ANONYMOUS v BRISTOL-MYERS SQUIBB

Promotion of Onglyza

An anonymous and non-contactable GP alleged that Bristol-Myers Squibb was asking its field force to get a GP to prescribe saxagliptin (Onglyza) for a pre-determined number of patients in a given period of time. The field force had to complete a form stating which GP was going to prescribe saxagliptin, for how many patients – within a week, month, etc. GPs were expected to text their representative when they had completed the agreed number of prescriptions.

The complainant was against such pressure from a pharmaceutical company and would treat his patients in the manner that he saw fit, in line with his clinical experience.

The detailed response from Bristol-Myers Squibb is given below.

The Panel noted that the complainant had provided little information on which to enable Bristol-Myers Squibb to investigate the allegation; his identity, the region in which he practised and the identity of the representative were all unknown.

Bristol-Myers Squibb explained that a representative had worked with a GP who had, of his own volition, texted the representative. In order to track potential progress on an ongoing basis representatives might create their own form on which they would reference prescribers who had indicated a willingness to prescribe based on the call. In that regard the Panel noted that it was important that representatives did not use such forms with health professionals. Any material used with health professionals must be certified in accordance with Clause 14 and otherwise comply with the Code.

The completion of a certified form was not necessarily unacceptable. The alleged request for the GP to text the representative when they had completed the agreed number of prescriptions was denied by Bristol-Myers Squibb. The Panel queried whether such a request was necessarily in breach of the Code.

The Panel considered that there was a difference of view between the complainant and the respondent. Even if a representative had asked a doctor to complete a certified form and text data this was not *de facto* a breach of the Code; the nature of the representative's request and the form provided would be crucial. In this case the complainant provided no details about either. Given the information before it, the Panel ruled no breach.

An anonymous and non-contactable GP complained about the promotion of Onglyza (saxagliptin) by representatives of Bristol-Myers Squibb Pharmaceuticals Limited.

Onglyza was indicated in combination with other oral hypoglycaemics in patients with type 2 diabetes to improve glycaemic control. The marketing authorization was held by Bristol-Myers Squibb and AstraZeneca.

COMPLAINT

The complainant alleged that Bristol-Myers Squibb's management was asking its field force to get a GP to prescribe saxagliptin for a pre-determined number of patients in a given period of time. The field force had to complete a form stating which GP was going to prescribe saxagliptin, for how many patients – within a week, month, etc. GPs were expected to text their representative when they had completed the agreed number of prescriptions.

The complainant was against such pressure from a pharmaceutical company and would treat his patients in the manner that he saw fit, in line with his clinical experience in treating diabetes.

When writing to Bristol-Myers Squibb, the Authority asked it to comment in relation to Clauses 9.1, 9.2 and 15.2 of the Code.

RESPONSE

Bristol-Myers Squibb stated that the performance of sales representatives was judged on their ability to demonstrate core behaviours and to achieve a prescription target for their region. Bristol-Myers Squibb tracked the prescription target by monitoring territory and practice level data provided by IMS. No specific requests for actual patient numbers per GP was expected or had been briefed.

Bristol-Myers Squibb provided an outline of the training programme it used for representatives. At no point was pressuring doctors to text in their prescribing of a product described.

It had come to light that at a training meeting in February, attended by a regional business director, a 'sharing good practice' session took place. One representative had worked with a GP using hypothetical patient profiles suitable for saxagliptin based on their glycaemic profile and in accordance with the saxagliptin licensed indications. The GP was pleased with the outcome of the call and, of his own volition, texted the representative with his

findings following on from the visit. This was shared as an example of how a good call could result in a positive outcome for patients, GPs and Bristol-Myers Squibb, but it was not suggested to other representatives that that they should actively seek this type of communication from the health professionals on whom they called.

Neither since the meeting in February, nor before, had briefing or training been developed to institute mandatory texting of results. GPs were free to communicate with representatives using any channels they pleased and there had not been, nor would there be, any plan to coerce them to do so. Representatives were carefully trained on how often and in what manner to communicate with GPs, as per the Code.

Bristol-Myers Squibb stated that its investigation had not identified any person or area from where this recent behaviour could have emanated.

Bristol-Myers Squibb believed that its models of sales training were robust and that high standards had been maintained. Bristol-Myers Squibb therefore denied any breach of Clauses 9.1, 9.2 and 15.2.

In response to a request for further information, Bristol-Myers Squibb stated that it tracked prescription targets by monitoring territory and practice level data by IMS. No specific request for actual patient numbers per GP was expected or had been briefed to the sales team.

As part of their local planning some representatives would estimate the number of prescriptions required to achieve their target. No direction had been given to any representative to request a set number of prescriptions from a single prescriber.

In order to track potential progress on an ongoing basis, representatives might create a tracker on which they would reference those prescribers who had indicated a willingness to prescribe based on the call. This might include a potential number of prescriptions from that prescriber; however this was solely based on feedback from the prescriber and was not driven by the representative or their managers. An example of such a tracker was provided.

During the 'sharing good practice' session at the training meeting in February, a representative stated that they had received an unsolicited text from a GP; however it was made very clear by the representative that this had not been requested and that the GP had sent it of their own volition based on their positive experience with the medicine. The regional business director present at the training session had stated the following:

'The representative concerned was very clear during the good practice session that this has been an isolated case and that the text had not been requested or suggested during the sales call. I followed-up by reinforcing the fact that we should not ask or expect communication of this nature from our HCPs [healthcare professionals], however it was an example of an excellent call which had been specifically focused on the needs of the patient and the GP resulting in extremely unexpected and positive feedback. No direction was given to any team member to replicate the GP text aspect of the good practice or has been since the meeting.'

The local manager involved in the training meeting had categorically stated that no member of his team had proactively requested text communication from any health professionals nor were any attempts made to coerce them to do so. Given the manager's response Bristol-Myers Squibb did not consider it was appropriate to contact the representatives individually. Bristol-Myers Squibb was not aware of any such issues with any other representatives who were not at the meeting. In addition, there was no evidence to link the complaint with this particular event given that the meeting occurred six months before the complaint was received.

Using the sales model, representatives were trained to focus their calls on the individual prescriber's needs and to tailor their calls appropriately.

Within the one-to-one process, the 'commit' phase included 'State action you will take to facilitate changes'. This statement was envisaged to encompass only those activities that would be permissible within the Code and might include, but were not limited to:

- Arranging a follow-up visit with the customer
- Arranging to see another member of the customer's practice or team to support what had been agreed in the call
- Provision of additional data or information as requested by the customer.

A copy of workshop slides was provided. This was an internal Bristol-Myers Squibb training programme and was the only selling skill training representatives received.

Bristol-Myers Squibb submitted that as standard practice, it checked that all representatives joining the company (including on contract) had taken their ABPI examination and if not, that they were entered for it as required under the Code. All representatives were regularly reminded of their responsibilities under the Code and received regular updates (eg field force meetings) on relevant cases and Code changes.

PANEL RULING

The Panel noted that as the complaint was solely about the conduct of a Bristol-Myers Squibb representative it did not consider that it was necessary for AstraZeneca, which co-promoted the product, to respond to the complaint.

The Panel noted that the complainant was anonymous and that, as set out in the introduction to the Constitution and Procedure, complainants had the burden of proving their complaint on the balance of probabilities. Anonymous complaints were accepted and like all complaints were judged on the evidence provided by the parties.

The Panel noted the complainant alleged that the representatives had been provided with a form to complete stating which GP was going to prescribe saxagliptin and for how many patients. GPs were expected to text their representative when they had completed the agreed number of prescriptions.

The Panel noted that the complainant had provided little information on which to enable Bristol-Myers Squibb to investigate the allegation. The identity of the complainant, the region in which he practised and the identity of the representative were all unknown.

Bristol-Myers Squibb explained that a representative had worked with a GP who had, of his own volition, texted the representative. In order to track potential progress on an ongoing basis representatives might create their own tracker form on which they would reference prescribers who had indicated a willingness to prescribe based on the call. In that regard the Panel noted that it was important that representatives did not use such forms with health professionals. Any material used with health professionals must be certified in accordance with Clause 14 and otherwise comply with the Code.

The Panel considered that representatives would, of course, encourage health professionals to prescribe Onglyza and provided all activity was in accordance with the Code, this was reasonable. The completion of a certified form was not necessarily unacceptable. The alleged request for a GP to text the representative when they had completed the agreed number of prescriptions was denied by Bristol-Myers Squibb. The Panel queried whether such a request was necessarily in breach of the Code.

The Panel was concerned that the sharing of best practice by representatives might lead to difficulties if it resulted in discussions and possible endorsement of practices that were not in accordance with the Code. However, there was no evidence that this was so in this case. The Panel considered that there was a difference of view between the complainant and the respondent. Even if a representative had asked a doctor to complete a certified form and text data to the representative this was not *de facto* a breach of the Code; the nature of the representative's request and the form provided would be crucial. In this case there were no details about either provided by the complainant. On the basis of the information before it, the Panel ruled no breach of Clause 15.2.

The Panel considered that on the material before it Bristol-Myers Squibb had not failed to maintain a high standard nor failed to recognise the special nature of medicines. The Panel ruled no breach of Clauses 9.1 and 9.2.

Complaint received **13 August 2010**

Case completed **20 September 2010**