ANONYMOUS v GLAXOSMITHKLINE

Patient outcomes and information service

An anonymous and non-contactable complainant enquired whether the patient outcomes and information service (POINTS) offered by GlaxoSmithKline was within the Code. There was a complex authorization form. Did people really know what they were signing? The complainant thought that it had to be signed for each report. Why had some PCTs banned it? Was GlaxoSmithKline being honest with its staff and customers? It looked like a monitoring tool for the representative. How could users be sure that the data were not seen by their local Seretide representatives? The person offering the service was the Seretide representative last year. They had had a nurse in previous years. Where had she gone? The complainant refused the service and other support had disappeared (spirometry training and staff training to run reports).

The detailed response from GlaxoSmithKline is given below.

The Panel noted that explanatory notes which accompanied the POINTS authorization form stated that the service would be provided on the understanding that the participating doctor agreed that it was in the best medical interests of patients and that the doctor would retain complete control of the service at all times. It was further stated that the provision of POINTS was separate from the prescription, supply, administration, recommendation or promotion of specific medicines and all written material provided in association with the service would be non-promotional. The explanatory notes also stated no individual would be identifiable from the data sent from the practice. There was no evidence that POINTS was a monitoring tool for Seretide representatives or that data was seen by Seretide representatives as alleged.

The Panel considered that the roles of the GlaxoSmithKline promotional staff and non-promotional Respiratory Care Associates (RCAs) appeared to be clearly separated. When the representatives promoted medicines they did not discuss individual services although they might introduce the local RCA to the practice. None of the RCA activities nor other GlaxoSmithKline activities were contingent upon the uptake of POINTS.

The Panel considered that much would depend on the practice which had control of the process. It did not appear to the Panel that the arrangements were in general unacceptable.

The Panel noted that some PCTs had refused the POINTS service, not because of the service *per se*, but due either to incompatibility of software or to local IT policies.

The complainant had provided no evidence to show that a refusal to accept the POINTS service had led to other GlaxoSmithKline-sponsored support being withdrawn. The Panel noted that the complainant's anonymity would not have allowed GlaxoSmithKline to investigate this allegation further. The Panel noted GlaxoSmithKline's submission that practices which declined to participate in POINTS continued to be eligible for all other services from GlaxoSmithKline.

Overall the Panel considered that the service offered was not unacceptable; it would enhance patient care. The provision of the service was not linked to the prescription of any specific medicine. The decision of what to prescribe lay with the patient's doctor. The Panel did not consider that the service was an inducement to prescribe, supply, administer, recommend or buy any medicine. No breach of the Code was ruled.

An anonymous and non-contactable complainant complained about the patient outcomes and information service (POINTS) offered by GlaxoSmithKline UK Ltd.

COMPLAINT

The complainant enquired whether POINTS was within the Code.

There was a complex authorization form. Did people really know what they were signing? The complainant thought that it had to be signed for each report.

A primary care trust (PCT) in the South East and other PCTs around the county had banned it. Why? The representative looked most uncomfortable when asked. Was GlaxoSmithKline being honest with its staff and customers?

It looked like a monitoring tool for the representative. How could users be sure that the data were not seen by their local Seretide representatives? Indeed the person offering the service was the Seretide representative last year. They had had a nurse in previous years. Where had she gone?

The complainant refused the service and other support had disappeared (spirometry training and staff training to run reports).

When writing to GlaxoSmithKline, the Authority asked it to respond in relation to Clauses 2, 9.1, 18.1 and 18.4 of the 2006 Code.

RESPONSE

GlaxoSmithKline regretted that a health professional was concerned about POINTS and felt confused or uncomfortable about it. GlaxoSmithKline believed POINTS was a valuable service to patients and the NHS and that it was in keeping with both the letter and the spirit of the Code; specifically the company denied a breach of Clauses 2, 9.1, 18.1 or 18.4.

Overview

POINTS was a software based audit tool provided in the interests of patients and the NHS. It aimed to improve the standards of care for COPD patients in areas with a higher than average disease burden and it was consistent with national guideline recommendations. POINTS was sponsored by GlaxoSmithKline and provided as a service to medicine by its Respiratory Care Associates (RCAs), an entirely non-promotional team. A third party was involved in the set-up and running of the service.

Rationale for POINTS

Patients with complex long-term progressive conditions, such as COPD, benefited from regular structured review as part of their long-term management.

Audit was a well established and encouraged method of assessing practice performance in relation to local or national guidance, and allowed practices to identify areas where there was scope for improvement on the existing standard of care. POINTS was an audit tool which allowed practices to do this and could be tailored to meet practice needs; furthermore it allowed 're-audit' so that the impact of interventions made within the practice could be evaluated.

The National Institute for Health and Clinical Excellence (NICE) guidelines for the management of COPD (2004), recommended that 'health care commissioning organisations consider using patient-centred audit intermittently, to investigate the totality of services and identify particular areas that needed further development'.

POINTS

POINTS was a software package which provided an automated audit and analysis of practice records. The software had been developed by an independent computer software company. A third party installed the POINTS software and analysed the data to produce practice specific reports.

<u>POINTS contract</u>

- The contract for the service was held between the practice, a third party and GlaxoSmithKline and clearly outlined the responsibilities of all parties involved and covered important information including data protection; as a result it was a detailed and complex legal document. The most important function of the contract was to ensure that patients' interests were protected.

<u>POINTS software</u>

- If a practice chose to use POINTS, the software was installed, usually remotely onto the practice computer system. If the practice computer did not allow remote installation, then a technician would visit the practice and upload the software manually.

<u>POINTS reports</u>

- A baseline report was generated when the POINTS software was installed. This enabled the practice to assess the demographics and management of its COPD population, and to identify areas where there was inadequate data collection. The data included in the report were consistent with the NICE COPD guidelines.

- The baseline report was prepared by the third party and sent to the RCA. The RCA delivered the report to the practice and provided support in interpreting the report and the significance of any findings. Data which could identify individual patients were not included in the report.

- Further reports were generated in a similar fashion. Practices could decide the interval between reports and the period over which the audit tool was available. These reports were compared to the baseline report enabling the practice to assess the impact of measures which it had created and chosen to implement. Interpretation of reports could be complex; the RCA remained available to support the practices at this stage. As of 1 September 2008 a new contract (authorization form) was produced for each report generated.

<u>Patient confidentiality</u>

- The data sent to GlaxoSmithKline and the third party did not contain named patient or patient identifiable information. Identifiable patient information was held only on the practice computer systems. It was made clear to practices and to RCAs that patient identifiable information was not to be seen by GlaxoSmithKline staff at any time.

Respiratory Care Associates (RCAs)

POINTS was only offered by RCAs.

- RCAs were non-promotional representatives who delivered education and services to improve the care of COPD patients. They did not undertake any promotional activities. They were provided with separate materials, training, and objectives to the promotional representatives. RCAs had specific managers who did not manage the promotional representatives. RCAs were not remunerated on and did not participate in a bonus scheme which was based upon the sales of a single medicine, brand or therapy area. The service was separate from the prescription, supply, administration, recommendation or promotion of specific medicines and RCA materials did not bear the name of any medicine.

- Support which the RCA could offer to a practice included:

  • Hospital episode statistics reports
  • Educational input (workshops and support for diploma qualifications)
  • Protocol development (including anonymised patient notes review)
  • Patient review (including clinic support and screening services)
  • Audit (POINTS)

The RCA team focussed on areas where maximum patient and practice benefit would be achieved. Therefore practices with higher than average COPD prevalence or list sizes were targeted. A briefing document, sent to all RCA managers on 12 August 2008, which explained how to use the current 'Targeting and Segmentation' spreadsheet was provided. GlaxoSmithKline also offered to provide the spreadsheet database of practices should the Authority wish to review it.

- Practices were not targeted on market share or prescribing of GlaxoSmithKline medicines or indeed any other medicines. Activities that RCAs undertook were educational and services to medicine, as such other practices were entitled to request RCA services if they considered that they would improve the existing level of care at their practice.

- The local RCA might be introduced to a practice by the promotional representative, however the promotional representative did not discuss individual services that the RCA could provide. The promotional representative was not present whilst these services were discussed or delivered.

- RCAs underwent comprehensive training on appropriate communication between promotional and non-promotional representatives. This policy applied to all working relationships including, but not limited to, POINTS. Specifically, RCAs were briefed that they *'must not share information about individual customers' prescribing habits or beliefs'*.

- The RCA support to the practice was intended to help improve patient care. The RCA would also upskill the practice through education and tools such as POINTS, to help ensure that these benefits could be maintained. RCA services were provided for a period of time appropriate for the needs of the practice.

<u>Training of RCAs relevant to POINTS</u>

All RCAs received annual accredited therapy area training from independent educational bodies (Educational for Health and Respiratory Education UK) and had, or were working towards, diploma modules in COPD. All RCAs were trained on the provision of education, goods and services by the pharmaceutical industry.

Copies of the RCA training materials, briefing materials and materials to be used with practices were provided.

Provision of POINTS to a practice

Promotional teams were not provided with training or materials regarding POINTS. Promotional representatives did not offer POINTS. As a result, if a customer asked a promotional representative about POINTS the local RCA would answer the enquiry.

The RCAs had a number of services and educational materials which they could offer to enhance the management of COPD. The support they offered was tailored to the needs of the individual practice. POINTS might not be appropriate in a practice whose development needs were primarily educational.

None of the RCA activities were contingent upon the uptake of another service unless they were directly linked (for example training on POINTS reports would be inappropriate in a practice that was not using POINTS). Similarly, other GlaxoSmithKline activities were not contingent upon the uptake of POINTS.

POINTS was provided on the understanding that the practice considered that it was in the best medical interest of the patients; the practice retained full control of the service at all times.

POINTS might not be accepted by a practice or a PCT for a number of reasons such as a lack of computer facilities at the practice, POINTS software being incompatible with existing software or inadequate staffing resource. Similarly a practice which already had audit facilities was unlikely to benefit from POINTS.

Some PCTs had a policy that prohibited individual practices downloading 'non-PCT-approved'

software, or in some cases, working with the pharmaceutical industry on such activities. In these instances GlaxoSmithKline did not provide POINTS.

Summary

POINTS was an audit tool provided in the interests of patients and the NHS. It aimed to improve the standards of care for COPD patients in areas with a higher than average disease burden and it was consistent with national guidelines.

As evidenced by the supporting documentation, the service was not an inducement to prescribe, supply, administer or recommend any medicine. It did not bear the name of any medicine. The RCAs were comprehensively trained in COPD, POINTS and the appropriate provision of non-promotional services.

GlaxoSmithKline believed that the service complied with both the letter and the spirit of the Code; specifically it did not consider that it was in breach of Clauses 2, 9.1, 18.1 or 18.4.

In response to a request for further information, GlaxoSmithKline noted that it had been asked to respond specifically to the complainant's comments '… that a PCT in the South East and other PCT's around the country had banned POINTS'. GlaxoSmithKline stated that it was unclear what 'banned' referred to in this context as, to its knowledge, no PCT had banned POINTS due to a perceived problem with the service. GlaxoSmithKline did not record why any individual practices declined POINTS and would not expect RCAs to probe around the reasons behind such a decision.

POINTS software was compatible with the majority of practice systems but not all. If the software in a region was not compatible then the PCT might advise its practices not to install third party software and this was what had happened in the PCT named by the complainant. GlaxoSmithKline submitted that this did not represent a 'ban' of POINTS, but reflected the fact that software systems were simply not compatible. Similarly other areas had specific IT policies to restrict the type of software installed on a practice computer or the method of installation. It was not always possible to provide POINTS in a way which would meet local policies but, as above, GlaxoSmithKline did not consider that this represented a ban on POINTS.

The POINTS audit tool had been successfully used in over 1,350 practices. Whilst there had been occasional technical challenges setting up the software in an individual practice, GlaxoSmithKline had never had a complaint about the quality or the running of the service. No practice or PCT had stopped using POINTS as a result of being dissatisfied.

In relation to the availability of GlaxoSmithKline services to practices that declined participation in POINTS, GlaxoSmithKline stated that practices which declined to participate in POINTS continued to be eligible for all other services from GlaxoSmithKline.

PANEL RULING

The Panel noted that the complainant appeared generally unhappy about the arrangements for the POINTS service. The complainant was critical of the complexity of the authorization form and suggested that POINTS was a monitoring tool for representatives. The fact that some PCTs had 'banned' POINTS was noted and it was implied that a refusal to accept the POINTS service would lead to other GlaxoSmithKline-sponsored support being withdrawn.

The Panel noted that explanatory notes which accompanied the POINTS authorization form stated that the service would be provided on the understanding that the participating doctor agreed that it was in the best medical interests of patients and that the doctor would retain complete control of the service at all times. It was further stated that the provision of POINTS was separate from the prescription, supply, administration, recommendation or promotion of specific medicines and all written material provided in association with the service would be non-promotional. The explanatory notes also stated that neither GlaxoSmithKline nor the third party would be able to identify any individual from the data sent from the practice. There was no evidence that POINTS was a monitoring tool for Seretide representatives nor that data was seen by Seretide representatives as alleged.

The Panel considered that the roles of the GlaxoSmithKline promotional staff and non-promotional staff (RCAs) appeared to be clearly separated. When the representatives promoted medicines they did not discuss individual services although they might introduce the local RCA to the practice. None of the RCA activities nor other GlaxoSmithKline activities were contingent upon the uptake of POINTS.

The Panel considered that much would depend on the practice which had control of the process. It did not appear to the Panel that the arrangements were in general unacceptable.

The Panel noted GlaxoSmithKline's explanation as to why some PCTs had refused the POINTS service ie it was not because of the service *per se* but due either to incompatibility of software or to local IT policies which did not allow the installation of third party software.

The complainant had provided no evidence to show that a refusal to accept the POINTS service had led to other GlaxoSmithKline-sponsored

support being withdrawn. The Panel noted that the complainant's anonymity would not have allowed GlaxoSmithKline to investigate this allegation further. The Panel noted GlaxoSmithKline's submission that practices which declined to participate in POINTS continued to be eligible for all other services from GlaxoSmithKline.

Overall the Panel considered that the service offered was not unacceptable; it would enhance patient care. The provision of the service was not linked to the prescription of any specific medicine. The decision of what to prescribe lay with the patient's doctor. The Panel did not consider that the service was an inducement to prescribe, supply, administer, recommend or buy any medicine. No breach of Clauses 18.1 and 18.4 was ruled. The Panel also ruled no breach of Clauses 9.1 and 2.

Complaint received **21 October 2008**

Case completed **9 December 2008**