel had serious concerns about the impression given by the entire email. However, it did not consider that in the particular circumstances of this case the complainants had provided evidence to show that GlaxoSmithKline had failed to maintain high standards and no breach was ruled. This ruling was upheld following an appeal from the complainant.

Given its rulings of no breach of the Code the Panel consequently ruled that there was no breach of Clause 2.

An anonymous contactable group, which described itself as consisting of GPs, NHS leaders, pharmacists, NHS patients and current staff from a named third party service provider,

complained about a number of therapy review services provided by the named third party service provider on behalf of a number of pharmaceutical companies, including GlaxoSmithKline UK Limited. The GlaxoSmithKline service at issue was related to chronic obstructive pulmonary disease (COPD).

GlaxoSmithKline marketed a number of medicines for COPD including Serevent (salmeterol), Seretide (salmeterol/fluticasone propionate), Trelegy Ellipta (fluticasone furoate, vilanterol trifenatate, umeclidinium bromide) and Relvar Ellipta (fluticasone furoate, vilanterol trifenatate).

COMPLAINT

By way of background, the complainants stated that the named third party service provider claimed to be an 'independent' clinical service provider. The third party service provider received the vast majority of its income from pharmaceutical companies which paid it to deliver sponsored therapy review services.

The complainants stated that a therapy review service sponsored by a pharmaceutical company would, in the majority of cases, lead to an increase in prescribing of that pharmaceutical company's medicines; a fact widely known and accepted within the healthcare industry. It also followed that a therapy review service programme which did not demonstrate an increase in prescribing of the product of the sponsoring company would not lead to ongoing financial investment from the sponsoring company.

In order to remain profitable, the named third party service provider had to retain pharmaceutical companies as clients by providing them with a 'return on investment' when it delivered therapy review services. The third party did this by coaching its pharmacists on what it called 'client value' which was a guise for 'return on investment'. The third party had historically done this verbally, being careful not to put anything in writing. Like most untoward activities however the truth was eventually exposed.

The complainants stated that they now had written proof that the named third party service provider linked its therapy review services to the products of the sponsoring pharmaceutical company. This was commercial bias.

The third party service provider pharmacists were recruited under the façade of delivering 'independent' therapy reviews, improving outcomes for patients. Generally speaking, there was an industry-wide reluctance for employees to complain for fear of repercussion and damage to future career prospects. Uncomfortable with this commercial bias and having been misled during recruitment, most looked for another job and resigned after a short time instead of complaining to the PMCPA. The complainants alleged that the named third party service provider had very high staff turnover and this untoward activity had gone largely unreported until now.

The complainants stated that their complaint was based on an internal email sent by a very senior employee of the named third party service provider to the entire clinical team dated 14 August 2018 (copy provided). The complainants alleged that within the email there were several links made between pharmaceutical company product and therapy review service which was totally unacceptable and represented clear breaches of the Code.

The complainants stated that regardless of whether some of the services referred to were currently 'live' or not, the confidence and integrity of the pharmaceutical companies involved, along with the Code had already been breached by the sending of the email.

The complainants referred to a number of companies and used the example of linking some named products to some named companies as implying that other therapy reviews listed where no product was mentioned had a clear and obvious link to client product/therapy priorities. There was a number of cross referrals within the letter of complaint.

The email read as follows with regard to the involvement of GlaxoSmithKline:

> 'Dear All
>
> As most of you will be aware we are currently in the midst of several adjustments to the business as we introduce and train-in new services and align our activities to client priorities.
>
> The phasing of these changes will of course raise a few short term challenges but will also deliver the increase in client and therapy mix we have been working towards throughout 2018. To clarify these changes I list below the client plan for the remained [sic] of 2018
>
> …
>
> **GlaxoSmithKline**
>
> The GlaxoSmithKline COPD service continues to be universally welcomed by our NHS customers and we are current taking bookings at scale across the country with projects rolling out in [named geographical areas and numbers of practices] along with bookings from some of the biggest practices in England. We expect this work to build significantly for all regions with days hitting 100 plus over the coming months. Additional COPD training is already booked in for September.'

Another extract from the email (final two paragraphs), provided to GlaxoSmithKline was as follows:

> 'In addition to the range above we continue to hold large advance payments for our BGTS and PN clients who are all looking to us to do more between now and the end of the year to generate bookings against the many practice opportunities listed in [named database]. These reviews should not be devalued as simple cost cutting as when done well, they offer a range of great clinical outcomes for practices and patients alike.
>
> As the business evolves a constant challenge will be to transition and integrate client product/therapy priorities into our internal resource and schedules. The addition of new client such as [three named companies including GlaxoSmithKline] also add in the additional challenge of new clinical training. Whilst not every aspect will run exactly to plan the list above illustrates clearly that our reputation […] continues to grow and that our objectives of expansion and diversification are on track.'

The complainants noted the wording of the final paragraph of the email and submitted that it was not Code compliant for an 'independent' clinical service provider to email its pharmacists

about integrating client product/therapy priorities into its internal resources and schedules. The complainants alleged that this was an attempt to influence the pharmacists and set the expectation for client product where there should be no link at all. The wording implied that the therapy reviews named in the email had a clear and obvious link to 'client product/therapy priorities'.

As the therapy review from GlaxoSmithKline was referred to within the email, a breach of Clause 2 was alleged.

The complainants noted that under the PMCPA guidance for digital communications, a pharmaceutical company was responsible under the Code for any activities carried out on its behalf by a third party even if that third-party acted beyond the scope of its contract.

In summary, the complainants stated that in their view, the case for sponsoring company product linked to therapy review service (commercial bias) had been conclusively proven.

By operating in this way, the sponsored therapy review services were misleading, deceptive and unlawful. The services were not transparent to either those who used them or to patients who had their notes accessed and medicines altered without their consent or knowledge of this bias.

Based on the above, the named third party service provider should not be permitted to operate as a clinical service provider to the NHS where it was funded by pharmaceutical companies to deliver 'independent' services. It was inconceivable for the third party to be allowed to continue based on the information supplied.

The complainants stated that the matter was being reported to the NHS Counter Fraud Authority. The activities would soon be highlighted in the pharmaceutical and mainstream media as it was in the public interest. The public needed to know that GPs were being misled into signing up to 'independent' reviews and that patients had had their treatments changed by the named third party service provider which had a hidden agenda to provide a return on investment to the pharmaceutical companies which paid its wages in order for it to make a profit as a business. The NHS and the public needed protecting from this.

When writing to GlaxoSmithKline, the Authority asked it to consider the requirements of Clauses 2, 9.1, 12.1 and 19.2 of the Code. Relevant extracts of the email were provided to the company and not the complete email.

RESPONSE

GlaxoSmithKline submitted that it was sponsoring a COPD therapy review service to ensure that patients received optimal management of their COPD following a thorough and appropriate clinical assessment conducted by a qualified professional. The service offered review for COPD patients with all severities of disease, from mild to severe. The therapy review service was conducted in compliance with the relevant requirements of the 2016 Code. The service was referred to by GlaxoSmithKline as the 'COPD Therapy Review Service' and the company had never included product names within either this title or the associated documentation.

GlaxoSmithKline explained that COPD was a respiratory condition which affected around three million people in the UK. It was the second largest cause of emergency admissions to hospital in the UK, accounting for over 140,000 admissions and over a million bed days each year (1.7%

of all hospital admissions and bed days). An average general practice in the UK which cared for about 7,000 people would have up to 200 COPD patients on its list which equated to around 1.4 million GP consultations each year. It was estimated that 30% or more of patients might be sub-optimally treated, require non-pharmacological interventions and/or stepping up or down of pharmacological treatments. Best practice for managing COPD was set out in the Global Initiative for Chronic Obstructive Lung Disease COPD Guidelines (GOLD Guidelines) and the National Institute for Health and Care Excellence (NICE) COPD Guidelines.

GlaxoSmithKline stated that it had contracted the named third party service provider to provide a non-promotional COPD therapy review service in primary care. The service, delivered by a team of the third party service provider pharmacists, provided a full clinical review for individual patients leading to a management decision based on recognised guidelines and was aimed at ensuring that patients received optimal treatment in the form of non-pharmacological and pharmacological interventions. The service was designed to identify patients with COPD and clinically review the holistic management of their disease thereby assisting practices to implement a systematic approach to the management of COPD patients to improve patient outcomes.

The GP practice at which a therapy review service would be carried out nominated, in the authorisation form (copy provided) an authorising GP, or other health professional(s) on its staff to be responsible for the care of patients and retain full control over the entire process. The patients to be invited in for review were authorised by the authorising GP. The individual assessment form detailing the outputs from the clinic consultation, including any proposed pharmacological and/or non-pharmacological interventions, were presented to the authorising GP or authorised health professional following the clinic so that the final prescribing decision was made by a practice health professional and not the named third party service provider pharmacist.

The service was offered only to Local Health Economies (LHEs) with the greatest unmet patient need. This was estimated by using the following data: (i) Non-elective COPD admissions (taken from Hospital Episode Statistics (HES) Data) and (ii) the local COPD list size (taken from Quality Outcomes Framework (QOF) data). Non-elective admissions were an indicator of COPD patients who might not have their COPD optimally managed, as they were going into hospital for emergency admissions related to their COPD, for example due to exacerbation. The local COPD list size showed how many COPD patients were known to have COPD in that LHS ie a diagnosis of COPD was on their notes. These two figures were used to calculate the non-elective admission rate for each LHE. LHEs were then reviewed with above median areas considered for the therapy review service. Requests from other LHE or practices were also considered.

GlaxoSmithKline explained that LHEs wishing to take up the offering signed a medical and educational goods and services (MEGS) agreement with GlaxoSmithKline which emphasised that the health professionals in the patients' own GP practice retained control over the entire service and clearly stated that treatment choices arising as a result of the service remained the choice and sole decision of the authorising health professional.

The clinical protocol was the core service detail document which outlined the way in which patients were identified, selected and reviewed, with all other service documentation aligned to its content. The protocol explained the service in detail to the health care organisation. The named third party service provider was contractually obliged to follow this protocol.

Under the authorising health professional's direction, suitable patients were identified in accordance with the protocol. To ensure appropriate patients were selected for review they were stratified according to the level of their symptoms and exacerbations (according to GOLD Guidelines); this enabled the authorising health professional to decide which patients to prioritise for review:

The patients identified were then invited to attend a clinic with the named third party service provider pharmacist.

(i) Patients were invited by letter (template provided) or by telephone. GlaxoSmithKline's sponsorship of the service was clearly acknowledged in the letters and during the telephone call.

(ii) The named third party service provider pharmacists had a consultation with individual patients and provided a full clinical review of their COPD based on the GOLD COPD Guidelines and/or the NICE COPD Guidelines.

(iii) The review was conducted in accordance with the certified clinical protocol which was available to the authorising GP before he/she signed the MEGS agreement.

(iv) Following the face-to-face clinical review, the named third party service provider pharmacist used a patient assessment form to make recommendations to the authorising GP. Recommendations might include a non-pharmacological intervention (such as help with smoking cessation or education on inhaler technique) and/or pharmacological intervention (ie a change in medicine). The pharmacological recommendations were made at medicine class level only. No specific product was recommended by the named third party service provider pharmacist

(v) Following the clinical review, the named third party service provider pharmacist would meet the authorising health professional to present the outcomes and discuss recommended interventions. If the authorising health professional agreed with the recommendations, he/she selected the specific medicine within the recommended class and the named third party service provider pharmacist documented the interventions which had been authorised by the authorising GP in the GP's system.

(vi) Patients were sent a letter summarising the consultation and any interventions that had been agreed by the authorising GP.

(vii) Following the clinical review, the GP practice was provided with a report that would allow for evaluation of the review and support a sustained improvement in COPD management, providing benefit to both patients and the NHS.

GlaxoSmithKline submitted that it had carefully considered the requirements of the Code when it had designed and implemented the therapy review service. The service was offered as a MEGS ensuring that all requirements of Clause 19 and its supplementary information were and continued to be met. The proposal to commence a therapy review programme was taken to the GlaxoSmithKline UK non-promotional review board (comprised of medical, legal and compliance) where all aspects of governance were discussed and followed in accordance with

company policies. Core documents underwent legal and medical director review and approval prior to non-promotional certification as a MEGS by final signatory. The following paragraphs described the governance steps in place to ensure that the service was carried out in accordance with the requirements of the supplementary information to Clause 19.1.

Enhancing patient care or benefitting the NHS and maintaining patient care

Patients received a full clinical review based on recognised clinical guidelines. The GP practice was provided with a dashboard report that allowed for evaluation of the review and to support a sustained improvement in COPD management, providing benefit to both patients and the NHS.

Selection of practices

GlaxoSmithKline provided the service where there was greatest medical need. The service was offered only to LHEs with the greatest unmet patient need. Non-elective COPD admissions and the local COPD list size were used to calculate the non-elective admission rate for each LHE. LHEs were then ranked high to low with above median areas considered for review service offers. Requests from any LHE or practice were also considered. Prior to offer or approval of a reactive request, the local guidelines and formulary were reviewed to ensure that a therapy review service could be undertaken. In making this determination, the following criteria were considered:

(i) The LHE formulary guidelines must be in line with NICE Guidelines (ie national guidelines) or GOLD Guideline for the management of COPD, to ensure that patients would be managed appropriately.

(ii) The formulary must have a choice for each class of medicine that was not a GlaxoSmithKline product; so while a GlaxoSmithKline product might be on the formulary, it could not be the only one available to choose from in that class. GlaxoSmithKline would not support making available the therapy review service to an LHE where there was no alternative to a GlaxoSmithKline product in the relevant class on the formulary. For example, GlaxoSmithKline declined to make available the service to a named clinical commissioning group (CCG) as GlaxoSmithKline products were the sole choices available. The MEGS agreement also specified that NHS organisations must inform the company if a local guideline changed such that only a GlaxoSmithKline medicine was included within any therapeutic class. In that case, the service would be withdrawn.

(iii) There was no expectation or requirement for a GlaxoSmithKline product to be on the formulary. The provision of the service had been approved in one LHE where none of the more recently launched GlaxoSmithKline respiratory products were available on the local guidelines.

(iv) The LHE must not have a switch to GlaxoSmithKline products workplan either in place or pending. This was to avoid the patient review programme being used as a switch service, albeit after clinical review.

GlaxoSmithKline stated that it had considered a number of potential service providers but chose the named third party service provider because it demonstrated a detailed understanding of the Code in respect of therapy review services and provided high quality documentation. The third

party service provider also demonstrated a robust clinical governance framework which ensured that all working practices delivered the highest standards of care and safety and reflected the wide NHS strategy for clinical governance. The third party service provider senior management oversaw clinical and information governance adherence, training, policy creation and the design of procedures and ensured that all pharmacists remained up-to-date with any developments within the therapeutic area. The clinical protocol set out in detail the training requirements for the pharmacists involved in carrying out therapy reviews.

GlaxoSmithKline was clear that the therapy review was a non-promotional service and it took care to ensure separation from its promotional activities. A non-promotional team of respiratory project managers (RPMs) introduced the service in detail to the approved LHEs and practices. The third party service provider pharmacists might also do this. When the service was first introduced, representatives were permitted to briefly introduce the service in a separate part of the call. GlaxoSmithKline recognised the challenges in this separation and, given that the demand for the service outstripped the third party service provider pharmacist capacity, it was decided that the representatives were no longer even allowed to briefly introduce the service, even though this was allowed under Clause 19.

GlaxoSmithKline stated that the RPMs might introduce the third party service provider pharmacist to the practice at the start of the therapy review and might provide administrative support relating to the service but must not be present at any other time (such as when discussions took place around the protocol, during cohort generation or on screening and clinic days). The RPM never had access to any patient identifiable data. The roles and responsibilities of each party were set out in the clinical protocol.

GlaxoSmithKline stated that it enforced, and tracked, a 7-day promotion free window (PFW) either side of any therapy review service taking place to ensure that the promotion of its medicines could not unduly influence prescribing decisions during the review service. This meant that representatives were not allowed to make promotional calls to a practice seven days before or after its participation in a GlaxoSmithKline-sponsored therapy review. GlaxoSmithKline stated that it undertook regular monitoring to identify any deviations from this PFW.

GlaxoSmithKline explained that the third party service provider's remuneration for the service was based on activity, not on outputs and specifically not on sales of GlaxoSmithKline products as evidenced by the rate card within the Master Services Agreement. The third party was paid a set fee per clinic, per day, with some additional fees payable for variable activities (such as letters written).

The Master Services Agreement between GlaxoSmithKline and the named third party service provider, and the MEGS agreements between GlaxoSmithKline and the relevant practices, contained detailed provisions governing the handling of personal data. Pseudo-anonymised patient level data was collected by the third party service provider. The GP practice was the data controller and the third party was a data processor. No patient identifiable information left the practice. Neither GlaxoSmithKline nor its representatives were given access to data/records that could identify or be linked to particular patients as per the clinical protocol.

The named third party service provider was an approved NHS Business Partner and, as such, completed the NHS Information Governance Toolkit assessment on an annual basis. The NHS

Toolkit was a performance tool produced by the Department of Health to set out the NHS's information governance requirements.

GlaxoSmithKline stated that it had developed and certified a portfolio of non-promotional documents which set out detailed instructions for the named third party service provider and its pharmacists. These documents had been reviewed for compliance with Clause 19.1 and certified as required by Clause 14.3. The documents provided comprised the following:

Master Services Agreement – this governed the relationship between GlaxoSmithKline and the third party service provider and detailed what was required of the third party service provider..

MEGS Agreement – this was the agreement between GlaxoSmithKline and the practice and it set out the basis on which GlaxoSmithKline agreed to fund the provision of the therapy review service in line with Code. The MEGS Agreement stated that:

> *'Medical Educational Goods and Services (MEGS), are described in Clause 19 of the ABPI Code of Practice 2019. They should enhance patient care or benefit the NHS and maintain patient care. This is a non-promotional offering for the NHS and cannot be linked to the promotion of products in any way.*
>
> *The provision of the MEGS detailed in this Agreement is funded by GlaxoSmithKline and complies with Clause 19 of the ABPI Code 2019.'*

Notably, this agreement clearly stated that the service was not dependent on past, present or future prescribing of GlaxoSmithKline products:

> *'Whilst the service is funded and organised on behalf of GlaxoSmithKline, treatment choices arising from the patient review process remains the choice and sole decision of the authorising HCP and clinical responsibility for every patient remains the responsibility of the practice. The provision of the service is not dependent on any past, present or future prescribing or use of GlaxoSmithKline's products.'*

It also clearly stated that:

> *'The clinician responsible for the care of his/her patients retains full control over the entire process. Whilst the service is funded and organised on behalf of GlaxoSmithKline, treatment choices arising from the patient review process remains the choice and sole decision of the authorising HCP and clinical responsibility for every patient remains the responsibility of the practice. The provision of the service is not dependent on any past, present or future prescribing or use of GlaxoSmithKline's products. The practice is able to withdraw from the service at any time.'*

The MEGS Agreement also specified that NHS organisations must inform GlaxoSmithKline should a local guideline change such that only a GlaxoSmithKline medicine was included within any therapeutic class. This was to allow the service to be withdrawn for Code compliance reasons.

As noted earlier, the clinical protocol was the core service detail document which outlined the way in which patients were identified, selected and reviewed, with all other service documentation aligned to its content.

GlaxoSmithKline stated that at its request, the clinical protocol was reviewed by a named patient organisation which commented as follows: '*Protocol is clear and well written, Very welcome. There is little we add can or suggest as it is so well written. We have only a couple of VERY minor suggestions, these are …'* (full feedback was provided). These suggestions were then incorporated into the protocol.

GlaxoSmithKline submitted that the one named health board had positively endorsed the service. The health board had previously not had positive experiences of industry sponsored therapy review services but following a review of the clinical protocol and piloting the service in two practices, it had adopted the therapy review service more widely.

The clinical protocol had been written to be clear as to specific requirements to comply with the Code and the following extracts were taken directly from clinical protocol:

- *This service is funded by GlaxoSmithKline UK Limited, developed by [the named third party service provider] and GlaxoSmithKline UK Limited and delivered as a service to medicine by [the third party service provider].*
- *The authorising GP is responsible for the care of his/her patients and retains full control over the entire process.*
- *The arrangements for therapeutic review must enhance patient care or benefit the NHS and maintain patient care.*
- *…treatment choices arising from the patient review process remains the choice and sole decision of the authorising GP or other authorised healthcare professional (HCP) and clinical responsibility for every patient remains the responsibility of the practice.*
- *The provision of the service is not dependent on any past, present or future prescribing or use of GlaxoSmithKline's products.*
- *…this service provides a full clinical review for individual patients… [third party] pharmacists do not suggest and will not implement switch services, which simply change a patient from one medication to another without a full clinical assessment and clinical need.*
- *… the following clinical protocol must be strictly adhered to by the […] pharmacist*
- *All pharmacists involved in therapy review delivery:*
    - *Are qualified, registered members of the governing body relevant to their geographical area of work.*
    - *Are appropriately qualified as defined by the ABPI Code of Practice and have received appropriate training.*
    - *Will have a thorough working knowledge of the relevant guidelines and key principles of COPD management.*

The pharmacists' briefing (copy provided) further set out in detail the appropriate way for the pharmacists to conduct the therapy review service. It fully reflected the clinical protocol in terms of compliance with the Code. The third party pharmacists were contractually obliged to follow this briefing. The briefing set out detailed instructions, including:

- *You will need to familiarise yourself with the relevant local management guidelines and formularies prior to the review.*
- *Remember, treatment choices arising from the patient review process remain the choice and sole decision of the authorising GP or authorised HCP (defined in the 'Conduct of the Therapy Review') and clinical responsibility for every patient remains the responsibility of the practice.*
- *You must not suggest nor implement switch services, which simply change a patient from one medication to another without a full clinical assessment and clinical need.*
- *…the Respiratory Project Manager (RPM) must not be present during any aspect of service delivery including screening of patients or discussion around the clinical elements of the protocol. GlaxoSmithKline promotional representatives cannot be in contact with the surgery during the review activities and for an appropriate period before and after the review in accordance with GlaxoSmithKline's internal governance procedure.*
- *Please note that ALL materials used must be ones certified by GlaxoSmithKline as this is a requirement of the ABPI Code (as is the need for sponsorship declaration).*

To ensure that a modified formulary had not been substituted which might facilitate a switch, the following instruction was in place:

- *If a practice proposes a formulary or guideline that is not concordant with the approved LHE formulary, the […] pharmacist must inform their line manager. The review service cannot proceed without GlaxoSmithKline governance review of any formulary or guideline*.

To further ensure that there was free choice for the authorising GP, the following instruction was in place:

- *Pharmacological interventions are presented as therapy class level options and the recommended inhaler device should be based on the assessment of the patient's inhaler technique and dexterity. The GP will need to give written authorisation for the intervention(s) you have recommended (including where no intervention is the recommendation) by signing each IAF. Where a change in therapy is recommended the authorising GP/authorised HCP will also need to choose the inhaler device to use and annotate the individual assessment form (IAF). Where the authorising GP/authorised HCP makes any changes to the recommended plan he/she must document this on the IAF and sign to authorise the amended plan*.

GlaxoSmithKline stated that its involvement in the therapy review service was clearly acknowledged in all communications with practices and patients and clearly outlined in the MEGS Agreement between it and the relevant NHS organisations which took up the therapy review service. If patients were invited by telephone to attend the therapy review, GlaxoSmithKline's involvement was disclosed during that call.

The authorising GP, or a practice health professional approved by him/her, was responsible for the care of his/her patients and retained full control over the entire process. The patients to be invited for review were authorised by the authorising GP. During the face-to-face clinic assessment, the named third party service provider pharmacist completed an individual patient assessment form which detailed the outputs from the clinic consultation, including any proposed pharmacological and/or non-pharmacological interventions, and was presented to the

authorising GP or authorised health professional following the clinic for authorisation. The pharmacological suggestions were made at a drug class level and nonspecific product was recommended. The final prescribing decision was made by a practice health professional and not the third party pharmacist. All proposed interventions were made in accordance with the individual GP practice intervention specification (the governance approved guidelines and formulary). A practice health professional might sit in on the clinic for interest if he/she wished.

GlaxoSmithKline considered that the service represented a transfer of value to the GP practice or other organisation which received the service. GlaxoSmithKline stated that it disclosed on or through the industry designated platform and GlaxoSmithKline websites, the monetary value of the service provided. Disclosure was made on an individual basis. GlaxoSmithKline also disclosed a transfer of value against the individual third party service provider pharmacists who delivered the clinics.

GlaxoSmithKline had not identified, nor agreed with the third party service provider, any success criteria for the therapy review service. GlaxoSmithKline provided a copy of the latest Aggregated Programme Dashboard.

GlaxoSmithKline stated that it periodically requested and received a summary of the number of clinics delivered, number of patients seen per clinic, number of pharmacological and non-pharmacological interventions, and the number of patients moved between therapeutic classes as a result of the therapy review service (example reports were provided). The company looked at the data sets to determine efficiency of the service in terms of cancellations, numbers of patients seen and number of clinics held. The data also demonstrated that there was unmet need as illustrated by, for example, the patients who had not previously received symptom scores or needed referral for pulmonary rehabilitation. GlaxoSmithKline did not undertake any sub-analysis of this data and did not ask for or receive data on numbers of patients moving to GlaxoSmithKline products as a result of the therapy review service. GlaxoSmithKline stated that by measuring only these outputs, it demonstrated its commitment to the patient benefit derived from the service, rather than direct commercial gain to the company.

With regard to the proportion of patients changed to GlaxoSmithKline product as a result of the reviews, GlaxoSmithKline neither requested nor received that information from the third party service provider; it would not be appropriate to link any elements of the review service to a change in GlaxoSmithKline medicine.

GlaxoSmithKline stated that ‘Client Value’ as referred to by the complainants was not terminology that it had either heard or used with the third party during the development, operation or ongoing management of the patient review service. GlaxoSmithKline was not aware of any coaching related to delivery of client value and noted that ‘client value’ was not used in the unredacted portions of the email it had seen.

In conclusion, GlaxoSmithKline asserted that the therapy review service carried out by the third party service provider on its behalf, enhanced patient care by ensuring that patients received a thorough clinical review based on an approved clinical protocol in line with national or/and local guidelines. It included a comprehensive range of appropriate interventions, non-pharmacological and pharmacological. All interventions were agreed and overseen by the authorising GP. GlaxoSmithKline noted that it had ensured that a range of choices were available to the prescriber and the service would not be provided if only a GlaxoSmithKline medicine was available. The implementation of the service was not contingent on the

availability or use of GlaxoSmithKline medicines. GlaxoSmithKline did not measure the service based on the prescription of medicines or return on investment. As detailed above, the arrangements for the service complied with Clause 19.1, were documented and kept on record and were not an inducement to prescribe, supply, administer, recommend buy or sell any medicine. The decision to change or commence treatment was always made for each individual patient by the prescribing GP and every decision to change an individual patient's treatment was documented with evidence that it was made on rational grounds. GlaxoSmithKline therefore denied a breach of Clause 19.2.

GlaxoSmithKline asserted that the therapy review service was a non-promotional service; steps had been taken to ensure that the service was clearly separated from promotional activities and GlaxoSmithKline continued to monitor compliance with its own governance requirements. GlaxoSmithKline's involvement in the therapy review was made clear to practices and patients. GlaxoSmithKline therefore denied a breach of Clause 12.1.

GlaxoSmithKline asserted that it had maintained high standards in the design, implementation and monitoring of the therapy review service. This was demonstrated by the detailed documentation provided and in the robust ongoing monitoring that GlaxoSmithKline conducted. GlaxoSmithKline therefore denied a breach of Clause 9.1.

GlaxoSmithKline asserted that its therapy review service was a non-promotional activity, conducted in accordance with high standards. As GlaxoSmithKline denied any other breaches of the Code in its respectfully submitted that its activities did not amount to a breach of Clause 2.

PANEL RULING

General comments

The Panel noted that before considering each individual case, there were general points relevant to the therapy review services and the email in question which in its view were relevant to all of the cases. Each individual case would be considered on its own merits.

The Panel noted that under Clause 19 of the Code medical and educational goods and services which enhanced patient care or benefited the NHS and maintained patient care could be provided subject to the provisions of Clause 18.1. They must not be provided to individuals for their personal benefit. The supplementary information to Clause 19.1 gave further details. Pharmaceutical companies could promote a simple switch from one product to another but must not assist a health professional in implementing that switch. A therapeutic review which aimed to ensure that patients received optimal treatment following a clinical assessment was a legitimate activity for a pharmaceutical company to support and/or assist. The result of such clinical assessments might require, among other things, possible changes of treatment including changes of dose or medicine or cessation of treatment. It was not necessarily a breach of the Code for products from the company providing the service to be prescribed. However, a genuine therapeutic review should include a comprehensive range of relevant treatment choices including non-medicinal choices for the health professional and should not be limited to the medicines of the sponsoring pharmaceutical company. The decision to change or commence treatment must be made for each individual patient by the prescriber and every decision to change an individual patient's treatment must be documented with evidence that it was made on rational grounds.

The Panel noted that 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 Panel noted that the supplementary information to Clause 19.1 stated, *inter alia*, that service providers must operate to detailed written instructions provided by the company. These should be similar to the briefing material for representatives as referred to in Clause 15.9. The written instructions should set out the role of the service provider and should cover patient confidentiality issues. Instructions on how the recipients are to be informed etc should be included. The written instructions 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 pharmaceutical companies investing in therapy review services were very likely to have commercial interests in the area. One of the questions to be considered was whether the therapy review service would likely lead to the use of a particular medicine and whether such an outcome was appropriate bearing in mind the therapy area and available treatment options. How the activity might be perceived to all stakeholders including the public was important in this regard. Documentation with regard to the therapy review service offered and the instructions to the service providers were important as was the training provided in relation to the service and the therapy area. Materials whether they be from the company or third party should not link a therapy review to a particular product. The Panel considered that companies should be confident that those carrying out the service such as the third party service provider pharmacists were appropriately trained.

All discussions with the responsible GPs and other staff including all direct and indirect references to medicines must be non-promotional, fair and accurate and otherwise comply with the Code. This applied irrespective of the fact that the lead GP reviewed and mandated all clinical decisions as such decisions might be indirectly influenced by the preceding discussions eg with the pharmacist/company representative.

The Panel noted that the complaint, which was taken up with a number of companies, was based on an internal email sent by a senior employee of the named third party service provider to the entire clinical team. In the Panel's view, the email in question dated 14 August 2018 might be seen by the third party pharmacists as instructions on how the therapy reviews should be conducted.

The Panel noted that the email described the client plan for the remainder of 2018, specific details for each named pharmaceutical company client were included. The case preparation manager provided each company named in the email with the extract of the email that specifically applied to it together with the general statements which appeared to apply to all of the named companies. Context was important and the Panel reviewed the email in its entirety. In the Panel's view, the overall impression of the email was such that in the view of the author ie a senior employee of the third party service provider, the therapy services carried out by the third party were inextricably linked to the products of the sponsoring companies. In a few instances the email referred to reviews as being specific company product reviews. For one company the email stated '…you can still recruit any practice where baseline criteria are met and where formulary doesn't preclude [named company, not GlaxoSmithKline] products'. It was

extremely concerning that in places the email linked the service to particular products or only offered the service in practices where the formulary did not preclude the company's product. This and the reminder regarding developing the business including the phrase 'integrate client product/therapy priorities' could link company products to a therapy review service. Even where a particular product was not mentioned by name it was extremely likely that the company's product would be linked to the relevant therapy review, as understandably many of the recipients might see integrating client product/therapy priorities as increased prescribing of the company's medicines. The reputational gain from supporting implementation of NICE Guidelines and other relevant guidelines and the improvements in patient care might not be seen by recipients of the email as delivering client value or integrating product/therapy priorities. The important consideration for the Panel was the effect and influence of the email in question in relation to all the other arrangements for each therapy review.

The Panel noted that it was an established principle under the Code that pharmaceutical companies were responsible for third parties acting on their behalf even if that third party acted outside the instructions from the pharmaceutical company.

The Panel noted that it appeared from the email that the therapy reviews were not necessarily always driven by pharmaceutical companies, it appeared possible for the third party, a commercial organisation, to propose therapy reviews to a pharmaceutical company in an attempt to gain business.

The linking of product to client companies within the email was particularly concerning when the third party pharmacists could proactively offer a therapy review service to a practice.

The basis for a pharmaceutical company's decision regarding in which areas and in which practices a service would be offered, was important. It might be inappropriate to offer a service only in practices or areas in which a sponsoring company's product was not precluded or was the only or known recommended treatment choice.

The arrangements for delivering the service and its impact on prescribing in the practices targeted was another important consideration for the Panel. This might include how recommendations were made by the pharmacist; by therapy class, specific product, following notes or face-face clinical review.

The Panel noted the complainant's allegation that the third party service provider coached its pharmacists on client value which was a guise for return on investment and that this was historically done verbally. In addition conversations pharmaceutical company staff and third party staff had with practices was another important consideration. As was usually the case there was no evidence as to the content of verbal instructions and conversations.

Although companies were not provided with specific outcome data relating to prescribing medicines as the result of the therapy review in a particular practice following the third party pharmacist led clinics, overall data (non-product specific) appeared to be provided by the third party in some cases. The Panel considered that companies would be able to monitor use of their medicines and changes via other means for example sales data.

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The Panel noted its comments above with regard to the impression of the entire email but noted that the email did not refer to a specific GlaxoSmithKline medicine nor link the GlaxoSmithKline therapy review service to a specific medicine.

The Panel noted GlaxoSmithKline's submission that the COPD therapy review service was offered only to local health economies (LHEs) with the greatest unmet patient need. This was estimated by using non-elective COPD admissions (taken from Hospital Episodes Statistics data) and the local COPD list size (taken from Quality Outcomes Framework (QoF) data) to calculate the non-elective admission rate for each LHE. LHEs were then reviewed with above median areas considered for the therapy review service. Requests from other LHE or practices were also considered.

These details were included in the methodology statement which included information about segmentation at the LHE level and the practice level. The statement also included information about formulary screening to ensure that the review service did not inadvertently cause a switch to a GlaxoSmithKline medicine based on its sole availability within a particular therapeutic class. The process to be followed was that in any LHE where a GlaxoSmithKline medicine was the sole choice within a therapeutic class (or where GlaxoSmithKline single inhaler therapy was available with no other triple therapy options via any combination of inhalers), the review service would not be offered. In any LHE where GlaxoSmithKline was aware of an NHS led programme of switching to any single GlaxoSmithKline therapy, the review service would not be offered,

Where non-elective COPD admission rates were not available LHEs/practices with above UK/LHE median COPD prevalence respectively were suitable for the proactive introduction of the service.

The Panel noted GlaxoSmithKline's submission that the therapy review service could be introduced by its non-promotional team of respiratory project managers or the named third party service provider pharmacists; representatives were no longer allowed to briefly introduce the service. GlaxoSmithKline enforced a 7-day promotion free window either side of any therapy review service taking place to ensure practices were not unduly influenced. Remuneration for the service was based on activity, not outputs and specifically not sales of GlaxoSmithKline products.

The Panel noted GlaxoSmithKline's submission that patients were identified and invited to attend a clinic with the third party service provider pharmacist. Following the face-to-face clinical review, the third party pharmacist used a patient assessment form to make recommendations to the authorising GP. Recommendations might include a non-pharmacological intervention (such as help with smoking cessation or education on inhaler technique) and/or pharmacological intervention (ie a change in medicine). The pharmacological recommendations were made at therapy class level only. No specific product was recommended by the named third party service provider pharmacist. If the authorising health professional agreed with the recommendations, he/she selected the specific medicine within the recommended class and the named third party service provider pharmacist documented the interventions which had been authorised by the authorising GP.

The Panel noted GlaxoSmithKline's requirements for reviewing the local guidelines and formulary to ensure that a therapy review service could be undertaken. In making this determination, the following criteria were considered:

- The LHE formulary guidelines must be in line with NICE Guidelines (ie national guidelines) or GOLD Guideline for the management of COPD, to ensure that patients would be managed appropriately.

- The formulary must have a choice for each class of medicine that was not a GlaxoSmithKline product; so while a GlaxoSmithKline product might be on the formulary, it could not be the only one available to choose from in that class. The MEGS agreement also specified that NHS organisations must inform the company if a local guideline changed such that only a GlaxoSmithKline medicine was included within any therapeutic class. In that case, the service would be withdrawn.

- The LHE must not have a workplan in place or pending that involved switching to GlaxoSmithKline products.

The Panel noted GlaxoSmithKline's submission that there was no expectation or requirement for a GlaxoSmithKline product to be on the formulary.

The Panel noted GlaxoSmithKline's submission that the third party service provider staff were responsible for ensuring all pharmacists remained up to date with any developments within the therapeutic area. The clinical protocol stated that all pharmacists would have a thorough working knowledge of the relevant guidelines and key principles of COPD and would receive external COPD training from a RCGP accredited provider and internal training on the COPD therapy review service overseen by national and regional lead pharmacists. The Brief to the named third party service provider pharmacists stated that they would be trained, *inter alia*, on the therapy area (COPD) and COPD inhaler technique for all relevant devices.

The Panel noted GlaxoSmithKline's submission that 'client value' was not terminology it had heard of or used with the named third party service provider during the development, operationalisation, or ongoing management of the therapy review service. The Panel noted that the email itself did not refer to client value, it was a term referred to by the complainants.

The Panel further noted GlaxoSmithKline's submission that it periodically requested and received a summary of the number of clinics delivered, number of patients seen per clinic, number of pharmacological and non-pharmacological interventions, and the number of patients moved between therapeutic classes as a result of the therapy review service. GlaxoSmithKline submitted that it looked at the data sets to determine efficiency of the service in terms of cancellations, numbers of patients seen and number of clinics held and that the data also demonstrated that there was unmet need as illustrated by, for example, the patients who had not previously received symptom scores or needed referral for pulmonary rehabilitation. GlaxoSmithKline did not undertake any sub-analysis of this data and did not ask for or receive data on numbers of patients moving to GlaxoSmithKline products as a result of the therapy review service. GlaxoSmithKline stated that by measuring only these outputs, it demonstrated its commitment to the patient benefit derived from the service, rather than direct commercial gain to the company. The Panel noted the example report provided by GlaxoSmithKline which showed the management of patients by medicine class before and after the named third party service provider pharmacist-led clinic; this report appeared to show*, inter alia*, that after the clinic there was an increase in the number of patients on a combined LAMA/LABA (from 192 to 694) and on closed triple therapy (from 162 to 884). The Panel noted that GlaxoSmithKline was not the only company to market a combined LAMA/LABA or a closed triple therapy medicine.

The clinical protocol stated that the patients invited to clinic or had changes to medication were informed that the service was sponsored by GlaxoSmithKline and documentation identified GlaxoSmithKline as the sponsoring company.

The introduction to the PMCPA Constitution and Procedure stated that a complainant had the burden of proving their complaint on the balance of probabilities.

The Panel noted the complainants' allegation that they now had written proof that the third party service provider linked its therapy review services to the products of the sponsoring pharmaceutical company; historically the third party had done it verbally, being careful not to put anything in writing.

Whilst the Panel had concerns including about how the email portrayed the third party therapy services and its effects on the third party pharmacists and other staff, it nonetheless noted that the complainant bore the burden of proof. On the balance of probabilities, it was not unreasonable that some, if not all, of the pharmacists would associate the GlaxoSmithKline therapy review with GlaxoSmithKline products particularly based on the email at issue. However, taking all the circumstances into account including the Panel's view that GlaxoSmithKline's written arrangements for the review did not appear to amount to a switch to GlaxoSmithKline medicines, the Panel did not consider that the complainant had established, on the balance of probabilities, that the email demonstrated that the arrangements for the COPD therapy review supported by GlaxoSmithKline were such that they failed to meet the requirements of Clause 19.2. Nor had the complainants provided evidence that the therapy review constituted disguised promotion. The Panel therefore ruled no breach of Clauses 19.2 and 12.1 of the 2016 Code.

In the Panel's view, GlaxoSmithKline had been let down by its third-party. The Panel had serious concerns about the impression given by the entire email. However, it did not consider that in the particular circumstances of this case the complainants had provided evidence to show that GlaxoSmithKline had failed to maintain high standards and no breach of Clause 9.1 was ruled.

Given its rulings of no breach of the Code the Panel consequently ruled that there was no breach of Clause 2.

APPEAL BY THE COMPLAINANTS

The complainants appealed the Panel's ruling of no breach of Clause 9.1 failing to maintain high standards. The complainants were pleased with the following comments and ruling by the Panel:

> The Panel had serious concerns about the impression given by the entire email.
>
> In the Panel's view, GlaxoSmithKline had been let down by its third party.
>
> On the balance of probabilities, it was not unreasonable that some, if not all, of the named third party service provider pharmacists would associate the GlaxoSmithKline therapy review with GlaxoSmithKline's products.

> In the view of a senior employee of the third party service provider, the therapy services carried out by the third party were inextricably linked to the products of the sponsoring companies.
>
> In the Panel's view, the email in question might be seen by the third party service provider pharmacists as instructions on how the therapy reviews should be conducted.
>
> It was extremely concerning that in places the email linked the service to particular products…and the reminder regarding developing the business including the phrase 'integrate client product/therapy priorities' could link company products to a therapy review service. Even where a particular product was not mentioned by name, it was extremely likely that the company's product would be linked to the relevant therapy review, as understandably many of the recipients might see integrating client product/therapy priorities as increased prescribing of the company's medicines.
>
> The linking of product to client companies was particularly concerning when the third party service provider pharmacists could proactively offer a therapy review service to a practice.

The complainants requested that the Appeal Board consider the Panel's strongly worded comments above. The complainants alleged that these comments were not conducive to a therapy review service which was maintaining high standards of Code compliance.

The complainants started by setting context. The complaints alleged that the complaint was specifically based upon the email sent by a senior employee of the third party service provider dated 14 August 2018. It was widely accepted that the approved protocols and documents for an industry sponsored therapy review were never going to be found to make any link to the increased prescribing of the product of the sponsoring company. They would always be produced to refute any claims of bias and to avoid any reprimand. What the complainants were exposing was what went on behind the official paperwork. As an example, the Panel had rightly said, 'conversations pharmaceutical company staff and [third party service provider] staff had with practices was another important consideration. As was usually the case, there was no evidence as to the content of verbal instructions and conversations'. The complainants uncovered an email which exposed the true relationship between an 'independent' clinical service provider and the products of their clients.

The complainants stated the point for this appeal that although GlaxoSmithKline claimed to have been Code compliant, it was an established principle under the Code that pharmaceutical companies were responsible for third parties acting on their behalf even if that third party acted outside the instructions from the pharmaceutical company. It was clear that there had been a gross failing on the part of their third-party agency.

The complainants disagreed that they had not provided evidence to show that GlaxoSmithKline had failed to maintain high standards. The email of 14 August 2018 was enough evidence. Even though a specific GlaxoSmithKline product was not mentioned, the Panel had serious concerns about the impression given by the entire email and stated that 'on the balance of probabilities, it was not unreasonable that some, if not all, of the [third party service provider] pharmacists would associate the GlaxoSmithKline therapy review with GlaxoSmithKline's products'. This conclusion alone was damning enough, on the balance of probabilities, to rule a breach of Clause 9.1 in the complainants' opinion.

The complainants highlighted the following phrase which was the focus of the complaint: 'integrate client product/therapy priorities'. This phrase referred to ALL of the clients within the email. This was of major significance and the complainants requested that the Panel reviewed the wording again. Client product/therapy did not mean therapy area or disease area, it meant product of the client and therefore linked the product of any client referenced within the email to their respective therapy review. As the Panel had said, the phrase 'could link company products to a therapy review service. Even where a particular product was not mentioned by name, it was extremely likely that the company's product would be linked to the relevant therapy review, as understandably many of the recipients might see integrating client product/therapy priorities as increased prescribing of the company's medicines'.

The complainants agreed with this damning summary from the Panel which supported the complaint that it influenced the pharmacists and set the expectation for client product making a clear and obvious link between the therapy reviews named and product of the clients.

The complainants alleged that what GlaxoSmithKline perhaps did not understand was that within the email, several specific products were named and linked to therapy reviews from other companies. GlaxoSmithKline was named within this email and therefore the email as a whole caused serious concern to the complainants and the PMCPA.

GlaxoSmithKline had naively partnered with the third party service provider for commercial gain and as the Panel had rightly said, had been let down by them. There must be accountability in this case and under the Code, GlaxoSmithKline was responsible for the actions of the third party and therefore had not maintained high standards.

The complainants maintained that it must not be possible for a pharmaceutical company to partner with an 'independent' clinical service provider and an email of this nature to be written with no accountability or consequences whatsoever. The complainants appealed that a breach of Clause 9.1 at the very least, was entirely appropriate in this case, which might also serve as a warning to other pharmaceutical companies and clinical service providers wishing to partner in this manner, to show that this kind of behaviour would not be tolerated.

The complainants stated that GlaxoSmithKline had, of course, produced protocols and briefings to the Panel which showed this to be a Code compliant service, on paper. The complainants urged the Appeal Board not to rule that the complainants, on the balance of probabilities had not discharged their burden of proof that high standards had not been maintained. The complainants were certain that they had discharged the burden of proof, on the balance of probabilities, and the comments made by the Panel around the email in question supported this.

The complainants requested a fair appeal hearing and for the Appeal Board to consider the points above around the email dated 14 August 2018. Specifically, the responsibility around third parties acting on behalf of the pharmaceutical company and where the accountability lay.

FURTHER COMMENTS FROM THE COMPLAINANTS

The complainants understood how the companies concerned might not want to disclose certain documents due to confidentiality issues however at the very least it was highly relevant for the full therapy review protocols, pharmacist briefing documents, sales force briefing documents,

service introduction documents and all other documents concerning the therapy review for example - results presentation dashboards, final reports, etc to be supplied in all cases.

The complaints were regarding the email dated 14 August 2018 which related to the therapy review services and therefore the documentation relating to the therapy review services must be produced. The documents were widely used by the third party service provider, the NHS and pharmaceutical company sales teams so there was every reason to supply them.

COMMENTS FROM GLAXOSMITHKLINE

In relation to the appeal of Clause 9.1, GlaxoSmithKline maintained that the therapy review service in COPD sponsored by GlaxoSmithKline adhered to all aspects of the Code and, in particular, the company had continued to maintain high standards. GlaxoSmithKline disputed the merits of the complainants' appeal.

GlaxoSmithKline submitted it was important to note the recognised ongoing positive benefit that the service delivered to both patients and the NHS, a factor that was notable in the absence of its mention from both the original complaint and the complainant's appeal.

Summary of the Service

GlaxoSmithKline stated that the service aimed to ensure that patients receive optimal management of their COPD following a thorough and appropriate clinical assessment conducted by a qualified professional. The service offered a clinical review of COPD patients with all severities of disease, from mild to severe. GlaxoSmithKline asserted that the service was conducted in compliance with the relevant requirements of the 2019 Code. With reference to the complaint update received on 4 June 2019, for the avoidance of doubt, GlaxoSmithKline referred to the service as the 'COPD Therapy Review Service' and it had never included product names within either this title or the associated service documentation.

GlaxoSmithKline stated that it had contracted with the named third party service provider to provide a COPD therapy review service in primary care. The service was a non-promotional medical service provided by a team of pharmacists employed by the third party. The service provided a full clinical review for individual patients leading to a disease management decision based on recognised guidelines. The guidelines observed would typically be a local NHS medicines management COPD guideline, and/or formulary. These were checked by GlaxoSmithKline medical personnel for alignment to recognised national guidance, and also appropriateness of breadth of choice of treatment choices within any therapeutic class (there must be at least 2 treatment choices available in any therapeutic class). The guideline and/or formulary to be followed was defined by the authorising GP within section 4.1 of the clinical protocol. The service was aimed at ensuring that patients received optimal management in the form of non- pharmacological and pharmacological interventions. The service was designed to identify patients with unmet need within their COPD management as determined by their recorded symptom and exacerbation profile, then clinically review the holistic management of their disease. This thereby assisted practices to implement a systematic approach to the management of patients with COPD to improve patient outcomes.

It was clearly understood between the parties that the provision of the service was not dependent on any past, present or future prescribing or use of GlaxoSmithKline's products. There was no inducement, expectation or instruction for the named third party service provider

to increase prescribing of GlaxoSmithKline medicines as part of the service in any form, be that in writing or verbal, direct or indirect.

The service operated as follows:

- The service was offered only to Local Health Economies (LHE) with the greatest unmet patient need. This was estimated by GlaxoSmithKline within the approved Segmentation Screening Document by using the following NHS data: non-elective COPD admissions (taken from Hospital Episode Statistics (HES) Data) and the local COPD list size (taken from Quality Outcomes Framework (QOF) data).

- Director Level Medical and Non-promotional programme leads at GlaxoSmithKline reviewed the suitability of any CCG or Health Board requesting the service using the assessment card which captured the key information regarding appropriate unmet need and breadth of treatment choice in that area. This ensured that a comprehensive range of relevant therapeutic choices were available to authorising GPs and were not limited to GlaxoSmithKline medicines. GlaxoSmithKline provided examples of 2 LHEs which illustrate 2 highly relevant scenarios: Firstly, one named CCG was approved for deployment of the patient review service and no GlaxoSmithKline COPD inhaled therapies were approved by that CCG for use at that time. Secondly, another named CCG was not approved for deployment of the patient review service due to choices in that CCG being restricted to GlaxoSmithKline inhaled therapy in 2 therapeutic classes at that time.

- LHEs wishing to take up the offering sign a MEGS (Medical and Educational Goods and Services) agreement with GlaxoSmithKline. The MEGS agreement was explicit that the patients' own GP practice retain control over the entire service, clearly stating that any treatment choices that might be suggested as a result of the service were the choice and sole decision of the authorising health professional.

- The GP practice nominates, in the Authorisation Form an authorising GP (or other appropriate HCP/HCPs as defined within Section 7 of the clinical protocol) from their own practice staff practice approved by them, who was/were responsible for the care of his/her patients and retained full control over the entire process. This included the patients to be invited in for review. The individual assessment form detailed the outputs from the clinic consultation, importantly this meant any suggested changes in any patient management (non-pharmacological or pharmacological) were presented to the authorising GP or authorised HCP. If any pharmacological changes were suggested in the assessment form, this was by class of medicine only and not by any particular medicine (branded or non-branded). The authorising GP would therefore choose a medicine and any device based on their own clinical experience. The procedure was clearly designed to ensure that if following the review any change in medication occurred, the prescribing decision was made by a practice GP/HCP and them alone. The authorising GP was required to document this on the Individual assessment form, specifying the decision made by the authorising GP/HCP and their rationale for such a decision.

- The clinical protocol clearly defined the methodology by which patients were selected for clinical review, and the methodology by which any non-pharmacological and/or

pharmacological management recommendations, are identified, recommended and approved. This was fully described in Section 3 of the clinical protocol.

- The types of recommendations made and implemented were detailed in the aggregated dashboard and include the following: Addition of an inhaler spacer device, point-of-care FEV1, point-of-care pulse oximetry, use of in-check device, pulmonary rehabilitation referral, smoking cessation referral, Flu vaccination, Pneumococcal vaccination, referral for spirometry and referral to a secondary care service. Patients might also receive pharmacological management changes including escalation and de-escalation of their current therapy. These changes were monitored at an aggregated programme level by GlaxoSmithKline, at a CCG/Health Board Level by NHS project leads, and at individual practice level by the authorising GP. Example summaries of these changes could also be seen in summary in the 2 examples of posters produced with the NHS.

- Remuneration to the third party service provider for the service was based on activity only, as defined within the Master Services agreement.

- The service was introduced and administrated by GSK through a dedicated non-promotional role, the 'Respiratory Project Manager' (RPM). The certified job description for this role was provided within the original enclosures. The RPM must not be present during any aspect of service delivery including screening of patients or discussion around the clinical elements of the protocol. GlaxoSmithKline promotional representatives could not be in contact with the surgery during the review activities and for an appropriate period before and after the review in accordance with GlaxoSmithKline's internal governance procedure (as demonstrated by the promotion free window tracker.

GlaxoSmithKline stated that full details of all the written instructions that define all aspects of the service were provided with the original response. This included copies of the core legal and internal governance documentation regarding the service, specifically, the contract between GlaxoSmithKline and the named third party service provider, the MEGS agreement between GlaxoSmithKline and the NHS organisation, and the clinical protocol.

GlaxoSmithKline reiterated the following regarding measurement of the service:

- GlaxoSmithKline had not identified, nor agreed with the third party, any 'success' criteria for the therapy review service beyond the delivery of an agreed volume of clinic days, adherence to required written standards, and NHS feedback received.

- GlaxoSmithKline periodically requested and received a summary of the number of clinics delivered, number of patients seen per clinic, number of pharmacological and non-pharmacological interventions, and the number patients moving between therapeutic classes as a result of the service

- GlaxoSmithKline had specifically not requested any data on the proportion of patients that were changed to a GlaxoSmithKline medicine as a result of the review services as such information is inappropriate and was not the purpose of the agreement.

GlaxoSmithKline believed that the service enhances patient care and benefits the NHS. The company sought external feedback on the clinical protocol from the named patient organisation prior to the service going live, and received the following comments:

> '(our [named job title]) has had a look over the protocol and has the following feedback: Protocol is clear and well written, Very welcome. There is little we add can or suggest as it is so well written. We have only a couple of VERY minor suggestions.'

GlaxoSmithKline also received feedback from the NHS on the service, the examples below typify the positive comments that were received:

> 'All in all, I would highly recommend this service to other practices as it is a great additional resource to help manage patients with COPD' - Respiratory Lead GP

> 'The [third party party} Pharmacist has been comprehensive, professional and patient centred during her time with our practice and we have appreciated her clinical expertise' – GP

> 'During these unprecedented times it has been a huge relief to be able to rely on the pharmacist, from [the named third party service provider], in the support and management of our patients with COPD' – Practice Manager.

GlaxoSmithKline's response to the appeal

GlaxoSmithKline noted that the complainant's grounds for appeal appeared to be based on a selection of excerpts taken from the Panel ruling (dated December 2019). GlaxoSmithKline maintained that these excerpts were one-sided and not a fair reflection of the Panel's overall findings in which the Panel found the service not in breach of the Code. GlaxoSmithKline stated that it would address these comments below, however, the complainant had provided no evidence to substantiate or verify the allegations raised.

GlaxoSmithKline stated that the email referred to in the complaint was an internal email within the named third party service provider. It had not been requested by GlaxoSmithKline nor had GlaxoSmithKline seen or been involved in the content of it.

GlaxoSmithKline acknowledged the possibly poor choice of language used within the internal email that could be viewed, without context and balance, as not aligning to the impartiality of the service. Therefore, following the complaint GlaxoSmithKline took steps to seek to understand the context of the email and ensure the named third party service provider was still compliant with all written agreements regarding the service and to seek to understand the context of the email. The outcome of these discussions was summarised in the following position statement received from the third party service provider which GlaxoSmithKline held on file:

> '"Client value" is not a term we recognise or use in [third party name] communication (including within the communication item that has been referenced in the complaint). When we are describing the value of a service, we refer to the benefits and improved patient outcomes that are delivered to the NHS and to patients and that these recipients of our services also feel satisfied with their experience of the service.

> On reflection, since the complaint was raised, we have proactively reviewed our training and guidance on communications. Whilst we already have ABPI Code training as part of our induction process and annual refresher training including guidance on digital communications, we felt there was a requirement to make it clear to all staff about appropriate communications both internally and externally.
>
> As such, a communications policy has been created and released by [named team] which outlines the principles of what ABPI Code compliant communications are and introduces a mandatory process of review and approval of communications about services or medicines/products through the compliance department. The policy also outlines clear channels of communication so that messages are sent out from appropriate channels for example from a training or compliance mailbox, so that it is clear to the recipients what the nature of the message is.'

With regard to the alleged 'commercial gain', GlaxoSmithKline drew attention to the following points to provide context, balance and transparency to the aspects of the appeal content referring to the association of the third party pharmacists of the service with GlaxoSmithKline products and the general use of GlaxoSmithKline medicines as a result of the service:

GlaxoSmithKline stated that all prescribing decisions were made solely by the relevant health professional. These were based on their clinical experience and local guidelines and formularies. As previously mentioned, to ensure the impartiality of the service, measures were in place to only provide the service to areas where there was sufficient treatment choice available under those guidelines and on the formularies and was not conditional on GlaxoSmithKline being on the formulary but simply based on patient need (examples provided). Local NHS organisations did recognise that certain medicines should be used by way of local guidelines and formularies.

There were several CCGs and health boards using the service, that had undertaken their own independent review of changes in the use of inhaled therapies to assess the overall balance of the service. This had been done retrospectively on completion of review clinics. No complaints or concerns had been raised with GlaxoSmithKline, the third party or externally as a result of these reviews of therapy use change.

GlaxoSmithKline was concerned about the complainant's allegations that the service did not run strictly to the written documentation. As had been mentioned above and enclosed in GlaxoSmithKline's original response there was extensive documentation relating to the service. All original documentation had been legally reviewed and medically certified by GlaxoSmithKline. Front-end monitoring of the agreement was conducted at the time and GlaxoSmithKline had also undertaken considerable due diligence since the complaint and had found no evidence that the spirit of the agreement was not fully complied with. GlaxoSmithKline stated that the complainant had provided no evidence that the service was not provided in accordance with the written agreement between the 2 parties nor evidence of any verbal briefings differing from the written documents. GlaxoSmithKline strongly refuted this aspect of the appeal.

The complainant also commented on the following quote from the Panel ruling:

> 'conversations pharmaceutical company staff and [the named third party service provider] staff had with practices was another important consideration. As was usually the case, there was no evidence as to the content of verbal instructions and conversations.'

GlaxoSmithKline stated that from this quote the complainant had concluded that the Panel thought conversations were different or implied that they were different, however, they had no evidence to suggest this. GlaxoSmithKline would reassert the following points in response to this:

- The promotion free window ensured that no contact, verbal or otherwise, took place between promotional representatives and practices 7 days before or after any activity by the third party service provider with the practice.
- Conversations that took place between the third party service provider and the practice were subsequently documented and agreed within the written agreements between the parties.

GlaxoSmithKline strongly believed that no negative connotations could be drawn from the fact that no evidence could be found to the nature of the conversations. No evidence that either party acted in any way other than in accordance with both the written documentation and the spirit of the agreement had been provided.

The key agreements made between the NHS and the third party service provider were captured within the service MEGS agreement and the practice authorisation form. Furthermore, there was no evidence to suggest that the service execution and delivery differed in any way from the extensive details documented within these agreements. GlaxoSmithKline completed management monitoring for the service and reviewed the following key controls on a monthly basis:

- Briefings to all personnel completed regularly (at least twice per year) with training record maintained.
- 100% audit of promotional activity vs. promotion free window requirements completed monthly.
- At a minimum, an annual, PMCPA case-based and Code updated risk review was performed for this activity by the Business Owner to assess existing and emerging risks. Risk registers and monitoring plans were updated in line with the review.
- Key Account Managers (RAMs) and Respiratory Project Managers (RPMs) flagged any changes in the environment that would lead to changes in the project's approval status.
- Programme Owner performs a monthly review of a sample of project cards to ensure the information was accurately reflected and no changes were required
- Non-promotional review board met monthly to review ongoing/proposed UK Pharma activities to ensure oversight of all non-promotional activities
- Business Owner completed periodic performance reviews with the third party to review service deliverables, including health professional feedback and third-party feedback. This was completed at least annually in conjunction with the TPO Manage and Monitor requirement, where third party risks were assessed, and any red flags addressed. Quarterly check on new personnel and training records.
- Project plan completed monthly by Project Owner to ensure key steps and documents had been completed

- Documentation governance log maintained to identify all associated service documentation.

GlaxoSmithKline stated that it also managed verbal and written communications wherever possible and maintained written records of 'catch and correct' activity where any potential issues regarding failure to adhere to standards were identified.

As a result of management monitoring and catch and correct activity, failure to comply was subject to GlaxoSmithKline's process deviation and performance management investigation procedures. These resulted in formal sanctions up to and including dismissal as a result of failing to comply to required standards.

GlaxoSmithKline stated that the complainant made reference within the appeal letter to the likelihood of the third party service provider pharmacists associating the service with GlaxoSmithKline products, and that this was enforced by the wording of the internal email referencing client value. The complainant again quoted from the Panel ruling:

> 'on the balance of probabilities, it was not unreasonable that some, if not all, of the [named third party service provider] pharmacists would associate the GSK therapy review with GSK's products and could link company products to a therapy review service. Even where a particular product was not mentioned by name, it was extremely likely that the company's product would be linked to the relevant therapy review, as understandably many of the recipients might see integrating client product/therapy priorities as increased prescribing of the company's medicines.'

GlaxoSmithKline reiterated that the Panel did not find the service in breach of the Code. The purpose of the service had never been to increase prescribing of GlaxoSmithKline products and GlaxoSmithKline deliberately set up the service in such a way that the third party service provider pharmacist was not able to do this, even unintentionally. If a change in medication was required according to treatment guidelines the pharmacist could not recommend any particular medicine only a class of medicine. The sole choice and decision of medication and prescription was the responsibility of the practice (authorizing GP). So even if the pharmacist had associated the therapy review with GlaxoSmithKline products, they were not able to recommend or prescribe a specific product. Therefore, GlaxoSmithKline believed it had removed any potential for 'commercial bias' intentionally or even unintentionally as the complainant had alleged.

An excerpt from the clinical pharmacist brief showed that there were very clearly defined standards:

> 'Remember, treatment choices arising from the patient review process remain the choice and sole decision of the authorising GP or authorised HCP (defined in the "Conduct of the Therapy Review") and clinical responsibility for every patient remains the responsibility of the practice.'

GlaxoSmithKline stated again, there was no evidence that the service had deviated from the very clear documentation.

GlaxoSmithKline disagreed with the statements made by the complainant regarding the standards maintained in the appointment of the named third party service provider as a supplier.

Stating that GlaxoSmithKline 'naively partnered with [the third party service provider] for commercial gain' and quoting the Panel ruling stating 'GlaxoSmithKline had been let down'.

GlaxoSmithKline was confident that from the selection and appointment of the third party as a service provider, through to the ongoing operational controls regarding the service (namely training records, NHS service evaluation, adverse event reporting and management monitoring processes), that the third party service provider had consistently provided a Code compliant service to a high standard. This included scheduled management monitoring of the supplier, pharmacist training records, completion of all required internal and external reporting, and regular revalidation of GlaxoSmithKline's engagement through contract renewal and its third-party oversight processes. It was also noteworthy that the NHS procured the services of the third party directly and as such appointed it directly as their own supplier.

In addition, GlaxoSmithKline had a robust process to select third party vendors, in fact a number of other patient review service providers had been identified for selection during the past 2 years and GlaxoSmithKline had not proceeded with them due to concerns regarding their ability to maintain the high standards required by GlaxoSmithKline. Evidence of the standard of the service was best illustrated by the NHS demand for the Service, as well as independent evaluation and recognition for it and details were provided including reference to published material as well as l.

- NHS health professional service evaluation: On completion of review clinics in a practice, they were sent a survey request soliciting an anonymous evaluation of the service received. 132 completed survey responses had been received during the course of the patient review service with the results summarised and details were provided.

- Ongoing demand for the service – since the commencement of the service in July 2019 the named third party service provider had delivered nearly over 3800 clinic days in over 500 practices across over 50 CCGs and health boards in the UK. There had been no complaints regarding the quality of service received during this time.

GlaxoSmithKline stated that the complainant referred to a 'damning summary' from the Panel however GlaxoSmithKline found the observations of the Panel useful and constructive which ensured that it retained a quality Code compliant service. In conclusion, GlaxoSmithKline asserted that the service carried out by the third party on GlaxoSmithKline's behalf enhanced patient care by ensuring that patients received a thorough clinical review based on an approved clinical protocol in line with national or/and local guidelines. It included a comprehensive range of appropriate interventions, non- pharmacological and pharmacological. All interventions were agreed and overseen by the authorised GP. GlaxoSmithKline ensured that a range of choices were available to the prescriber, in fact the service would not be provided if it was only a GlaxoSmithKline medicine that was available. The implementation of the service was not contingent in any way on the availability or use of GlaxoSmithKline medicines. GlaxoSmithKline did not measure the service based on the prescription of medicines or return on investment. The arrangements for the service were documented and kept on record and did not constitute an inducement to prescribe, supply, administer, recommend buy or sell any medicine. The decision to change or commence treatment was always made for each individual patient by the authorising GP and every decision to change an individual patient's treatment was documented with evidence that it was made on rational grounds.

GlaxoSmithKline asserted that the service carried out by the third party service provider on GlaxoSmithKline's behalf was a non-promotional service. GlaxoSmithKline stated that it had taken the steps described in the original response to ensure clear separation of the service from GlaxoSmithKline's promotional activities and continued to monitor compliance with its own governance requirements. GlaxoSmithKline's involvement in the therapy review was made clear to practices and patients.

GlaxoSmithKline asserted that it had maintained high standards in the design, implementation and monitoring of the service. This was demonstrated by the detailed documentation provided and in the robust ongoing monitoring that GlaxoSmithKline conducted.

GlaxoSmithKline asserted that the service was a non-promotional activity and was conducted in accordance with high standards. The complainant maintained that a copy of an internal third party email relating to a GlaxoSmithKline therapy review service without mention of a specific GlaxoSmithKline Respiratory medicine (contrary to the complainants' assertion) could be evidence of linkage of the service to GlaxoSmithKline products. GlaxoSmithKline had outlined all steps taken to ensure the service adhered to the Code and steps taken to minimize any potential bias.

GlaxoSmithKline submitted that it had demonstrated the benefits to patients and the NHS whilst complying with all code requirements. GlaxoSmithKline believed the original ruling of the Panel was fair and appropriate, and that through this appeal process, the company had provided further evidence of the quality and benefit of the GlaxoSmithKline service in addition to continuing to maintain high standards.

FURTHER COMMENTS FROM THE COMPLAINANTS

There were no further comments from the complainants.

APPEAL BOARD RULING

The Appeal Board noted the Panel's general comments above and considered that they were relevant to all the related therapy review cases and the email in question. Each individual case would be considered on its own merits. In that regard, the Appeal Board noted that it could be argued that the email in question did not refer to a specific GlaxoSmithKline medicine nor link the GlaxoSmithKline therapy review service to a specific medicine. The Appeal Board noted however that the phrase 'integrate client product/therapy priorities' appeared towards the end of the email and appeared to apply to all the therapy reviews.

In the Appeal Board's view, it appeared that GlaxoSmithKline's documentation was not unreasonable in that it did not appear to link the therapy review service to GlaxoSmithKline's product. The Appeal Board noted that within the email at issue another pharmaceutical company's medicine had been linked to that company's therapy review service.

The Appeal Board noted that the complainants had alleged that the focus of their complaint was in relation the term 'integrate client product/therapy priorities' that appeared in the email. The Appeal Board noted that the email at issue was a single internal communication within the named third party service provider. The Appeal Board was concerned that the third party

service provider had linked another company's product to a therapy review service in the email. Whilst the Appeal Board considered that the wording of the phrase 'integrate client product/therapy priorities' could be improved it did not consider overall that the phrase in itself or in the context of the email related to a particular GlaxoSmithKline medicine. No evidence was provided by the complainants to show that the email in question impacted on the delivery of the GlaxoSmithKline service.

In the Appeal Board's view, GlaxoSmithKline had been let down by its third-party service provider. The Appeal Board noted the Panel's serious concerns about the impression given by the entire email. However, the Appeal Board did not consider that, in the particular circumstances of this case, the complainants had provided evidence that GlaxoSmithKline had failed to maintain high standards and it upheld the Panel's ruling of no breach of Clause 9.1. The appeal was unsuccessful.

This case was one of a number of cases as follows; Case AUTH/3188/4/19 Bayer, Case AUTH/3190/4/19 Takeda, Case AUTH/3191/4/19 Amgen, Case AUTH/3193/4/19 Novartis, Case AUTH/3195/4/19 Chiesi and Case AUTH/3197/4/19 Ethypharm.

Complaint received **30 April 2019**

Case completed **14 October 2020**