CASE AUTH/2649/10/13

VOLUNTARY ADMISSION BY GLAXOSMITHKLINE

Retrospective certification of joint working project

GlaxoSmithKline voluntarily admitted that materials relating to a joint working project were certified after the project had started.

As Paragraph 5.6 of the Constitution and Procedure required the Director to treat a voluntary admission as a complaint, the matter was taken up with GlaxoSmithKline.

GlaxoSmithKline explained that an ongoing disciplinary process had revealed that material relating to a joint working project, which was due to run from October 2011 to October 2012, was not certified before use. When this oversight was noted in May 2012 corrective action was taken immediately and the materials were certified. GlaxoSmithKline submitted that lack of certification at the proper time was an administrative error by an ex-employee.

The detailed response from GlaxoSmithKline is given below.

The Panel noted that the Code required that material prepared in relation to joint working between the NHS and the pharmaceutical industry be certified before use in its final form, to which no subsequent amendments would be made, by two persons, one of whom must be a registered medical practitioner.

The Panel noted that the joint working project at issue was due to run from October 2011 to October 2012. Relevant materials, however, were not certified until May/June 2012, 7-8 months in to the 12 month project. The joint working project had commenced and the material had been used before it had been certified. A breach of the Code was ruled as acknowledged by GlaxoSmithKline. The Panel considered that the material was not covered by the certification requirements for promotional material and no breach of the Code was ruled in that regard.

The Panel noted the importance of certification and its role in underpinning the self-regulatory compliance system. The Panel considered that as material which should have been certified had been used before final sign-off, high standards had not been maintained. A breach of the Code was ruled.

The Panel noted GlaxoSmithKline's submission that the lack of sign-off was an isolated incident, due to one person's action rather than due to lack of process. The Panel noted, however, that although the individual in question had inexplicably cancelled the job within Zinc, the joint working project had nonetheless gone ahead. In the Panel's view this should not have been possible. The Panel noted GlaxoSmithKline's submission that because the job had been cancelled in Zinc, the executive summary had not been made publicly available before the project started. In the Panel's view, the requirement to publish the executive summary before the arrangements were implemented, as required by the Code, should have prompted an investigation into the matter at the outset. The lack of certification however, was not noted until May 2012 and although materials were certified retrospectively, senior managers were not informed that company process had not been followed. The matter only came to senior managers' attention in connection with another matter.

The Panel noted that the joint working project at issue involved one particular NHS area working in partnership with GlaxoSmithKline to improve local chronic obstructive pulmonary disease (COPD) healthcare. That the project went ahead without key documents being certified was unacceptable. Given the direct impact that joint working projects must have on patient care, all parties to a joint working agreement must be sure that the arrangements had been robustly scrutinised and signed off at the highest level before implementation. The Panel noted its comments above about the importance of certification and considered that an approval system which could be circumvented such as to allow a joint working project with the NHS to proceed with uncertified materials brought discredit upon, and reduced confidence in the pharmaceutical industry. A breach of Clause 2 was ruled which was appealed.

The Appeal Board noted that this case had arisen from a voluntary admission and GlaxoSmithKline's submission that since this matter had come to light the company had improved its compliance procedures to ensure that such issues could not arise in future. The Appeal Board also noted GlaxoSmithKline's submission that a review of all of its other joint working projects had not revealed any problems similar to those that had occurred with the project at issue in this case.

The Appeal Board noted from the Zinc route map that the head office employee responsible for ensuring that the joint working project at issue was certified, had not completed the certification process. The employee had received the job bag in Zinc, after it had been initially reviewed by a number of people, in September 2011 but did nothing with it until February 2012 when the employee cancelled it for reasons unknown. This individual had left GlaxoSmithKline. In the meantime, the project started in October 2011. The procedure within GlaxoSmithKline at the time, which allowed such projects to start, was that the responsible head office employee would inform the responsible field based employee that the project was certified; no documentation of this exchange was required. (The field based employee had no access to Zinc to check that certification was indeed complete).

Once informed by his/her head office colleague that certification was complete, the field based employee could draw down funds to start the project, which he/she was able to do, albeit in the absence of certification, in this case.

The Appeal Board noted from GlaxoSmithKline at the appeal that as a result of a company reorganisation, an internal audit had discovered that the joint working project had not been certified; materials were thus retrospectively certified in May and June 2012. The Appeal Board was very concerned that, given their key role in compliance, none of the three signatories involved immediately reported the retrospective approval to senior colleagues. In the Appeal Board's view, this lack of action by the signatories compounded the original error. The Appeal Board noted that only when the lack of prior certification of the project arose in mid October 2013 as a result of another matter, did GlaxoSmithKline make a voluntary admission to the PMCPA.

The Appeal Board considered that joint working arrangements with the NHS and pharmaceutical companies were complex and would directly affect patient care. Companies must have robust processes to ensure that such arrangements complied with the Code and were certified before projects started. The Appeal Board did not consider the appropriateness *per se* of the project at issue which appeared to benefit COPD patients. That this project went ahead without prior certification of the arrangements was completely unsatisfactory. The Appeal Board considered that, at the time, GlaxoSmithKline's compliance procedures, financial controls and structural relationships between head office and the field regarding joint working projects were wholly inadequate.

The Appeal Board considered that by not certifying the joint working project before it started, and its subsequent failings in its compliance procedures, GlaxoSmithKline had brought discredit upon, and reduced confidence in, the pharmaceutical industry. The Appeal Board thus upheld the Panel's ruling of a breach of Clause 2. The appeal on this point was unsuccessful.

GlaxoSmithKline voluntarily admitted that materials relating to a joint working project were certified after the project had started.

As Paragraph 5.6 of the Constitution and Procedure required the Director to treat a voluntary admission as a complaint, the matter was taken up with GlaxoSmithKline.

VOLUNTARY ADMISSION

GlaxoSmithKline explained that as a result of an ongoing disciplinary process it was noted that a joint working project between GlaxoSmithKline and the NHS in a named area had been certified after the project had started. The job bag retrieved from the Zinc system showed that it had been certified retrospectively, including the 'child' job which contained the executive summary. An associated file note indicated that the retrospective certification was due to a 'colleague misunderstanding'.

GlaxoSmithKline explained that the Zinc route map showed that the job was initiated by the business owner on 4 August 2011, reviewed by a number of colleagues and passed back to the business owner in August 2011. A certification cycle was started on 22 September 2011 by the business owner and the job was back with him (uncertified) on 27 September. The job then remained with the business owner with no further action until 29 February 2012 when he cancelled it. The job was reactivated by a Zinc administrator on 3 May 2012 and delegated to another member of the team who initiated the certification round and the job was certified by the medical advisor and business unit director on 15 May 2012.

GlaxoSmithKline explained that the certification oversight was noticed during a mini-audit of joint working projects during the final stages of a major reorganisation of GlaxoSmithKline in the UK. Corrective action was applied immediately. This was supported by the audit trail which showed that the new business owner took control of the job in Zinc and progressed it to certification and ensured that an executive summary was posted on the company's external-facing website.

GlaxoSmithKline stated that because the original business owner was no longer employed by the company, it was unable to further investigate the circumstances which led him to act in a way that was inconsistent with company expectations.

GlaxoSmithKline submitted that independent of this issue and as part of the reorganisation referred to above, a revised joint working project had been developed and had been in place since September 2012 based primarily on the ABPI joint working roadmap. All active joint working projects were now reviewed for compliance with mandatory reporting requirements on a monthly basis.

GlaxoSmithKline submitted that this was an administrative error on the behalf of an ex-employee. Whilst this was no excuse for the error, the company was confident that this was an isolated incident. GlaxoSmithKline took its obligations for compliance with the Code seriously and was committed to ensuring that all staff were appropriately trained and acted in compliance with the Code.

When writing to GlaxoSmithKline, the Authority asked it to respond to Clauses 2, 9.1, 14.1 and 14.3 of the Code.

RESPONSE

GlaxoSmithKline accepted that the joint working project in question was not certified in advance as required by Clause 14.3. However, as soon as the omission was noticed, the material was certified by senior medical and commercial personnel as required by Clause 14.1.

Since the executive summary of a joint working project was a dependent document of the main project it was therefore also impossible for this to have been certified in accordance with Clause 14.3 and the executive summary itself was not publicly available before the arrangements of the project

were implemented. The executive summary was certified on 29 June 2012.

The audit map of the project in Zinc clearly showed that the individual in question took the irregular step of cancelling the certification process for the project on 29 February. Importantly, it was an internal audit that identified that the project had not been certified before it started. Immediate steps were taken to rectify the issue; certification responsibility for the business case was delegated to another employee on 3 May 2012 and certification was completed 12 days later. At this stage the matter and the remedial actions taken should have been notified to senior management as being out of process. GlaxoSmithKline regretted that this did not occur and it was only early in October 2013 that this shortcoming was noticed in connection with another matter and immediately brought to the attention of senior management. The individual had since left the company.

GlaxoSmithKline expected its employees to comply with the Code, laws and regulations, the GlaxoSmithKline code of practice and policies and maintain high standards at all times. It appeared that the individual in question had deliberately acted in a way that was inconsistent with the company's expectations for reasons unknown.

However, once the problem was identified corrective action was immediately taken to ensure that the required standards were met.

Subsequent to, and independent of, the post-hoc certification of the joint working activity, GlaxoSmithKline had substantially reorganised its UK structure which required the development and training of a revised joint working process. This process, based on the ABPI joint working roadmap, had been in place since September 2012. All active joint working projects were reviewed for compliance with mandatory reporting requirements on a monthly basis.

GlaxoSmithKline considered that the process it currently operated, which was different to that which was in operation at the time of this event, greatly reduced the likelihood of any further such event occurring.

GlaxoSmithKline always strove to maintain high standards as required by Clause 9.1 and in this instance the company considered that the root cause of the problem was not a lack of process but a breach by an individual. GlaxoSmithKline did not consider that a breach of Clause 9.1 was warranted as the company took relevant action to correct the issue as soon as it became apparent.

GlaxoSmithKline stated that it was committed to open and transparent behaviour.

As set out above, the company had identified that the cause of this event was an individual whose actions were inconsistent with the company's expectations. A senior manager was made aware of the issue and took immediate and appropriate action to ensure it was investigated which resulted in the voluntary admission.

GlaxoSmithKline regretted that a breach of the Code had occurred, however it strongly considered that it had acted quickly and transparently to bring this to the attention of the PMCPA. As such, the company did not believe that it had brought the industry into disrepute.

PANEL RULING

The Panel noted that Clause 14.1 required that promotional material must not be issued unless its final form, to which no subsequent amendments would be made, had been certified by two persons on behalf of the company. One of the two persons must be a registered medical practitioner or a UK registered pharmacist. Clause 14.3 required other material to be similarly certified, including material prepared in relation to joint working between the NHS and the pharmaceutical industry. Material referred to in Clause 14.3 must be certified by two persons, one of whom must be a registered medical practitioner.

The Panel noted that the joint working project at issue was due to run from October 2011 to October 2012. The business case and the executive summary, however, were not certified until May and June 2012 respectively, 7-8 months in to the 12 month project. The joint working project had commenced and the material had been used before it had been certified. A breach of Clause 14.3 was ruled as acknowledged by GlaxoSmithKline. The Panel considered that as the material at issue was not promotional, it was not covered by the certification requirements of Clause 14.1. No breach of that clause was ruled.

The Panel noted the importance of certification and its role in underpinning the self-regulatory compliance system. The Panel considered that as material which should have been certified had been used before final sign-off, high standards had not been maintained. A breach of Clause 9.1 was ruled.

The Panel noted GlaxoSmithKline's submission that the lack of sign-off was an isolated incident, due to one person's action rather than due to lack of process. The Panel noted, however, that although the individual in question had inexplicably cancelled the job within Zinc, the joint working project had nonetheless gone ahead. In the Panel's view this should not have been possible. The Panel noted GlaxoSmithKline's submission that because the job had been cancelled in Zinc, the executive summary had not been made publicly available before the project started. In the Panel's view, the requirement to publish the executive summary before the arrangements were implemented, as required by Clause 18.5, should have prompted an investigation into the matter at the outset. The lack of certification however, was not noted until May 2012 and although materials were certified retrospectively, senior managers were not informed that company process had not been followed. The matter only came to senior managers' attention in connection with another matter.

The Panel noted that the joint working project at issue involved NHS organisations in one particular area working in partnership with GlaxoSmithKline to improve local chronic obstructive pulmonary disease (COPD) healthcare. The project had an overall goal of reducing hospital admissions and outpatient referrals. The business case for the project stated that GlaxoSmithKline would fund and implement the delivery of automated patient audit tools in 27 practices. That the project went ahead without key documents being certified was unacceptable. Given the direct impact that joint working projects must have on patient care, all parties to a joint working agreement must be sure that the arrangements had been robustly scrutinised and signed off at the highest level before implementation. The Panel noted its comments above about the importance of certification to the self-regulatory system and considered that an approval system which could be circumvented such as to allow a joint working project with the NHS to proceed with uncertified materials brought discredit upon, and reduced confidence in the pharmaceutical industry. A breach of Clause 2 was ruled.

APPEAL FROM GLAXOSMITHKLINE

GlaxoSmithKline strongly submitted that a breach of Clause 2 was a disproportionate sanction given that this was a voluntary admission about an administrative error discovered via internal processes and checks. The importance of good governance and high standards had been acknowledged from the outset and GlaxoSmithKline had outlined steps for continually improving its systems. Finally, the joint working project itself was considered appropriate and had been reviewed by appropriate GlaxoSmithKline and NHS staff before it started.

GlaxoSmithKline submitted that it took its responsibilities under the Code extremely seriously and in order to maintain confidence in the industry from patients, the NHS and the general public it considered voluntary admission to be a key aspect of self-regulation.

GlaxoSmithKline submitted that in this case it was a gross oversimplification to equate failure to certify the activity in advance with circumvention of the approval process. The project had been reviewed through the Zinc system which meant that its components had been scrutinised and commented on. The project had not been marked as rejected which indicated that the reviewers were satisfied that it was fit to proceed towards certification with minor amends. The comments from the reviewers at this stage did not materially affect the nature of the proposed work.

GlaxoSmithKline submitted that the last step of certification clearly did not happen although, as stated above, this was for reasons unknown as the business owner responsible no longer worked for the company.

GlaxoSmithKline submitted that it had identified the problem internally and immediately rectified the situation. Subsequently, and before it made its voluntary admission, GlaxoSmithKline had implemented a revised approach to joint working which followed the ABPI joint working roadmap published at around the time that this issue occurred.

In addition, as a result of its ongoing review of this matter, GlaxoSmithKline had introduced a further safeguard to the physical joint working agreement template such that it had to be countersigned by one of the certifying signatories before it could be signed by the NHS to initiate the project.

In conclusion, GlaxoSmithKline submitted that the Panel's ruling of a breach of Clause 2 was disproportionate given that the company's response should have retained or improved confidence in the pharmaceutical industry, and the robustness of voluntary admission within a self regulatory framework.

APPEAL BOARD RULING

The Appeal Board noted the Panel's comments regarding the importance of certification to the self-regulatory system and its subsequent rulings of breaches of Clauses 14.3 and 9.1 of the Code which GlaxoSmithKline had accepted.

The Appeal Board noted that this case had arisen from a voluntary admission and GlaxoSmithKline's submission that since this matter had come to light the company had improved its compliance procedures to ensure that such issues could not arise in future. The Appeal Board also noted from the GlaxoSmithKline representatives at the appeal that a review of all of its other joint working projects had not revealed any problems similar to those that had occurred with the project at issue in this case.

The Appeal Board noted that it had to consider the actions of GlaxoSmithKline employees between August 2011 and May 2012. Although noting the passage of time and that a key individual had left the company, the Appeal Board was very concerned that the GlaxoSmithKline representatives at the appeal were unable to answer a number of questions. One of the representatives had only assumed responsibility for the matter after the event and the field-based employee who signed the contract between GlaxoSmithKline and the NHS, and who should have known a lot about how the project had evolved, was not present.

The Appeal Board noted from the Zinc route map that the head office employee responsible for ensuring that the joint working project at issue was certified, had not completed the certification process. The employee had received the job bag in Zinc, after it had been initially reviewed by a number of people, in September 2011 and instead of submitting it for final certification, had done nothing with it until February 2012 when he cancelled it. The reasons for the employee's actions were unknown. This individual had left GlaxoSmithKline. In the meantime, the project started in October 2011. The procedure within GlaxoSmithKline at the time, which allowed such projects to start, was that the responsible head office employee would inform the responsible field based employee that the project was certified; no documentation of this exchange was required. (The field based employee had no access to Zinc to check that certification was indeed complete). Once informed by his/her head office colleague that certification was complete, the field based employee could draw down funds against a field based budget to start the project,

which he/she was able to do, albeit in the absence of certification, in this case.

The Appeal Board noted from GlaxoSmithKline at the appeal that as a result of a company reorganisation, an internal audit had discovered that the joint working project had not been certified; the business case was thus retrospectively certified in May 2012 and the executive summary in June 2012. The Appeal Board was very concerned that, given their key role in compliance, none of the three signatories involved immediately reported the retrospective approval to senior colleagues. In the Appeal Board's view, this lack of action by the signatories compounded the original error. The Appeal Board noted that only when the lack of prior certification of the project arose in mid October 2013 as a result of another matter, did GlaxoSmithKline make a voluntary admission to the PMCPA in late October 2013.

The Appeal Board considered that joint working arrangements with the NHS and pharmaceutical companies were complex and would directly affect patient care. Companies must have robust processes to ensure that such arrangements complied with the Code and were certified before projects started. The Appeal Board did not consider the appropriateness *per se* of the project at issue which appeared to be beneficial to patients with an overall goal of reducing hospital admissions and outpatient referrals for COPD. That this project went ahead without prior certification of the arrangements was completely unsatisfactory. The Appeal Board considered that, at the time, GlaxoSmithKline's compliance procedures, financial controls and structural relationships between head office and the field regarding joint working projects were wholly inadequate.

The Appeal Board considered that by not certifying the joint working project before it started, and its subsequent failings in its compliance procedures, GlaxoSmithKline had brought discredit upon, and reduced confidence in, the pharmaceutical industry. The Appeal Board thus upheld the Panel's ruling of a breach of Clause 2. The appeal on this point was unsuccessful.

Voluntary admission made	**31 October 2013**
Case completed	**8 January 2014**