

ANONYMOUS v TAKEDA

Sponsorship of 'One Stop Shops' for Diabetes.

An anonymous non contactable complainant was concerned about Takeda UK's sponsorship of One Stop Shops whereby a third party would complete annual diabetes checks for diabetics at one appointment. The complainant presumed that a chiropodist, dietician and a retinal screener would be on hand but was concerned that there was no way to check their professional credentials.

Other concerns were that as the service had its own diabetologist, was it agreed with local consultants and did it take into account local prescribing protocols? Who managed any titration of medicines? Was follow-up care arranged? Were all diabetics seen for this annual evaluation or only patients on oral medicines? If so was it an exclusive service?

The service provider was run by an ex-employee of Takeda – was this therefore a truly independent service? Would Takeda feel any loyalty to this person? Or the third party to Takeda? Was return on pharmaceutical company investment more important than patient outcomes?

Whilst the complainant understood the value of the concept and realised that the GPs would be assisted in ticking Quality and Outcomes Framework (QOF) boxes, he was suspicious of a service that was sponsored by a pharmaceutical company, which understandably would expect a return on its considerable investment.

The detailed response from Takeda is given below.

The Panel noted that it appeared from the company's submission that it had little to do with the service other than funding the third party. It was not entirely clear how the service was promoted to health professionals and Takeda's role, if any, in that regard. The third party was solely responsible for promoting the One Stop Shop service to the NHS. It was unclear from the contract who told the NHS about the nurse review service. However the complainant had made no specific allegation about the promotion of the service.

The third party document 'Type 2 Diabetes, Annual Review and Patient Segmentation' clearly stated that it was provided as a service to medicine by Takeda UK; it appeared to be aimed at GPs and made no mention of PCT approval. The document stated that the third party was providing assistance to GPs to help ensure that patients with type 2 diabetes had the best possible care. The practice was in control of all processes throughout and any change to a patient's medicine had to be authorized by the GP. The GP remained responsible for patient

care including follow up. There appeared to be two offerings firstly, a nurse-led review, patient identification and profiling and secondly a diabetes One Stop Shop. The One Stop Shop included a podiatry check, retinal screening, education and dietary advice.

The contract set out the disease indicators which were assessed within the One Stop Shop. The third party had to ensure that all personnel were trained and accredited to the professional standard required by their role.

The nurse-led review was limited to patients with type 2 diabetes. It was not clear whether a similar limitation applied to the One Stop Shop.

The fact that the third party provider was run by a previous Takeda employee was not necessarily unacceptable and neither was the fact that Takeda had a commercial interest in the therapeutic area. The document 'Type 2 Diabetes Annual Review and Patient Segmentation' did not mention any medicines by name other than insulin. The Panel had no information as to how this document was used.

The Panel noted that some aspects of the service were not examined as they fell outside the scope of the complainant's narrow allegations. No evidence had been provided by the complainant who was anonymous and non contactable. The Panel considered that much would depend on the health professionals who controlled the process. The practice could decide what action to take. It was vital that those conducting the nurse-led review or One Stop Shop followed instructions and complied with their own professional codes. There was no evidence that they had not done so or to indicate that the arrangements in principle amounted to an inducement to prescribe a specific medicine or that they failed to satisfy the criteria for a therapeutic review programme. No breach of the Code was ruled including Clause 2.

An anonymous non contactable complainant was concerned about Takeda UK Ltd's sponsorship of One Stop Shops for diabetes and urged the Authority to investigate the service to ascertain whether it was in keeping with the Code.

COMPLAINT

The complainant stated that clinics, called 'One Stop Shops', were planned in an area of London in which he worked. Under the service, diabetics would complete their annual diabetes check all at

one appointment. In that regard the complainant presumed that there would be a chiropodist, dietician and a retinal screener in attendance. The complainant, however, was concerned that there was no access to details of professionals to check credentials.

Other concerns were that as the service had its own diabetologist, was it agreed with local consultants and did it take into account local prescribing protocols? This might upset local health professionals, if there was no consultation/ correspondence with them to agree to the service. Who managed any titration of medicines? Was follow-up arranged in the care of this group of patients? Were all patients with diabetes seen for this annual evaluation or only patients on oral medication? If so was it an exclusive service?

Whilst the complainant understood the value of the concept, he was concerned as to the funding arrangements. He understood that these were being carried out by a third party sponsored, at some considerable cost, by Takeda.

Another concern was that the third party was run/directed by a previous employee of Takeda – could this therefore be seen as a truly independent service? Would Takeda feel any loyalty to this person? Or the third party to Takeda? The complainant queried whether return on pharmaceutical company investment was perhaps more important than patient outcomes?

Whilst the complainant realised that the GPs would be assisted in ticking Quality and Outcomes Framework (QOF) boxes, he was suspicious of a service that was run by outside staff sponsored by a pharmaceutical company at undoubtedly great cost, which understandably would expect a return on its investment.

In writing to Takeda attention was drawn to the requirements of Clauses 2, 9.1, 15.2, 18.1 and 18.4 of the Code.

RESPONSE

Takeda provided copies of its contract with the third party and the protocol used for the One Stop Shop.

The targeting of a One Stop Shop was agreed directly between the NHS organisation and the third party which used specific criteria to target the One Stop Shop service, eg:

- Areas with high disease prevalence.
- Primary care trusts (PCTs)/practices which registered patient exclusion levels above average within their diabetes/cardiometabolic service.
- PCTs/practices which experienced significant pressure points in one of more parts of their diabetes service eg:

- underperformance of their retinal screening service against number of patients seen vs target or unacceptable waiting times.
- performance against annual review targets within the year.

- PCTs which planned to re-design their current diabetes/cardiometabolic service so as to manage a greater percentage of appropriate patients in a primary care setting as per government guidance.

The decision to contract with particular NHS providers for provision of One Stop Shops was entirely at the discretion the third party. The One Stop Shop was provided by the third party with the approval of the NHS provider, in its own name under a separate written contract with the NHS provider to which Takeda was not a party and had no involvement.

Takeda had financially supported a pilot project of the One Stop Shop, which started in December 2008. This project was supported centrally, with no regional account director (sales) involvement. Takeda's support was solely financial, as a service to medicine. All conduct, including responsibility for selection of regions (eg PCTs) to offer the One Stop Shop resided solely with the third party.

The third party told the NHS provider that the service was funded by Takeda as a 'service to medicine' and ensured that Takeda's involvement was made clear to all relevant health professionals and administrative staff involved in the provision of services.

Takeda believed that the One Stop Shop was an appropriate and valid service to medicine which improved patient care and benefited the NHS, and was not linked in any way to the use of a particular medicine. Takeda therefore denied a breach of Clauses 18.1 and 18.4.

The third party was an independent company; its managing director had worked for Takeda, however this had no bearing on the delivery of the service or the independence of it from Takeda, as reflected in the terms and conditions set out in the contract. As the third party was not in any way a representative of Takeda, it refuted the allegation of a breach of Clause 15.2.

As Takeda did not believe that the activities were in breach of Clauses 15.2, 18.1 or 18.4, it therefore refuted any allegation of a breach of Clause 9.1 or 2.

The third party provided the One Stop Shop service through its own clinical staff. Takeda did not choose the health professionals or other contractors performing the tests. In its contract with Takeda, IMC warranted that all staff were trained and accredited to the professional standard their role required and carried the necessary insurance to undertake the prescribed duties. The third party also ensured that all staff maintained their training to the

required standards as part of their ongoing clinical and professional development.

The service did not include a diabetologist and was not designed to replace secondary care. The One Stop Shop clinics were provided on the basis of a therapy review programme, with the aim of ensuring that patients received optimal treatment following a clinical assessment. The third party ensured that such reviews included a comprehensive range of treatment choices, including non-medical choices where appropriate, and were not limited to Takeda's products. Any treatment protocol would be based upon national or local guidance.

Any decisions to change or start treatment in an individual patient only occurred after review by the relevant third party health professional, and every decision to change an individual's treatment was documented with evidence that it was made on rational grounds. Furthermore any change to a patient's medicine would only be implemented after it had been agreed and signed by a GP from the patient's practice.

Follow-up care was conducted by the patient's own health professional.

The third party worked with NHS providers to offer the One Stop Shop service to any type 2 diabetics agreed with the practice as suitable for the service. There was no exclusion or limitation to patients solely on oral diabetes therapy.

There was no link between the support of this service and the use of any particular product. The service aimed to improve patient care and support the NHS delivery of services for type 2 diabetics. Within this service, patients were evaluated for a variety of diagnostic tests contained within the QOF eg podiatry, retinal screening, HbA1c control. As a result of this it might be appropriate to change a patient's medicine, including those prescribed for type 2 diabetes, however, any change would be agreed with the patient's own GP and be based upon national/local guidance.

Takeda hoped that its response allayed any concerns about the One Stop Shop and its support of the service, and demonstrated that neither this project nor the company's involvement with the third party service provider was in breach of the Code in particular Clauses 2, 9.1, 15.2, 18.1 and 18.4. The project was an initiative set up to benefit patients and the NHS with no link to the use of a particular medicine.

PANEL RULING

The Panel noted that pharmaceutical companies could provide medical and educational goods and services, including therapy review programmes. Such services need to comply with the Code, particularly Clause 18.4. It was not necessarily a

breach of the Code for products from the company providing the service to be prescribed.

The Panel examined the two documents provided by Takeda; 'Type 2 Diabetes, Annual Review and Patient Segmentation' and the Takeda/third party contract. It appeared from the company's submission that it had little to do with the service other than providing money. It was not entirely clear how the service was promoted to health professionals and Takeda's role, if any, in that regard. The contract stated that the commercial function of the third party was solely responsible for promoting the One Stop Shop service to the NHS. It was unclear from the contract who told the NHS about the nurse review service. However the complainant had made no specific allegation about the promotion of the service.

The document 'Type 2 Diabetes, Annual Review and Patient Segmentation' clearly stated that it was provided as a service to medicine by Takeda UK; it appeared to be aimed at GPs and made no mention of PCT approval. The document stated that the third party was providing assistance to GPs to help ensure that patients with type 2 diabetes had the best possible care. The practice was in control of all processes throughout the service and any change to a patient's medicine had to be authorized by the GP. The GP remained responsible for patient care including follow up. There appeared to be two offerings firstly, a nurse-led review, patient identification and profiling and secondly a diabetes One Stop Shop. The One Stop Shop included a podiatry check, retinal screening, education and dietary advice.

The contract between Takeda and the third party set out the disease indicators which were assessed within the One Stop Shop. It required the third party to ensure that all personnel were trained and accredited to the professional standard required by their role.

The nurse-led review was limited to patients with type 2 diabetes. It was not clear whether a similar limitation applied to the One Stop Shop.

The fact that the third party company was run by a previous Takeda employee was not necessarily unacceptable. No evidence had been provided by the complainant in this regard. Clearly Takeda had a commercial interest in the therapeutic area as it had medicines for treating type 2 diabetes. Again this was not necessarily unacceptable. All the arrangements needed to comply with the Code, in particular Clause 18.4. The document 'Type 2 Diabetes Annual Review and Patient Segmentation' did not mention any medicines by name other than insulin. The Panel had no information as to how this document was used.

The Panel noted that some aspects of the service were not examined as they fell outside the scope of the complainant's narrow allegations. No evidence had been provided by the complainant

who was anonymous and non contactable. The Panel considered that much would depend on the health professionals who controlled the process. The practice could decide what action to take. It was vital that those conducting the nurse-led review or One Stop Shop followed instructions and complied with their own professional codes. There was no evidence that they had not done so. There was no evidence before the Panel to indicate that the arrangements in principle amounted to an inducement to prescribe a specific medicine contrary to Clause 18.1 or that they failed to satisfy the criteria for a therapeutic review

programme under Clause 18.4. No breach of Clauses 18.1 and 18.4 was ruled. There was no evidence provided by the complainant that Takeda representatives had failed to comply with the Code or that high standards had not been maintained. No breach of Clauses 9.1 and 15.2 was ruled. The Panel also ruled no breach of Clause 2.

Complaint received **17 June 2009**

Case completed **14 July 2009**
