SANOFI PASTEUR MSD v MASTA

Epaxal promotional email

Sanofi Pasteur MSD complained about an unsolicited promotional email headed 'Epaxal costings' which referred to the benefits of Epaxal Hepatitis A vaccine and was sent in October 2008 by a MASTA representative to a customer.

The detailed response from Masta is given below.

Sanofi Pasteur MSD noted that the start of the email indicated that cost related information had been requested, however the email was clearly promotional, containing six separate promotional claims (two of which could not be substantiated) and was thus unsolicited. In sending this email, which had not been through any internal approval, Masta had not maintained a high standard.

The Panel noted that Sanofi Pasteur MSD had not specified which two claims could not be substantiated. The Panel noted that the email included product claims and was promotional in nature; it did not include prescribing information and had not been certified by the company. The Panel considered that the representative had not maintained a high standard of ethical conduct and a breach of the Code was ruled as acknowledged by Masta.

Sanofi Pasteur MSD stated that during intercompany dialogue Masta had failed to assure it that its representatives had been appropriately rebriefed following its earlier complaint. The only evidence supplied was an unacceptable email from the Masta sales and marketing director to the sales team which stated:

'It may be worth reminding yourself of the ABPI Code of Practice which can be found at http://www.abpi.org.uk/links/assoc/PMCPA/pmcpa_code2006.pdf – not an exciting read but an important one'.

Sanofi Pasteur MSD was concerned that this email not only cited the out-of-date version of the Code but also did not constitute adequate training on the content of the Code. Sanofi Pasteur MSD alleged that Masta had failed to train its representatives adequately on the Code. In addition, it was alleged that high standards had not been maintained.

The Panel considered that the email to the sales team was inadequate. The previous Code booklet had been provided rather than the current edition. This was most unfortunate. The Panel considered that in that regard adequate training had not been given and that high standards had not been maintained. Thus breaches of the Code were ruled.

Sanofi Pasteur MSD stated that it had previously had inter-company dialogue on a similar matter, also arising as a result of an email sent to a customer by a Masta representative which contained an exaggerated and unsubstantiated claim. As a result, a written agreement was provided by Masta in November 2007. Despite these written assurances, similar activity had reoccurred and thus Sanofi Pasteur MSD alleged that Masta was in breach of the Code.

The Panel noted that it had not previously considered a complaint regarding a Masta representative's use of email. Masta agreed that the matter currently at issue was the second time a representative had sent an email contrary to company instructions. The Panel was concerned that despite instructions following Sanofi Pasteur MSD's complaint in 2007 yet again a representative had emailed a customer with what were alleged to be exaggerated and unsubstantiated claims. Masta needed to be certain that it and its staff were clear about the requirements of the Code. The Panel considered that high standards had not been maintained in relation to the training of representatives as set out above and considered that the ruling of a breach of the Code in that point covered the allegation now before it.

Sanofi Pasteur MSD complained about an unsolicited promotional email dated 20 October 2008 which was sent by a Masta representative to a customer. The email was headed 'Epaxal costings' and referred to the benefits of Epaxal Hepatitis A vaccine.

1 Promotional, unsolicited and unapproved email

COMPLAINT

Sanofi Pasteur MSD stated that the start of the email indicated that cost related information had been requested, however the email was clearly promotional, containing six separate promotional claims (two of which could not be substantiated) and was thus unsolicited. In sending this email, which had not been through any internal approval, Masta had not maintained a high standard and was in breach of Clause 15.2.

RESPONSE

Masta agreed that the email sent by the representative was in breach of the Code.

Masta understood that the email was 'solicited',

following a discussion on Epaxal, in that the customer requested that the information discussed be reiterated in an email.

The email contained claims and was therefore promotional. The claims used in the email from the representative had not been through approval and no prescribing information was included.

Sanofi Pasteur MSD alleged that two of the claims could not be substantiated. Masta believed that the profit claim could be substantiated: the amount of profit a GP practice could make from vaccines was specific to individual practices since different discounts might be offered to different practices by the various suppliers. Consequently no general claims regarding profit could be substantiated, this however was a specific email sent to an identified practice as a follow-up to specific discussions where competitor price details might have been shared. Masta acknowledged that the email breached Clauses 4.1, 14.1, 7.2 and 7.4.

Since the above breaches were due to the activity of one individual representative who had clearly not complied with all relevant requirements Masta acknowledged a breach of Clause 15.2.

PANEL RULING

The Panel noted that Sanofi Pasteur MSD had not specified which the two claims were that it alleged could not be substantiated. Only a breach of Clause 15.2 had been alleged. The Panel noted that the email sent by the representative had included product claims and was promotional in nature; the email did not include prescribing information and had not been certified by the company. The Panel considered that the representative had not maintained a high standard of ethical conduct and a breach of Clause 15.2 was ruled as acknowledged by Masta.

2 Failure to adequately train representatives

COMPLAINT

Sanofi Pasteur MSD stated that during intercompany dialogue Masta had failed to assure it that its representatives had been appropriately rebriefed following Sanofi Pasteur MSD's complaint. The only evidence supplied was an unacceptable email to the sales team which stated:

'It may be worth reminding yourself of the ABPI Code of Practice which can be found at http://www.abpi.org.uk/links/assoc/PMCPA/pmcpa_code2006.pdf – not an exciting read but an important one'.

Sanofi Pasteur MSD was concerned that Masta had directed its sales team to the 2006 Code; this demonstrated a lack of awareness of the most upto-date version. This email, particularly with the

apparent lack of importance it afforded the Code, not only cited the out-of-date version of the Code but also did not constitute adequate training on the content of the Code. Sanofi Pasteur MSD alleged that Masta had failed to train its representatives adequately on the Code in breach of Clause 15.1. In addition, it was alleged that high standards had not been maintained, in breach of Clause 9.1.

RESPONSE

Masta submitted that the email sent to the team, immediately after investigating the details of this case, laid out clear and direct instruction regarding emailing of customers. If these instructions were followed no further breaches would occur.

'The email must be at the request of the surgery – unsolicited emails must not be sent

There is no mention of any clinical or medical claims for any of our products – this essentially means that you cannot say anything about our products in any email you create

There is no mention of any competitor product.

If the surgery has a clinical or medical request can you forward that request to the medical department for them to answer.

If you are asked to email the surgery with commercial information such as prices, discounts or delivery information can you check with your manager first before sending.'

Representatives did not need to have a detailed understanding of the nuances of all the clauses of the Code. What was important was that they had a very clear understanding of the clauses they could be in breach of through their own activities. Masta therefore believed that it was better to focus representatives on the clauses directly relevant to them. Masta representatives should not generate promotional literature or advertisements - it was better to give such dogmatic instructions on what to do and not to do than to train them on the details of the clauses which were specific to tasks they should not be doing. Counter intuitively, giving detailed training on such areas risked representatives mistakenly believing that they then knew enough about the Code to be able to produce promotional materials.

The link to the 2006 Code was a genuine error – links to the 2008 and 2006 versions appeared on the same PMCPA web page, one directly beneath the other; the 2006 link was mistakenly pasted into the document to the representatives. As explained above, Masta did not rely on representatives reading the Code to train themselves but explained in simple terms the clauses that were directly relevant. Consequently directing representatives to an old version of the Code, embarrassing though it was, did not in itself constitute a lack of adequate

training on the Code.

Masta believed its representatives were adequately trained and had sufficient scientific knowledge to enable them to provide full and accurate information about the medicines which they promoted and were not in breach of Clause 15.1.

Masta also believed that high standards must be maintained at all times. On this occasion one representative, who had failed to follow clear instruction previously provided, was the cause of this breach. Masta understood the importance of having appropriate management processes in place to ensure that every member of staff adhered to the Code. That this had failed in this instance was frustrating and Masta would explore all mechanisms to prevent this in the future, however it did not believe that this was in breach of Clause 9.1 and its understanding of how this clause was intended.

PANEL RULING

The Panel considered that the email to the sales team was inadequate. The previous Code booklet had been provided rather than the current edition. This was most unfortunate. The Panel considered that in that regard adequate training had not been given and that high standards had not been maintained. Thus breaches of Clauses 9.1 and 15.1 were ruled.

3 Persistent activity despite Masta's previous assurances

COMPLAINT

Sanofi Pasteur MSD stated that this was not the first time that representative activity of this type had been brought to its attention; previously it had had inter-company dialogue on a similar matter, also arising as a result of an email sent to a customer by a Masta representative which contained an exaggerated and unsubstantiated claim. As a result, Masta provided a written agreement on 6 November 2007. Despite these written assurances, similar activity had reoccurred and thus Sanofi Pasteur MSD alleged a breach of Clause 9.1 of the Code.

RESPONSE

Masta submitted that the steps it had taken in response to both this complaint from Sanofi Pasteur MSD and a similar previous one should be sufficient to prevent such breaches. Rapid steps were taken and clear instruction given. This was followed up individually and with the entire sales team in terms of further instruction and checks that this had been understood. The issue here was that an individual had subsequently failed to follow this instruction. Masta utilised all available management processes to prevent such breaches, with the ultimate sanction of dismissing representatives that breached the Code: such consequences served to reinforce the importance of staff adhering to the Code but could only be applied retrospectively and therefore did not serve as a fool proof method of preventing future breaches.

Masta apologised to Sanofi Pasteur MSD and to the PMCPA for this breach and sought to reassure both parties that it took the Code very seriously and that it already did, and would continue to do, everything it could to prevent any similar future issues.

PANEL RULING

The Panel noted that it had not previously considered a complaint regarding a Masta representative's use of email. Masta agreed that the matter currently at issue was the second time a representative had sent an email contrary to company instructions. The Panel was concerned that despite instructions following Sanofi Pasteur MSD's complaint to Masta in 2007 yet again a representative had sent an email to a customer with what were alleged to be exaggerated and unsubstantiated claims. Masta needed to be certain that it and its staff were clear about the requirements of the Code. The Panel considered that high standards had not been maintained in relation to the training of representatives as set out in point 2 above and considered that the ruling of a breach of Clause 9.1 in that point covered the allegation now before it.

Complaint received 9 January 2009

Case completed 2 March 2009