CASE AUTH/2474/1/12

GLAXOSMITHKLINE EMPLOYEE v GLAXOSMITHKLINE

Promotional activities and training

An employee of GlaxoSmithKline UK complained about the company's promotion of, and/or staff training on, Revolade (eltrombopag), Seretide (fluticasone/salmeterol) and ReQuip XL (ropinirole).

The complainant alleged that a GlaxoSmithKline representative had promoted the unlicensed use of Revolade for myeloid fibrosis via an individual funding request (IFR). Revolade was indicated for immune (idiopathic) thrombocytopenic purpura (ITP).

The detailed responses from GlaxoSmithKline are given below.

The Panel noted that the subject matter of the representative's email, which was sent to a consultant at the request of the consultant's secretary, read 'Request for an appointment re an IFr submission for a patient with Myeloid Firosis [*sic*]'. The email referred to a telephone conversation with the consultant's secretary and suggested dates for an appointment to 'discuss putting together the IFR for your patient with Myeloid Fibrosis'.

The Panel noted the licensed indication for Revolade. The Panel also noted that according to GlaxoSmithKline, the consultant had asked the representative for information about Revolade to support a funding request for a patient with chronic ITP as the patient had myelofibrosis and asked for information about myelodysplastic syndrome and bone marrow failure syndromes. The representative sent the latter request to GlaxoSmithKline's medical information function for a response.

The Panel noted that whilst the subsequent meeting discussed an IFR for the use of Revolade in chronic ITP, the subject matter of the email in question referred to myeloid fibrosis as the representative had considered that this was the only way to identify the reason for the meeting. The Panel queried whether this was so. In his/her signed statement the representative acknowledged that the email could have been misconstrued and that during the subsequent meeting the consultant had the patient in mind but the representative had stressed that they could only talk about the use of Revolade in chronic ITP.

Whilst the email did not expressly refer to Revolade, it was an integral part of a series of communications about the medicine. The IFR referred to in the subject matter of the email was in relation to Revolade. The Panel considered that whilst there was no evidence that the subsequent meeting was unacceptable in relation to the requirements of the Code, the subject matter of the email in question implied that the IFR related to Revolade and its use in myeloid fibrosis and consequently promoted Revolade outside its licensed indication as alleged. A breach of the Code was ruled.

The Panel considered that the representative should have been mindful of the impression given by the subject matter of the email and noted the representative's acknowledgement that it could have been misconstrued. High standards had not been maintained in this regard by the representative and a breach of the Code was ruled. There was, however, no evidence that the company had failed to maintain high standards and the Panel ruled no breach of the Code including no breach of Clause 2.

The complainant alleged that a tactical brand plan for Revolade led representatives to promote the product for unlicensed indications.

The Panel noted that the Revolade brand plan and its covering email were provided to two GlaxoSmithKline employees in response to a request for background brand strategy information from a GlaxoSmithKline trainer to satisfy the training needs of a hospital healthcare business manager (HHBM). The author of the email in question was an individual aligned to the brand planning team.

The covering email explained that the global tactical brand plan was for background use only and that a UK brand plan would be produced subsequently. The email outlined six outputs from a UK brand plan day including 'Clinical Experience and KEG [Key Evidence Generation] Explore data to cover use in presurgery - off license but reported to team'. The Panel noted that it had to consider whether the provision of the global tactical brand plan and covering email to the HHBM (who was not a member of the brand planning team) encouraged the promotion of Revolade beyond its licence.

According to GlaxoSmithKline HHBMs worked with senior non-clinical NHS staff on local access to medicines and budget management; they were only expected to have a basic knowledge of GlaxoSmithKline medicines. They could offer support to specific brands by having discussions with payer customers. The role of the HHBMs was further described as, *inter alia*, driving the 'growth of GlaxoSmithKline brands through excellent account management in secondary care', and at the launch of the product they would 'lead and support the account team to drive rapid uptake of the brand, including plans for formulary inclusion'. Reference was made to subsequent commercialisation. Key contacts for most HHBMs included senior pharmacists.

The Panel noted that the first slide of the Revolade global tactical brand plan made it clear that all materials were subject to local review and approval. The plan discussed the disease, global market access challenges, growth strategies and performance measurement etc. There was no reference to off-licence use. The Panel did not consider that the

provision of the global tactical brand plan to the HHBM was contrary to the Code as alleged; it did not discuss unlicensed use of Revolade and the covering email made it clear that it was provided for background reading only. The Panel did not consider that there had been a failure to maintain high standards in relation to the content of the global tactical brand and its provision to an HHBM; no breach of the Code was ruled.

The Panel noted that the subject of the covering email was 'Brand Plan Global: Revolade reading only: [name]'. A bullet point read 'Explore data to cover use in presurgery – off licence but reported to the team'. GlaxoSmithKline explained that as this off-licence use had been reported to the brand team, its medical department would explore data generation and medical information responses. The Panel considered that the email did not make this clear and without the benefit of GlaxoSmithKline's explanation the bullet point in question was open to misinterpretation by field based staff who did not participate in the meeting. The Panel therefore did not accept GlaxoSmithKline's submission that as it was a medical department issue, no further qualification was needed and no follow up with the email recipients would have been necessary. The outputs of the meeting had been disseminated beyond the UK Brand Plan team to, *inter alia*, a member of a field based team without the benefit of GlaxoSmithKline's detailed explanation. The covering email, including the subject title, made it clear that the global brand plan was for background only but no such qualification was applied to the outputs of the UK brand planning meeting.

The Panel was concerned about the unqualified reproduction of the outputs from the UK brand meeting in the covering email which referred to the unlicensed use of Revolade and its provision to an HHBM who was not a member of the UK brand planning team. The Panel considered that the dissemination of such material to an HHBM who, *inter alia*, would have product related discussions with payer customers, would have to comply with the Code. The trainer to whom the email was also sent could not recall discussions following the email but had confirmed that approved materials were used for all subsequent training for the HHBM. The Panel considered that the unqualified reference to unlicensed use in the email in question together with its provision to an HHBM who was not a member of the UK brand planning team meant that high standards had not been maintained; a breach of the Code was ruled. The Panel did not consider that the circumstances warranted a sign of particular censure; no breach of Clause 2 was thus ruled.

The complainant alleged that the hospital business manager's team falsified a Seretide product certification examination. All of the managers sat the product knowledge test at the same time and the answers were read out by a team member as instructed by a manager. This deliberate action, following limited training, meant that the hospital business managers were not adequately trained on Seretide when they engaged with customers. The complainant subsequently provided additional material in support of this allegation.

The Panel noted that it firstly had to consider whether the HHBMs satisfied the definition of a representative under the Code. The Code defined a representative as anyone calling on members of the health professions and administrative staff in relation to the promotion of medicines. This was a wide definition and could cover the activities of those employees that companies might not call or consider as representatives.

The Code defined promotion as 'any activity undertaken by a pharmaceutical company or with its authority which promoted the prescription, supply, sale or administration of its medicines'.

The Panel noted GlaxoSmithKline's submission that the HHBMs worked with senior non-clinical NHS staff on, *inter alia*, formularies. They could also offer additional support to specific brands by having discussions with senior managers and payers for which they underwent product training as there was a possibility that HHBMs would be required to have discussions with senior managers and payers, and the training event in question was designed to satisfy this additional training need in relation to Seretide. The Panel noted that the personal development plans (PDPs) provided referred primarily to a facilitation and account mapping role in relation to Seretide.

The Panel noted GlaxoSmithKline's submission that HHBMs could offer additional support to specific brands by having discussions with payer customers. In this regard the Panel also noted that a document provided by the complainant entitled 'The role of the HHBM within the Respiratory Market Access' stated that within specific accounts identified by the area business manager (ABM) the HHBM would proactively raise Seretide to discuss the current situation. The Panel noted the HHBMs' broad role as set out in the papers provided by both parties. The Panel noted the definitions of promotion and representative in the Code as set out above and considered that merely because HHBMs did not interact with prescribers did not mean that such interactions were not promotional as defined in the Code. The Panel considered that a limited aspect of the HHBMs' role was likely to involve discussion of specific medicines, and taking all the circumstances into account, the Panel considered that, in relation to this part of their role, they acted as representatives as set out in the Code.

The Panel noted that the parties' accounts of the training event differed. It was difficult to determine precisely what had occurred. The Panel noted that the complainant bore the burden of proving his/her complaint on the balance of probabilities. The complainant alleged that it was not a *bona fide* training event and the answers were read out to participants. GlaxoSmithKline explained that it was a knowledge consolidation event rather than evaluation, at the end of an online product training course. The Panel noted that, according to the unsigned witness statements provided by GlaxoSmithKline, whilst at least one participant completed the test alone, the majority appeared to have completed the informal test collaboratively, with the benefit of discussion.

The Panel noted that the Code required representatives to be given adequate training and have sufficient knowledge to enable them to provide full and accurate information about the medicines which they promoted. The Panel considered that it was acceptable to run informal training sessions to consolidate rather than evaluate participants' product knowledge as described by GlaxoSmithKline. However, the overall training package must satisfy the relevant requirements of the Code. The complaint on this point related solely to the specific training event. The Panel noted GlaxoSmithKline's submission that further extensive training was provided to HHBMs. The Panel did not consider that the conduct of the training event in question was such that the company had failed to satisfy the broader product training requirements of the Code as alleged. No breach of the Code was ruled. The company had not failed to maintain high standards in relation to the event; no breach of the Code was ruled. The Panel consequently ruled no breach of Clause 2.

The complainant alleged that at another training event GlaxoSmithKline employees falsified another examination to ensure compliance with the Code. The team had received repeated text messages in the preceding weeks which set out the questions and answers within the examination. The team sat the examination at the same time and the answers were read out by a manager. The complainant submitted that many of the questions in the test, particularly around the NHS, were very difficult and that he/she had never received any formal relevant training.

The complainant alleged that the HHBMs were not trained to a standard that allowed them to have accurate discussions with customers.

The Panel noted that the complaint concerned the conduct of the pilot annual product knowledge review. The Panel noted its comments above about the role and status of HHBMs and considered that they applied here.

The Panel noted that, once again, the parties' accounts differed and it was difficult in such circumstances to determine precisely what had occurred. The Panel noted that the complainant bore the burden of proving his/her complaint on the balance of probabilities.

The Panel noted GlaxoSmithKline's submission that the annual product knowledge review was first piloted with the HHBMs in 2011. The process had been carried out successfully over a number of years with representatives to test their level of product knowledge.

The Panel noted that GlaxoSmithKline had provided a number of unsigned witness statements from HHBMs who took part in the pilot test. All interviewees refuted the allegation that answers were read out as alleged. The witness statement of the HHBM national business manager explained that on the day of the test he decided to run it as an open book test with access to online information for participants. Some participants were helped where to look online. The test was described as a knowledge and information seeking test to see how they got on. It was acknowledged that this activity needed to be run differently next time.

The Panel considered that in principle it was acceptable to run pilot training sessions to inform and improve the overall product training package. However, the overall training package should comply with the Code. The complaint on this point related solely to the training event at issue. The Panel noted GlaxoSmithKline's submission that further extensive training was provided to HHBMs. The Panel did not consider that the conduct of the second training event demonstrated that the company had failed to satisfy the broader product training requirements of the Code; no breach of the Code was ruled. The Panel consequently ruled no breaches of the Code including no breach of Clause 2.

The complainant alleged that GlaxoSmithKline's overall product training standards were below that expected by the Code. The complainant subsequently submitted further material which mainly concerned the promotion of GlaxoSmithKline's medicines to NHS customers by representatives who had not received formal and certified internal training. The complainant also provided documents about the promotion of ReQuip XL using integrated healthcare managers (IHMs), although those IHMs had never received any formal training. The complainant provided a copy of a presentation which he/she found wholly unethical as it was entitled 'Revolade Smashing targets'. The complainant referred to an email from the Revolade marketing team to the representatives that revealed the locations and names of doctors using Revolade under the named patient programme.

The complainant also alleged that the lack of adequate training was evidenced in personal development plans.

The Panel noted GlaxoSmithKline's submission that its representatives were thoroughly and comprehensively trained on Seretide. Training slides and other relevant material were provided. The complainant had provided no material in support of his/her allegation on this point. The Panel considered that on the material before it there was no evidence to demonstrate that GlaxoSmithKline's sales representatives were not given adequate training and sufficient scientific knowledge to enable them to provide full and accurate information about the medicines they promoted. No breach of the Code was ruled.

In relation to HHBMs and Seretide, the Panel noted its comments about the role of the HHBMs and the role of the HHBMs with regard to Seretide as described in the document 'The role of the HHBM within Respiratory Market Access' which referred to specific circumstances where HHBMs were contracted to proactively discuss Seretide. The Panel noted that neither the document nor its covering email limited such discussion to financial implications as stated by GlaxoSmithKline. The document stated that the knowledge level required for HHBMs generally included 'a basic understanding

of Seretide to include the SPC [summary of product characteristics], preparations and prices'. The undated document was circulated to HHBMs in April 2011 and the covering email referred to its previous circulation to HHBMs in February 2011.

The Panel noted GlaxoSmithKline's submission that when HHBMs had discussions with payer customers to support specific brands, they underwent product training. The Panel noted GlaxoSmithKline's submission that in 2011 HHBMs received 20 days of training of which 13 were product training which GlaxoSmithKline considered provided them with knowledge above and beyond that required by their role. The Panel noted that the HHBM training for Seretide in 2011 comprised product training on two separate days (neither were full days). In addition, the HHBM team did distance learning for Seretide and brand managers delivered updates at HHBM team meetings. The Panel noted GlaxoSmithKline's submission about the need for further training to enable HHBMs to have more detailed discussions. The Panel noted that GlaxoSmithKline had, in effect, acknowledged the need for further training on Seretide. The Panel noted that the complainant bore the burden of proof. The Panel had some concerns about the HHBM Seretide training but did not consider that the complainant had demonstrated on the balance of probabilities that the product training was inadequate given the nature of calls likely to be made; no breach of the Code was ruled.

The Panel noted the allegation that IHMs promoted ReQuip XL without any formal training. The Panel noted that the job template for the IHMs which described their key responsibility. IHMs reported into the business manager. GlaxoSmithKline submitted that the IHMs had never promoted ReQuip XL.

The Panel did not consider that the material provided by the complainant in relation to IHMs and ReQuip XL demonstrated that they had any promotional role in relation to ReQuip XL as alleged. An email to the HHBM team referred to IHMs facilitating introductions for an HHBM. The complainant had not established that the IHMs had any promotional role in relation to ReQuip XL and thus there was no requirement that they be trained on it; no breach of the Code was ruled.

The Panel noted that the purpose of the internal presentation to the Revolade head office team entitled 'Smashing targets' was to help the team understand the importance of managed market access and the effect on national targets of small local brand achievements. The Panel did not consider that the title 'Smashing targets' was unethical given the audience and content; no breach of the Code was ruled.

In relation to the email which discussed the names and locations of investigators who had used Revolade under the named patient programme, the Panel noted that it was sent to HHBMs rather than to sales representatives as stated by the complainant. No confidential patient data was disclosed. A funding issue had arisen and thus the HHBMs were to discuss ongoing funding with budget holders at the relevant hospitals. The complainant had referred to this email but did not state why it was unacceptable under the Code. The Panel noted that the complainant had not established that the email in question was unacceptable and thus ruled no breach of the Code.

The Panel noted that it had asked GlaxoSmithKline to respond to Clause 2 on this point and noting its no breach rulings above consequently ruled no breach of Clause 2.

A GlaxoSmithKline UK Limited employee complained about the promotion of and/or staff training on Revolade (eltrombopag), Seretide (fluticasone/salmeterol) and ReQuip XL (ropinirole). Both before the initial response was received and subsequent to that response, further allegations were made.

When responding to the complaint the Authority asked GlaxoSmithKline to bear in mind Clauses 2, 3.2, 9.1, 15.1, 15.2 and in addition, in relation to point B3, Clause 15.9 of the Code.

A Alleged off-licence promotion of Revolade

1 Email sent by a representative

COMPLAINT

The complainant alleged that GlaxoSmithKline had promoted the use of Revolade outside its current licensed indication for immune (idiopathic) thrombocytopenic purpura (ITP). The complainant provided a copy of an email which he/she alleged showed that a representative had promoted the use of Revolade via an individual funding request (IFR) for myeloid fibrosis.

RESPONSE

GlaxoSmithKline stated that Revolade, according to its summary of product characteristics (SPC), was indicated for adult chronic ITP in splenectomised patients refractory to other treatments (eg corticosteroids, immunoglobulins). Revolade might be considered as second line treatment for adult non-splenectomised patients where surgery was contraindicated.

As Revolade was not recommended by the National Institute for health and Clinical Excellence (NICE) for use within its marketing authorization, primary care trusts (PCTs) would not routinely fund it and so clinicians who wished to use it would have to raise an IFR.

An email from a GlaxoSmithKline representative to a hospital consultant was provided by the complainant. The representative was a very experienced representative with many years in the pharmaceutical industry during which his/her conduct had never been questioned. He/she had been trained on the licensed indication for Revolade and on chronic ITP.

GlaxoSmithKline explained that the representative had delivered a presentation on Revolade at a hospital meeting and let it be known that GlaxoSmithKline had an approved document that contained on-licence clinical data to support clinicians when completing a form to request funding for Revolade on an individual patient basis. After the meeting a consultant asked the representative for information on Revolade to use to support a funding request for one of his patients with chronic ITP. The patient also had myelofibrosis and the consultant requested information on myelodysplastic syndrome (MDS) and bone marrow failure syndromes (of which myelofibrosis was one). The representative referred this unsolicited request to the medical team to follow up. The consultant asked the representative to arrange an appointment to discuss the GlaxoSmithKline IFR materials. When the representative contacted the consultant's secretary, he/she was asked to email the consultant directly for an appointment. By way of a reminder, the representative referred to the patient as having 'myeloid fibrosis'. The representative met the consultant to discuss an IFR for use of Revolade in chronic ITP, using the approved materials. Only data relating to chronic ITP was discussed. The case details of the patient in question were not discussed.

GlaxoSmithKline had contacted the consultant for corroborating information, but had not received any information to date, but a signed statement from the representative explaining the context of the email was provided.

GlaxoSmithKline therefore submitted that the evidence indicated that the representative did not promote Revolade out of licence.

PANEL RULING

The Panel noted that the subject matter of the email at issue read 'Request for an appointment re an IFr submission for a patient with Myeloid Firosis [*sic*]'. The email referred to a telephone conversation with the consultant's secretary and suggested dates for an appointment to 'discuss putting together the IFR for your patient with Myeloid Fibrosis'. The email in question was sent by the representative to the consultant at the request of his secretary.

The Panel noted the licensed indication for Revolade. The Panel also noted that according to GlaxoSmithKline, the consultant had, after a hospital meeting about Revolade, asked the representative for information about Revolade to support a funding request for a patient with chronic ITP as the patient had myelofibrosis and asked for information about MDS and bone marrow failure syndrome. The representative ensured that the latter request was satisfied via GlaxoSmithKline's medical information function.

The Panel noted that whilst the subsequent meeting discussed an IFR for the use of Revolade in chronic ITP using approved materials, the subject matter of the email in question referred to myeloid fibrosis as the representative had considered that this was the only way to identify the reason for the meeting. The Panel queried whether this was so. In his/her signed statement the representative acknowledged that the email could have been misconstrued and that during the subsequent meeting the consultant had the patient in mind but the representative had stressed that they could only talk about the use of Revolade in chronic ITP.

Whilst the email did not expressly refer to Revolade, it was an integral part of a series of communications about the medicine. The IFR referred to in the subject matter of the email was in relation to Revolade. The Panel considered that whilst there was no evidence that the subsequent meeting was unacceptable in relation to the requirements of the Code, the subject matter of the email in question implied that the IFR related to Revolade and its use in myeloid fibrosis and consequently promoted Revolade outside of its licensed indication as alleged. A breach of Clause 3.2 was ruled.

The Panel considered that the representative should have been mindful of the impression given by the subject matter of the email and noted the representative's acknowledgement that it could have been misconstrued. High standards had not been maintained in this regard by the representative and a breach of Clause 15.2 was ruled. There was no evidence that the company had failed to maintain high standards and the Panel ruled no breach of Clause 9.1 and consequently no breach of Clause 2.

2 Tactical brand plan

The complainant provided a copy of an internal email written in August 2010, from an HHBM, to two GlaxoSmithKline employees, entitled 'Brand Plan Global: Revolade reading only' which reproduced the outputs of the UK brand plan day and attached a copy of the global tactical brand plan.

COMPLAINT

The complainant alleged that, *inter alia*, the tactical brand plan for Revolade led representatives to promote the product for unlicensed indications.

RESPONSE

GlaxoSmithKline submitted that the 'Revolade ITP Annual Brand Plan 2011' was an internal, above-country document which outlined the life cycle strategy for Revolade for 2011 and beyond in Europe, Asia-Pacific, Japan and the emerging markets and was provided as reference material for local operating companies to develop their local brand plan.

This document was for internal planning purposes and was used by the brand planning team to create the UK plan taking the UK marketing authorization and other local requirements into account. The brand planning team consisted of a number of aligned individuals one of whom was also the author of the email in question.

The brand plan was sent as an attachment to two employees as background reading as one employee required information on brand strategy following a period of sick leave. The other employee was copied

in as he/she was the trainer helping the first employee with some refresher training and he/she was new to the brand.

The rest of the email contained brainstorming ideas from an internal meeting set up to create ideas for commercial and marketing activities as well as medical and data generation activities. The only reference to an off-licence indication was the line 'Explore data to cover use in presurgery – off license but reported to the team' under the heading 'KEG' (key evidence generation) which was a medical strategy for clinical trials and data generation.

Neither the global brand plan nor the email contained any information that suggested plans for off-licence promotion.

In addition GlaxoSmithKline provided certified archived materials to show that representatives were comprehensively trained on the Revolade SPC and that all training was consistent with the marketing authorization. In addition, representatives were trained in the company's procedure to deal with unsolicited requests for off-licence information.

In response to a request for further information GlaxoSmithKline confirmed that the employee, who required training, was a member of the HHBM team.

HHBMs were a field based team working in secondary care with senior non-clinical NHS staff; they acted as a link to GlaxoSmithKline as account managers (an explanatory slide set of their role was provided). They were only expected to have a basic knowledge of GlaxoSmithKline medicines. Their conversations were centred on local access to medicines and budget management and they sought insight into the local health economies in relation to GlaxoSmithKline medicines. They had access to representatives and other in-house experts who could be called upon to discuss GlaxoSmithKline medicines and their use. They could also offer additional support to specific brands by having discussions with payer customers.

The email in question contained the outputs/minutes of an internal brand planning meeting. An excerpt from the author's witness statement was reproduced. As the minutes were shared in their entirety, there was reference to the medical affairs part of the brand plan. As stated above, the only reference to off-licence use was the line 'Explore data to cover use in presurgery – off license but reported to the team' under the heading 'KEG' (key evidence generation) which was a medical strategy for clinical trials and data generation. As this off-licence use had been reported to the brand team, the medical department would have to explore further in order to produce medical information responses as well as explore possibilities for data generation in clinical trials. As this was clearly a medical department issue, no further qualification was needed and no follow up with the email recipients would have been necessary.

The author of the email in question stated in his/her witness statement,

> 'I have not received training for off licence use or future indications. I have never seen any literature about this. In the early marketing materials used for in approved Advanced Planning Information in Sept 2009, I think it was generically mentioned under other ongoing trials discussed that there may be more indications/further research, maybe hepatitis, but it was anticipated this would never happen so we were told we shouldn't talk about it.'
>
> 'I never felt asked or encouraged to discuss off licence ... colleagues have never done this.'

GlaxoSmithKline stated that in its follow-up with the trainer who received the email, he/she could not recall the discussions following the email; however he/she had confirmed that any training for individuals would only use approved materials and follow the same format and agenda as for a wider group.

PANEL RULING

The Panel noted that the Revolade tactical brand plan and covering email were provided in response to a request for background brand strategy information from a GlaxoSmithKline trainer to satisfy the training needs of an HHBM. The author of the email in question was an individual who was aligned to the brand planning team.

The covering email explained that the global tactical brand plan was for background use only and that a UK brand plan would be produced subsequently. The email outlined six outputs from a UK brand plan day including 'Clinical Experience and KEG [Key Evidence Generation] Explore data to cover use in presurgery - off license but reported to team'. The Panel noted that it had to consider whether the provision of the global tactical brand plan and covering email to the HHBM (who was not a member of the brand team) encouraged the promotion of Revolade beyond its licence.

According to GlaxoSmithKline HHBMs worked with senior non-clinical NHS staff on local access to medicines and budget management; they were only expected to have a basic knowledge of GlaxoSmithKline medicines. They could offer support to specific brands by having discussions with payer customers. The role of the HHBMs was further described in an internal presentation (UK/PPM/0158/11) as, *inter alia*, driving the 'growth of GlaxoSmithKline brands through excellent account management in secondary care', and at the launch of the product they would 'lead and support the account team to drive rapid uptake of the brand, including plans for formulary inclusion'. Reference was made to subsequent commercialisation. Key contacts for most HHBMs included senior pharmacists.

The Panel noted that the first slide of the Revolade global tactical brand plan made it clear that all materials were subject to local review and approval. The plan discussed the disease, global market access challenges, growth strategies and performance measurement etc. There was no reference to off-licence use. The Panel did not consider that the

provision of the global tactical brand plan to the HHBM was contrary to the Code as alleged; it did not discuss unlicensed use of Revolade and the covering email made it clear that it was provided for background reading only. GlaxoSmithKline had not been asked to respond to Clause 15.9 on this point. The Panel did not consider that there had been a failure to maintain high standards in relation to the content of the global tactical brand and its provision to an HHBM; no breach of Clause 9.1 was ruled.

The Panel noted that the subject of the covering email was 'Brand Plan Global: Revolade reading only: [name]'. A bullet point in the email read 'Explore data to cover use in presurgery – off licence but reported to the team'. GlaxoSmithKline explained that as this off-licence use had been reported to the brand team, its medical department would explore data generation and medical information responses. The Panel considered that the email did not make this clear and without the benefit of GlaxoSmithKline's explanation the bullet point in question was open to misinterpretation by field based staff who did not participate in the meeting. The Panel therefore did not accept GlaxoSmithKline's submission that as it was a medical department issue, no further qualification was needed and no follow up with the email recipients would have been necessary. The outputs of the meeting had been disseminated beyond the UK brand plan team to, *inter alia*, a member of a field based team without the benefit of GlaxoSmithKline's detailed explanation. The covering email, including the subject title, made it clear that the global brand plan was for background only but no such qualification was applied to the outputs of the UK brand planning meeting.

The Panel was concerned about the unqualified reproduction of the outputs from the UK brand meeting in the covering email which referred to the unlicensed use of Revolade and its provision to an HHBM who was not a member of the UK brand planning team. The Panel considered that the dissemination of such material to an HHBM who, *inter alia*, would have product related discussions with payer customers, would have to comply with the Code. The trainer to whom the email was also sent could not recall discussions following the email but had confirmed that approved materials were used for all subsequent training for the HHBM. The Panel noted that GlaxoSmithKline had not been asked to respond in relation to Clause 15.9 which covered representatives' briefing material in relation to this allegation. The Panel considered that the unqualified reference to unlicensed use in the email in question together with its provision to an HHBM who was not a member of the UK brand planning team meant that high standards had not been maintained. A breach of Clause 9.1 was ruled. The Panel did not consider that the circumstances warranted a ruling of a breach of Clause 2 which was used as a sign of particular censure and reserved for such; no breach of Clause 2 was thus ruled.

B Training

1 Seretide product knowledge test

COMPLAINT

The complainant alleged that in November 2011 a team of hospital business managers falsified a Seretide product certification examination. All of the managers sat the product knowledge test at the same time and the answers were read out by a team member as instructed by the team line manager. This deliberate action, following limited training, meant that the hospital business managers were not adequately trained on Seretide when they engaged with customers.

RESPONSE

GlaxoSmithKline stated that the HHBMs were a field based team that worked in secondary care with senior non-clinical NHS staff and acted as a link to GlaxoSmithKline as account managers. They could be involved in advance planning notification, share knowledge of business processes and discuss formularies. They were only expected to have a basic knowledge of GlaxoSmithKline medicines but had access to representatives and other in-house experts who could be called upon to discuss GlaxoSmithKline medicines and their use. They could also offer additional support to specific brands by having discussions with payer customers. When this was required, the HHBMs underwent product training which contained elements of the training programme for representatives, but was not as comprehensive.

Seretide was an important brand for GlaxoSmithKline and due to the changing NHS environment there was the possibility that the HHBMs might have to discuss Seretide with senior managers and payers. The team manager decided that they would benefit from some basic training on the brand. As they were not routinely trained on Seretide one of the team was asked to pull together a programme consisting of a series of online materials, modules, background reading and webinars with experts in the company. To finish the training and consolidate knowledge, a quiz was put together which used questions from the Seretide test for representatives. The quiz took place in November 2011 during a team meeting.

GlaxoSmithKline submitted that as part of its thorough investigation it interviewed, with minimal warning, the five people involved on the day. None of the five signed responses detailing events on the day supported the complainant's allegations that answers were read out or that the quiz was falsified. HHBMs frequently received relevant training on products and account management. In 2011 they received 20 days' training of which 13 days were product training. As they were not product specialists, this training provided them with knowledge above and beyond that required for their role.

Based on the evidence above, GlaxoSmithKline strongly refuted the allegation that the quiz was conducted inappropriately and that the HHBMs were not adequately trained.

FURTHER COMMENTS FROM THE COMPLAINANT

In response to a request for comments on GlaxoSmithKline's response, the complainant provided copies of emails and other documents which he/she considered showed that HHBMs had actively promoted Seretide before they had been trained and undertaken the test. The complainant stated that it was therefore clear that HHBMs had promoted Seretide to NHS colleagues and had been targeted by their manager as shown in the personal development plan (PDP) before they had been formally trained and certified as 'customer safe' in their product test. The complainant considered that this was unacceptable and in breach of the Code as promotion had taken place as shown in documents provided. The complainant confirmed that he/she was in the room on the day and the answers were read out by an HHBM under the guidance of a manager. The complainant was not surprised by the response of fellow colleagues and suggested they were briefed by telephone before the investigation and interviews took place, despite GlaxoSmithKline's response. As the HHBMs had to log in to GlaxoSmithKline's on-line learning platform to undertake the test then GlaxoSmithKline's electronic records would show that all HHBMs were logged on at the same time. In addition, the test results would also show that every HHBM got the price of the dose of Seretide wrong in the test as this was the price that was provided as part of the pre-reading for the test. Indeed further evidence of this would be found in the same email sent by the training department to every HHBM correcting them on the actual price after the test had taken place.

FURTHER COMMENTS FROM GLAXOSMITHKLINE

In response to a request for further information, GlaxoSmithKline reiterated that it believed that both HHBMs and sales representatives received comprehensive and appropriate training and that the depth and breadth of this training was evident from the enclosures provided with its response above. As outlined above, the HHBM role was different from that of a product representative; the training they received reflected this.

The assessment in question was an informal end-of-training quiz, the purpose of which was knowledge consolidation and not knowledge evaluation.

As previously stated, the HHBMs were not product experts and were not expected to have clinical conversations. Representatives' training courses ended in an invigilated examination with a pass mark of 90% to ensure that their knowledge met the high standards required.

If clinical or medicine related conversations were required then HHBMs were able to draw upon appropriately trained representatives to do this.

PANEL RULING

The Panel noted that GlaxoSmithKline had been asked to respond, *inter alia*, in relation to Clause 15.1 of the Code which applied to representatives and in this regard the Panel firstly had to consider whether the HHBMs satisfied the definition of a representative under the Code. GlaxoSmithKline had submitted that HHBMs did not promote medicines. The Code defined a representative in Clause 1.6 as anyone calling on members of the health professions and administrative staff in relation to the promotion of medicines. This was a wide definition and could cover the activities of those employees that companies might not call or consider as representatives.

Clause 1.2 defined promotion as 'any activity undertaken by a pharmaceutical company or with its authority which promoted the prescription, supply, sale or administration of its medicines'.

The Panel noted GlaxoSmithKline's submission that the HHBMs worked with senior non-clinical NHS staff on, *inter alia*, formularies. They could also offer additional support to specific brands by having discussions with senior managers and payers for which they underwent product training as there was a possibility that HHBMs would be required to have discussions with senior managers and payers and the training event in question was designed to satisfy this additional training need in relation to Seretide. The Panel noted that the PDPs provided referred primarily to a facilitation and account mapping role in relation to Seretide.

The Panel examined the HHBM presentation, 'Hospital Healthcare Business Managers – supporting access to medicines', which outlined the HHBM role. Its overall objective was to 'drive the growth of GlaxoSmithKline brands through excellent account management in secondary care'. Pre-launch, launch and post-launch functions were described. Accelerating formulary inclusion and expanding product use; facilitating managed entry and market access were mentioned. The HHBM team had experience in designing and delivering formulary submission business cases to business managers, senior clinicians, commissioners and pharmacists. A slide headed 'Where do we fit into the account team?' listed senior pharmacists and drug and therapeutic committee (DTC)/formulary committee and senior trust directors as amongst the HHBMs' customers.

The Panel noted GlaxoSmithKline's submission that HHBMs could offer additional support to specific brands by having discussions with payer customers. In this regard the Panel also noted that a document provided by the complainant entitled 'The role of the HHBM within the Respiratory Market Access' stated that within specific accounts identified by the area business manager (ABM) the HHBM would proactively raise Seretide to discuss the current situation. The Panel noted the HHBMs' broad role as set out in the papers provided by both parties. The Panel noted the definitions of promotion and representative in the Code as set out above and considered that merely because HHBMs did not interact with prescribers did not mean that such interactions were not promotional as defined in the Code. The Panel considered that a limited aspect of the HHBMs' role was likely to involve discussion of

specific medicines and taking all the circumstances into account, the Panel considered that, in relation to this part of their role, they acted as representatives as set out in the Code.

The Panel noted that the parties' accounts of the training event in November differed. It was difficult to determine precisely what had occurred. The Panel noted that the complainant bore the burden of proving his/her complaint on the balance of probabilities. The complainant alleged that it was not a *bona fide* training event and the answers were read out to participants. GlaxoSmithKline explained that it was a knowledge consolidation event rather than evaluation, at the end of an online product training course. The Panel noted that according to the unsigned witness statements provided by GlaxoSmithKline whilst at least one participant completed the test alone, the majority appeared to have completed the informal test collaboratively, with the benefit of discussion.

The Panel noted that Clause 15.1 required representatives to be given adequate training and have sufficient knowledge to enable them to provide full and accurate information about the medicines which they promoted. The Panel considered that it was acceptable to run informal training sessions to consolidate rather than evaluate participants' product knowledge as described by GlaxoSmithKline. However, the overall training package must satisfy the relevant requirements of the Code. The complaint on this point related solely to the training event at issue. The Panel noted GlaxoSmithKline's submission that further extensive training was provided to HHBMs. The Panel did not consider that the conduct of the training event in question was such that the company had failed to satisfy the broader product training requirements of Clause 15.1 as alleged. No breach of Clause 15.1 was ruled. The company had not failed to maintain high standards in relation to the event; no breach of Clause 9.1 was ruled. The Panel consequently ruled no breach of Clause 2.

2 Product knowledge review

COMPLAINT

The complainant alleged that in November 2011 at GlaxoSmithKline's UK head office, GlaxoSmithKline employees falsified their annual product certification examination to ensure compliance with the Code. The team, directed by a manager, had received from him/her and the team trainer repeated text messages in the preceding weeks which set out the questions and answers within the examination. The team sat the examination at the same time and the answers were read out by a manager. This deliberate action meant that given the nature of their cross portfolio role, the HHBMs were not trained to a standard that allowed them to have accurate discussions with customers.

RESPONSE

GlaxoSmithKline considered that the complainant's reference to an 'annual product certification examination' was to the product knowledge review process used to ensure that representatives continued to have excellent knowledge relevant to the therapy area and products they promoted.

Although HHBMs were not product specialists and did not require formal product knowledge review, in 2011 it was decided to pilot with them this format of knowledge review. Questions for the pilot were selected from a bank of questions used for representatives, including some NHS environment questions. Participants could have three attempts to pass the test with the opportunity to review incorrect answers. A pass mark of 90% or more was required. Some coaching questions were sent by text message in the preceding weeks to indicate the types of questions likely to be asked and provide guidance for revision. The pilot took place in November 2011.

GlaxoSmithKline submitted that in its thorough investigation, it interviewed, with minimal warning, five people involved on the day. These interviews could be considered to be individual responses and indicated that three questions were received by text as prompts, however no answers were provided. In addition, all interviewees refuted the allegation that answers were read out.

GlaxoSmithKline submitted that the HHBMs were adequately trained for their role. The decision to pilot an annual test was part of its drive for the highest possible standards; the learnings from this pilot would be incorporated into a tailored future training plan.

GlaxoSmithKline submitted that it had not discovered any evidence to support any of the allegations and therefore it denied any breach of the Code.

GlaxoSmithKline invested heavily in the training of its employees; there were over 50 people in the commercial training and development team in the UK.

GlaxoSmithKline considered that it took its business very seriously and ensured that employees were equipped to the highest standards to perform their roles whoever they were. GlaxoSmithKline also believed that its culture understood the importance of upholding its high ethical values. A survey in late 2009 showed that the vast majority of employees understood what constituted ethical business practice and conduct in their job; considered that their working environment encouraged ethical behaviour even in the face of pressures to meet business objectives and that leaders in their departments created an atmosphere of trust in which concerns could be raised.

FURTHER COMMENTS FROM THE COMPLAINANT

The complainant refuted GlaxoSmithKline's suggestion that this was a pilot as the entire company was subject to annual product certification and this was not done by HHBMs in the past but as the IHMs had to undertake the test then it was considered that the HHBMs should also be certified in 2011. The complainant had never seen a document saying it was a pilot and did not believe it existed. The questions and answers were produced by GlaxoSmithKline's

head office by an employee who had also selected the questions for the IHMs. This bank of questions was sent to the relevant manager and it was first shown to the HHBMs at a team meeting in September 2011. It was decided at the meeting that a series of questions would be sent by text messages as sending them by email would be suspicious. An HHBM undertook this task and whilst he/she was on annual leave a manager sent texts via the company text system as well. The complainant refuted that just three texts were sent as he/she received far more than that and he/she was sure his/her fellow colleagues did too. The complainant suggested that GlaxoSmithKline provide the telephone records of the HHBM sending the questions by text as this would demonstrate that many more than three texts were sent out and the GlaxoSmithKline text system would also show the manager sent messages via this route. The team undertook the test using the company's on-line learning platform and once again GlaxoSmithKline's electronic records would show that almost everyone scored the same as the answers were read out. However, one HHBM sat a different set of test questions and just passed the test but he/she was helped extensively by the manager and fellow HHBMs after they had finished their test. The complainant submitted that many of the questions in the test, particularly around the NHS, were very difficult and that he/she had never received any formal training on the subject matter examined in this test. The complainant knew that without the answers he/she would not have passed the examination and he/she was sure almost all other HHBMs would have failed had the answers not been read out.

FURTHER COMMENTS FROM GLAXOSMITHKLINE

In response to a request from the Panel for further information, GlaxoSmithKline submitted that the annual review process was piloted with the HHBMs' role for the first time in November 2011. The process had been carried out successfully over a number of years with representatives to test their level of product knowledge. The test was computer based; each individual completed it online whilst in a room together and the results were recorded electronically. The bank of questions was presented to each individual in a random order which meant that at any one time individuals completed different questions from the bank in a different order. There was the opportunity to sit the test three times if the required pass mark was not reached. If a pass was still not achieved, a period 'off the road' and retraining was conducted (frequently asked questions were provided).

The results report from this test showed a range of final scores which suggested that this was not a result of collaboration (a copy was provided). The time taken to complete the tests was also shown; again there was a range. The HHBM who sat a different test had a bespoke set of questions to reflect the regional health economies that he/she covered (a copy was provided).

In addition, the signed witness statements consistently refuted the allegations regarding the conduct of individuals on the day. Any learnings from this pilot would be incorporated when the annual test was officially rolled out. GlaxoSmithKline was confident that it had properly evaluated the knowledge of both the HHBM team and its representatives.

There were 30 questions in total in the bank of sample questions with product questions taken from the much larger bank of questions in the representatives' training programmes. No answers were sent out. The aim of the text was to stimulate individual revision and learning ahead of the annual review amongst a field based team.

GlaxoSmithKline believed that HHBMs were adequately trained for their role. The annual test was piloted as part of the company's drive for the highest possible standards; the learnings from this pilot would be incorporated into a tailored future training plan.

GlaxoSmithKline took its business very seriously and ensured that its employees were equipped to the highest standards to perform their roles, whoever they were. It had a culture that understood the importance of upholding its high ethical values.

FURTHER COMMENTS FROM THE COMPLAINANT

The complainant strongly argued that there was evidence to suggest that the Code had been breached. The complainant also noted that people had been dishonest in their responses to these matters, which was astonishing given that GlaxoSmithKline's electronic records would show this to be the case particularly with regard to the two examinations undertaken in November 2011.

The complainant stated that he/she was present during the tests and the meetings and found it disturbing that GlaxoSmithKline had managed to engineer fictitious responses to these allegations from his/her colleagues. This demonstrated the cover up attitude that existed when GlaxoSmithKline did not like the behaviour of its employees as seen before when other failures had come to light.

PANEL RULING

The Panel noted that the complaint concerned the conduct of the pilot annual product knowledge review which took place in November 2011. The Panel noted its comments above at point B1 about the role and status of HHBMs and considered that they applied here.

The Panel noted that, once again, the parties' accounts differed and it was difficult in such circumstances to determine precisely what had occurred. The Panel noted that the complainant bore the burden of proving his/her complaint on the balance of probabilities.

The Panel noted GlaxoSmithKline's submission that the annual review process was first piloted with the HHBMs in November 2011. The process had been carried out successfully over a number of years with representatives to test their level of product knowledge.

The Panel noted that GlaxoSmithKline had provided a number of unsigned witness statements from HHBMs who took part in the pilot test. All interviewees refuted the allegation that answers were read out as alleged. The witness statement of a manager explained that on the day of the test he/she decided to run it as an open book test with access to online information for participants. Some participants were helped to think about where to look online. The test was described as a knowledge and information seeking test to see how they got on. It was acknowledged that this activity needed to be run differently next time.

The Panel considered that in principle it was acceptable to run pilot training sessions to inform and improve the overall product training package. However, the overall training package should comply with the Code. The complaint on this point related solely to the training event at issue. The Panel noted GlaxoSmithKline's submission that further extensive training was provided to HHBMs. The Panel did not consider that the conduct of the training event in November demonstrated that the company had failed to satisfy the broader product training requirements of Clause 15.1. No breach of Clause 15.1 was ruled. The Panel consequently ruled no breach of Clauses 9.1 and 2.

3 Promotional practice and training

COMPLAINT

The complainant's stated that in his/her view, GlaxoSmithKline's overall product training standards were below that expected by the Code, it was acceptable in some teams and roles to just 'get through' the necessary examinations and this might be a more widespread company issue.

The complainant subsequently submitted further documents about the promotional practices and representatives' training at GlaxoSmithKline. The material mainly concerned the promotion of GlaxoSmithKline's medicines to NHS customers by representatives who had not received formal and certified internal training. The complainant provided emails and PDPs as well as other documents which he/she considered showed that the knowledge of, and support for, this practice was widespread across many roles and levels within GlaxoSmithKline. Some key performance targets for people appeared in their development plans and activities before they were trained on the product. The complainant noted, for example, that the HHBM team were only formally trained on Seretide in November 2011, yet the untrained team actively promoted the product to NHS customers, as encouraged by their line manager and business unit directors, in 2010.

The complainant subsequently provided new documents about the promotion of ReQuip XL using IHMs, although those IHMs had never received any formal training internally. The complainant provided a copy of a presentation by a manager to the Revolade marketing team which he/she found wholly unethical as it was entitled 'Revolade Smashing targets'. The complainant referred to an email from the Revolade marketing team to the representatives that revealed the locations and names of doctors using Revolade under the Named Patient Programme.

In response to a request for comments on GlaxoSmithKline's initial response, the complainant reiterated that the standards of training at GlaxoSmithKline were below standard. He/she could list and provide many more examples of where he/she had been in customer calls with representatives who clearly should not have been allowed to promote medicines as they did not have the necessary knowledge to accurately present product information. The complainant did not consider that it was acceptable or ethical; NHS colleagues expected pharmaceutical company employees engaged in discussions about a medicine to have a minimum standard of training and knowledge to provide evidence based information accurately. The complainant considered it was not sufficient to state that HHBMs only had basic product knowledge. The complainant also considered that a customer having granted an HHBM time for an interaction would think it was unacceptable for that person each time to organise for another representative or other GlaxoSmithKline expert to come back with the answer.

It was also difficult to argue that promotion had not taken place when clearly documents and emails showed people had engaged with customers almost a year before receiving certification, a clear breach of the Code.

The complainant understood why GlaxoSmithKline would wish to refute these allegations as it was a failure on its part in this regard. It must also be particularly difficult when GlaxoSmithKline portrayed itself as conducting business in an ethical manner yet within it things were markedly different to the image portrayed. The complainant stood by his/her complaints.

In addition to the Clauses previously cited, GlaxoSmithKline was also asked to respond in relation to Clause 15.9.

GlaxoSmithKline noted that the complainant had raised further allegations about the promotional practice and training of representatives, the promotion of Seretide, ReQuip XL and Revolade and again, the conduct of a manager. Both the original and the additional complaint had resulted in thorough internal investigations and on this basis GlaxoSmithKline continued to strongly refute these allegations.

GlaxoSmithKline noted that the further allegations from the complainant resulted from two emails; one sent in early February 2012 and one in late February 2012.

FURTHER COMMENTS FROM THE COMPLAINANT

In this email the complainant stated 'The documents attached are mainly concerning the promotion of GSK medicines to NHS customers without those

representatives having received formal and certificated training internally. I enclose emails and PDPs as well as other documents showing that the knowledge of this practice and the support for this practice is widespread across many roles and levels within GSK. Some key performance targets for people appear in their development plans and activities prior to them being trained on the product. It should be noted for example that the HHBM team only received formal training for Seretide in November 2011, yet the team actively engaged with NHS customers in promotion without training as encouraged by their line manager and business unit directors in 2010' [*sic*].

RESPONSE

GlaxoSmithKline stated that it invested heavily in the training of its employees; over 50 people were in its commercial training and development team in the UK. Sales representatives were thoroughly and comprehensively trained on Seretide (the agenda and copies of the training slides were provided). They also underwent an annual product knowledge review to ensure that they had sufficient scientific knowledge to enable them to provide full and accurate information.

The complainant specifically referred to the HHBMs which, as stated above, were a field based, secondary care team which worked with senior non-clinical NHS staff and acted as a link to GlaxoSmithKline as account managers. They were only expected to have a basic knowledge of GlaxoSmithKline medicines but had access to representatives and other in-house experts who could be called upon to discuss GlaxoSmithKline medicines and their use. They could also offer additional support to specific brands by having discussions with payer customers. When this was required, they underwent product training which contained elements of the representatives' training programme but was not as comprehensive. HHBMs were not product specialists and were adequately trained for their role.

In 2011 HHBMs received 20 days' training of which 13 were product training. As they were not product specialists, this training provided them with knowledge above and beyond that required by their role.

GlaxoSmithKline strongly refuted the allegation that representatives did not receive formal training and the evidence showed that representatives underwent a thorough formal training programme for Seretide. GlaxoSmithKline stated that the allegation that employees engaged in promotion without training was unfounded.

A number of materials were provided by the complainant as follows:

1 Email from a manager, April 2011

This email was entitled 'The role of the HHBM within Respiratory Market Access 2011' and had an attachment of the same name.

A manager had written an email to clarify that if, during the course of their work, HHBMs obtained information that was relevant to the Seretide brand, then they would refer this to the appropriate individual within the company. They were informed that they were not to have proactive discussions about this brand and, as discussed above, this email predated the Seretide training for HHBMs that took place later in the year. This was made clear in the email where it stated 'The HHBM will NOT proactively raise Seretide or respiratory with a customer unless this has been specifically contracted between the ABM and the HHBM'.

The attachment to the email supported this and showed that HHBMs could be consulted about market access or facilitate introduction of the appropriate role (eg representative). This was clearly stated in the material provided under point 3 of 'the HHBM role' – 'Following identification of an opportunity or threat the HHBM will facilitate the appropriate intervention eg introduction of IHM/HOC [health outcomes consultant]/TS [sales representative] as required'. In the specific circumstance where an HHBM was contracted to proactively discuss the financial implications of Seretide with a budget holder or payor, a basic knowledge level was required (SPC, preparations and prices) as outlined in the document.

GlaxoSmithKline believed that HHBMs were adequately trained for their role. The email supplied reinforced that for areas out of scope they called on resources and acted as facilitator for appropriate roles in the organisation.

2 A manager's Performance & Development Plan (PDP)

This document outlined performance and behavioural objectives for 2011.

The performance objectives were related to the role of the HHBMs as outlined previously.

The complainant specifically referred to Seretide and the fact that HHBMs did not receive product training until late 2011. It clearly stated in the PDP that Seretide support was 'Mainly focused on providing insight and providing specific support in agreed targeted units'.

Specifically with regard to Seretide, the HHBMs were tasked to provide insight where applicable. As stated above, they were clearly steered not to have proactive conversations about this product, and if there were specific circumstances where they would, they were required to have a minimum level of knowledge and facilitate introduction of the appropriately trained representative.

3 Email about an HHBM meeting

This email outlined the agenda for an HHBM team meeting, in June 2011. The agenda clearly showed a full day business meeting to discuss the business environment and propose training for the team. GlaxoSmithKline submitted that there was nothing in this email to support any of the allegations made.

4 NHS budget email to HHBM team in December 2010

This email had the subject 'BMJ Getting better value from the NHS drug budget – guess what's at the top of the list?' and a copy of the BMJ 2010 article 'Getting better value from the NHS drug budget' was attached and circulated within the team for interest as it mentioned GlaxoSmithKline products. Again, GlaxoSmithKline submitted that there was nothing in this email to support any of the allegations made. Understanding the financial pressures of the NHS was part of the HHBM role.

5 An HHBMs' PDP in February 2011

The complainant had made allegations regarding Seretide. In this draft document, there was only one reference to Seretide under 'other' where the HHBM was tasked with discussing the role the HHBM could play with this brand. There was no instruction for any externally facing interaction.

As discussed previously, the HHBM role with regards to Seretide in 2011 was to understand the environment (field intelligence) and facilitate introductions with appropriate roles (eg sales representative).

6 Email about role of HHBMs

This email outlined a possible role for HHBMs in intelligence gathering about the local health economy, based on an actual example. No promotion of Seretide took place, it was clearly field intelligence. Where further conversations were to be had, the relevant person was clearly outlined as being the person drafted in to have that conversation.

As discussed previously, the HHBM role with regard to Seretide in 2011 was to understand the environment (field intelligence) and facilitate introductions with appropriate roles (eg sales representatives).

7 Presentation about HHBM's manager

The attachment to this email was a slide set presentation by GlaxoSmithKline's HHBM. It outlined the performance and development plan for the HHBM including working alongside the local team for Seretide.

Seretide was not mentioned under 'HHBM Core Role' on slide 3 and under 'Activity Overview' on slide 6 it was stated 'Further trust agenda by facilitating meeting between GGC/Lanarkshire HB med management and GSK business director with a view to scoping JWIs [joint working initiatives] in respiratory'.

This clearly showed the HHBM's involvement as being one of facilitation.

As discussed previously, the HHBM role with regards to Seretide in 2011 was to understand the environment (field intelligence) and facilitate introductions with appropriate roles (eg business director).

GlaxoSmithKline's investigation showed that sales representatives were comprehensively trained on GlaxoSmithKline products and that the HHBM team did not promote Seretide but gathered field intelligence and facilitated introduction of appropriate GlaxoSmithKline employees in 2011. This was consistent throughout the enclosures provided.

8 Requip and IHMs

GlaxoSmithKline noted the complainant's statement 'I have also enclosed some new documents concerning the promotion of Requip XL using IHMs in GSK, despite those IHMs having never received any formal training internally' [*sic*].

GlaxoSmithKline submitted that the IHMs (job description was provided) did not promote ReQuip XL brand. ReQuip XL sales representatives were comprehensively trained (ReQuip XL training programme was provided). Furthermore, HHBMs were trained to undertake associated activities and their training took place on 13/14 April 2011 (HHBM Training 2011).

The email to HHBM from a manager which forwarded an email with the subject 'FW: ReQuip XL 60% Price Reduction – opportunity for IHM involvement?' clearly outlined the request to make use of existing relationships, introductions and local knowledge. This was clear from where it stated 'Would it be possible for us (the 3 Neurology ABMs) to contact some of your IHMs?' and also 'Could we use an IHM's knowledge of/relationship with a prescribing advisor (or equivalent) to facilitate an introduction for one of the 3 Neurology ABMs'. There was no suggestion whatsoever that IHMs should be involved in the promotion of, or indeed any customer interaction with regard to, ReQuip XL.

IHMs had never promoted ReQuip XL. Roles that were involved in promotion of this brand had received thorough and comprehensive training. GlaxoSmithKline included details of the representatives' comprehensive training programme for ReQuip XL.

The email with the subject 'FW: Requip XL generic entrants information; FYI Only not to be shared with customers' had an email trail that mentioned an updated budget impact model for dopamine agonists that was available to appropriate members of the account team. An attachment 'ReQuip XL & generic entry June 2011' was a slide presentation for internal training purposes on generics and the competitive environment with regards to ReQuip.

GlaxoSmithKline stated that it was difficult to determine what allegation this enclosure supported. HHBMs were trained on ReQuip XL in April 2011 and started using the budget impact model with payor customers after this. When the price changed, the budget impact model was updated. Knowledge of the competitive environment with regard to generics was pertinent to the HHBM role.

9 Revolade presentation

The presentation 'Revolade Smashing targets' was an internal presentation to help the head office oncology team understand the importance of appropriately managed market access. If appropriate budgetary information was provided in a timely manner, the local healthcare economies could plan in advance. Thus when small numbers of patients were prescribed new medicines in a locality, the overall picture in the country 'smashes' its commercial targets.

GlaxoSmithKline submitted that the setting business targets for an overall brand plan and its achievement in a commercial environment was not unethical.

10 Named patient programme

Revolade received a marketing authorization in the EU on 11 March 2010.

An email from a trainer forwarded a list of investigators who had accessed Revolade for patients under a named patient programme prior to marketing authorization. This information was not sent to sales representatives but to HHBMs following a funding issue in a hospital for one of these patients. The HHBMs then had to find the budget holders in the hospitals relevant to this list in order to discuss ongoing funding. No confidential patient information was disclosed.

GlaxoSmithKline submitted that its investigations had not discovered any evidence to support allegations made in January and early/late February 2012 and it was therefore confident that no breach of any of the clauses stated had occurred.

GlaxoSmithKline reiterated that it believed that it took the conduct of its business very seriously and ensured that its employees were equipped to the highest standards to perform their roles whoever they were. GlaxoSmithKline also truly believed that its culture understood the importance of upholding its high ethical values. A survey in late 2009, indicated that the vast majority of employees understood what constituted ethical business practice and conduct in their job; considered that their working environment encouraged ethical behaviour even in the face of pressures to meet business objectives and that leaders in their departments created an atmosphere of trust in which concerns could be raised.

PANEL RULING

The Panel noted the extensive documentation provided by both parties. With regard to material provided by the complainant it was not always clear which materials the allegations related to. The complainant referred to both representatives and HHBMs but most of the material supplied by the complainant related to HHBMs. The Panel noted that the complainant had the burden of proving his/her complaint on the balance of probabilities.

The Panel noted GlaxoSmithKline's submission that its representatives were thoroughly and comprehensively trained on Seretide. Training slides and other relevant material were provided. The complainant had provided no material in support of his/her allegation on this point. The Panel considered that on the material before it there was no evidence to demonstrate that GlaxoSmithKline's sales representatives were not given adequate training and sufficient scientific knowledge to enable them to provide full and accurate information about the medicines they promoted. No breach of Clause 15.1 was ruled.

In relation to HHBMs and Seretide, the Panel noted its comments about the role of the HHBMs at point B1 above. The Panel noted the role of the HHBMs with regard to Seretide as described in the document 'The role of the HHBM within Respiratory Market Access' and discussed at point B1 above which referred to specific circumstances where HHBMs were contracted to proactively discuss Seretide. The Panel noted that neither the document nor its covering email limited such discussion to financial implications as stated by GlaxoSmithKline. The document stated that the knowledge level required for HHBMs generally included 'a basic understanding of Seretide to include the SPC, preparations and prices'. The undated document was circulated to HHBMs in April 2011 and the covering email referred to its previous circulation to HHBMs in February 2011.

The Panel noted GlaxoSmithKline's submission at point B1 that when HHBMs had discussions with payer customers to support specific brands, they underwent product training. The Panel noted GlaxoSmithKline's submission that in 2011 HHBMs received 20 days' of training of which 13 were product training which GlaxoSmithKline considered provided them with knowledge above and beyond that required by their role. The Panel noted that the HHBM training for Seretide in 2011 comprised product training on 20 October and 3 November (neither were full days). In addition, the HHBM team did distance learning for Seretide and brand managers delivered updates at HHBM team meetings. The Panel noted GlaxoSmithKline's submission at points B1 and B2 about the need for further training to enable HHBMs to have more detailed discussions. The Panel noted that GlaxoSmithKline had, in effect, acknowledged the need for further training on Seretide. The Panel noted that the complainant bore the burden of proof. The Panel had some concerns about the HHBM Seretide training but did not consider that the complainant had demonstrated on the balance of probabilities that the product training was inadequate given the nature of calls likely to be made; no breach of Clause 15.1 was ruled.

The Panel noted the allegation that IHMs promoted ReQuip XL without any formal training. GlaxoSmithKline had responded to this point in relation to, *inter alia*, sales representatives and ReQuip XL but the Panel did not consider that it had an allegation on this point in relation to sales representatives and thus made no ruling on this matter. The Panel noted that the job template for the IHMs described their key responsibility as, *inter alia*, leading the production and implementation of locality account plans to deliver commercial objectives via managed entry, market access and

service development/implementation to ensure an optimum environment for the uptake of GlaxoSmithKline medicines both current and future. IHMs reported into the business manager. GlaxoSmithKline submitted that the IHMs had never promoted ReQuip XL.

The Panel did not consider that the material provided by the complainant in relation to IHMs and ReQuip XL demonstrated that they had any promotional role in relation to ReQuip XL as alleged. An email to the HHBM team in January 2011 merely referred to IHMs facilitating introductions for an HHBM. The complainant had not established that the IHMs had any promotional role in relation to ReQuip XL and thus there was no requirement that they be trained on it; no breach of Clause 15.1 was ruled.

The Panel noted that the purpose of the internal presentation to the Revolade head office team entitled 'Smashing targets' was to help the team understand the importance of managed market access and the effect on national targets of small local brand achievements. The Panel did not consider that the title 'Smashing targets' was unethical given the audience and content; no breach of Clause 9.1 was ruled.

In relation to the email in May 2010 which discussed the names and locations of investigators who had used Revolade under the named patient programme, the Panel noted that it was sent to HHBMs rather than to sales representatives as stated by the complainant. Revolade received its marketing authorization on 11 March 2010. No confidential patient data was disclosed. A funding issue had arisen and thus the HHBMs were to discuss ongoing funding with budget holders at the relevant hospitals. The complainant had referred to this email but did not state why it was unacceptable under the Code. The Panel noted that the complainant had not established that the email in question was unacceptable and thus ruled no breach of Clause 15.9 of the Code.

The Panel noted that it had asked GlaxoSmithKline to respond to Clause 2 on this point and noting its no breach rulings above consequently ruled no breach of Clause 2.

Complaint received **25 January 2012**

Case completed **6 September 2012**