

VOLUNTARY ADMISSION BY OTSUKA

Representatives' briefing material

Otsuka Pharmaceuticals voluntarily admitted that a regional business manager (RBM) had briefed his/her sales team such that he/she appeared to set a call frequency target which would lead to a breach of the Code.

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 Otsuka.

Otsuka submitted that following a team teleconference in late October 2012, the RBM in question emailed the team with the following:

'The focus is on next fortnight till end of October should consist of as follows:

1. List of target customers who have already been seen on a frequency of 2 – 4 times and need to move them to 8 – 9 calls. Please put in your plans when you plan to see them this month.
2. Who you plan to follow up after your meetings (1st call within 48 hours and followed by a second call in 10 days)'.

In Otsuka's view, 'calls' used in this context implied proactivity. The call frequency stipulated exceeded that which had been agreed in the performance appraisal document and exceeded those that were acceptable under the Code (maximum 3 unsolicited calls per year). Otsuka stated that the email specified plans for customers seen 'less than 3 times' and plans to achieve this target and plans for a single follow-up post-meeting, both of which were within the Code. Otsuka understood that the RBM might have used the word 'call' in error instead of 'contact'. However, even if this was so, stipulating the requirement for increased activity to potentially require 6-7 contacts with individual customers in a 3-month period remained excessive, as was 2 contacts within a 10-day period.

Otsuka submitted that the RBM's instruction was in breach of the Code. All field employees underwent training. It was unclear if this instruction translated to actual non-compliant activity by the representatives, but the assumption had to be that it had.

The detailed response from Otsuka is given below.

The Panel noted that the email sent to two sales teams stated that the focus of the next fortnight until the end of the month should consist of; list of target customers who had already been seen 2-4 times and move them to 8-9 calls. In the Panel's view 'calls' implied unsolicited 1:1 meetings with a doctor or other health professional which, as noted

above, should not normally exceed three on average each year. The RBM stated in the email 'Please put in your plans when you plan to see them this month'. The Panel considered that the email implied that, having already called upon a customer 2-4 times, representatives should arrange to see them a further 4 to 7 times within a fortnight. The email also referred to a follow up call within 48 hours following their meetings, followed by a second call in 10 days.

The Panel considered that the RBM's email advocated a course of action which would not comply with the requirements of the Code. The Panel noted Otsuka's submission that it was unclear if the email had translated into non-compliant activity by the sales force but the assumption had to be that it had and on that basis the Panel ruled a breach of the Code as acknowledged by Otsuka.

The Panel further noted that the Code required representatives' briefing material to be certified. In so much as the email instructed representatives about how many times they should see customers to promote a named medicine, the Panel considered that the email should have been certified which it had not been. A breach of the Code was ruled as acknowledged by Otsuka.

Otsuka Pharmaceuticals (UK) Limited voluntarily admitted that a regional business manager (RBM) had briefed his/her sales team such that he/she appeared to set a call frequency target which would lead to a breach of the Code.

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 Otsuka.

COMPLAINT

Otsuka noted that Clause 15.4 of the Code referred to the frequency and manner of calls on doctors and others prescribers. The company's annual objectives template for sales representatives contained metrics by which their activities were measured. Specific metrics related to individual territories based on geographical size and customer base. However, the over-arching specification for the objectives was that they had to adhere to the Code as follows:

'All activity objectives must be met only by following [in-house standard operating procedures (SOPs)] and in compliance with ABPI Code of Practice guidance (particularly Clause 15.4). Reference to "calls" in these objectives means 1:1 activity, which in addition to unsolicited calls will include those prearranged, or requested by a doctor or other prescriber, or calls made in order to respond to a specific

enquiry. Reference to “contacts” means all “calls” outlined above plus attendance at group meetings and visits to follow up on a report of an adverse reaction.’

Otsuka submitted that following a team teleconference in late October 2012, the RBM in question emailed the team with the following:

‘The focus is on next fortnight till end of October should consist of as follows:

1. List of target customers who have already been seen on a frequency of 2 – 4 times and need to move them to 8 – 9 calls. Please put in your plans when you plan to see them this month.
2. Who you plan to follow up after your meetings (1st call within 48 hours and followed by a second call in 10 days)‘.

In Otsuka’s view, ‘calls’ used in this context implied proactivity. The call frequency stipulated exceeded that which had been agreed in the performance appraisal document and exceeded those that were acceptable under the Code (maximum 3 unsolicited calls per year). Otsuka stated that the 30-day plan included in the email specified plans for customers seen ‘less than 3 times’ and plans to achieve this target and plans for a single follow-up post-meeting, both of which were within the Code. Otsuka understood that the RBM might have used the word ‘call’ in error instead of ‘contact’. However, even if this was the case, stipulating the requirement for increased activity to potentially require 6-7 contacts with individual customers within a 3-month period remained excessive, as was 2 contacts within a 10-day period.

Otsuka submitted that the RBM’s instruction was in breach of Clause 15.4. All field employees underwent an introductory presentation by medical affairs to emphasise adherence to the Code and various SOP requirements. It was unclear if this instruction translated to actual non-compliant activity by the representatives, but the assumption had to be that it had. It had been made clear to the RBM that this type of instruction was not acceptable. Business unit managers had been instructed to brief their managers on appropriateness of emails – any instructional emails must get a second opinion on the need for certification. All managers had also been mandated to attend Code re-training which would take place shortly.

RESPONSE

Otsuka provided copies of relevant documents and also noted a possible breach of Clause 14 as neither the RBM’s email nor the 30-day plan which accompanied it were reviewed or certified as required by Otsuka’s SOP which stipulated that all briefing materials had to be entered into Zinc. In addition the 30-day plan was subsequently dropped and not implemented.

Otsuka noted that Section 6.2 of its copy approval SOP stated that all representatives’ training and briefing materials related to the promotion of a medicine had to be certified and that written communications to representatives which contained instructions which might constitute a briefing (eg emails) must be certified. Otsuka provided a copy of the RBM’s self-study training form in which he/she stated that he/she had read and understood the copy approval SOP.

Otsuka also provided a copy of the certificate and template related to a sales representative’s annual performance objectives for 2012. The overarching direction for the activities stated that all activities objectives must be met only by following Otsuka SOPs and in compliance with the Code and drew attention to Clause 15.4. It also included a definition of ‘calls’ and ‘contacts’. The certified template allowed for the individual target call rate to be customised according to the territory size and number of potential doctors within it.

Otsuka further provided a copy of the certificate and email related to its corrective and preventative actions (CAPA) following the non-compliant email which noted that briefings must be certified through Zinc.

PANEL RULING

The Panel noted that the supplementary information to Clause 15.4 stated that companies should arrange that intervals between visits did not cause inconvenience. The number of calls made on a doctor or other prescriber by a representative each year should not normally exceed three on average. This did not include: attendance at group meetings, including audio-visual presentations and the like; a visit requested by a doctor or other prescriber or a call made to respond to a specific enquiry; a visit to follow up a report of an adverse reaction. When companies briefed representatives, they should distinguish clearly between expected call rates (ie not normally more than three on average in a year) and expected contact rates (ie calls plus group meetings, visits to follow up a report of an adverse reaction etc). Targets must be realistic and not such that representatives breached the Code in order to meet them.

The Panel noted that the email sent from the RBM in October to two product sales teams stated that the focus of the next fortnight until the end of the month should consist of; list of target customers who had already been seen 2-4 times and move them to 8-9 calls. In the Panel’s view ‘calls’ implied unsolicited 1:1 meetings with a doctor or other health professional which, as noted above, should not normally exceed three on average each year. The RBM stated in the email ‘Please put in your plans when you plan to see them this month’. The Panel considered that the email implied that, having already called upon a customer 2-4 times, representatives should arrange to see them a further 4 to 7 times more within the space of a fortnight. The email also referred to a follow up call within 48

hours following their meetings, followed by a second call in 10 days.

The Panel considered that the email sent by the RBM advocated a course of action which would not comply with the requirements of Clause 15.4. The Panel noted Otsuka's submission that it was unclear if the email had translated into non-compliant activity by the sales force but the assumption had to be that it had and on that basis the Panel ruled a breach of Clause 15.4 as acknowledged by Otsuka.

The Panel further noted that the Code required representatives' briefing material to be certified. In

so much as the email instructed representatives about how many times they should see customers to promote a named medicine, the Panel considered that the email should have been certified which it had not been. A breach of Clause 14.1 was ruled as acknowledged by Otsuka.

Complaint received

2 August 2013

Case completed

3 September 2013
