

# PHARMACIST PRACTITIONER v SANOFI-AVENTIS

## Provision of promotional aids for Acomplia

A pharmacist practitioner complained that no response had been received when he had returned reply paid cards for Acomplia (rimonabant) sent to him by Sanofi-Aventis.

The complainant stated that the practice recently received several reply paid cards for Acomplia announcing that the National Institute for Health and Clinical Excellence (NICE) had recommended this medicine for obesity.

The card offered copies of four rimonabant clinical studies and also some other items that the practice would have found useful (a laptop case, a USB stick and a laser pointer). The complainant indicated on the card that he did not want to see a representative. Four weeks had passed since the complainant completed and returned the card and the requested items had not been delivered.

The detailed response from Sanofi-Aventis is given below.

The Panel noted Sanofi-Aventis' arrangements for dealing with responses (via reply paid cards) to its mailings. It noted that Sanofi-Aventis had not received the complainant's reply paid card and that the company now assumed that it had got lost in the post. In the circumstances the Panel did not consider that the failure to deliver the requested items to the complainant meant that high standards had not been maintained. No breach of the Code was ruled, which was upheld by the Appeal Board on appeal by the complainant.

A pharmacist practitioner complained that he had received no response when he had returned reply paid cards for Acomplia (rimonabant) sent to him by Sanofi-Aventis.

### COMPLAINT

The complainant stated that the practice recently received several reply paid cards for Acomplia announcing that the National Institute for Health and Clinical Excellence (NICE) had recommended this medicine for obesity.

The card offered copies of four rimonabant clinical studies and also some other items that the practice would have found useful (a laptop case, a USB stick and a laser pointer). The complainant indicated on the card that he did not want to see a representative. Four weeks had passed since the complainant completed and returned the card and the requested items had not been delivered. The complainant had not been informed by any of the

reception staff that anyone had called to see him from Sanofi-Aventis and in this respect they were very reliable; the complainant had had items delivered by or seen representatives from other companies in this time.

When writing to Sanofi-Aventis, the Authority asked it to respond in relation to Clause 9.1 of the Code.

### RESPONSE

Sanofi-Aventis stated that it always aimed to maintain high standards in all matters.

Sanofi-Aventis submitted that it had only sent one reply paid card describing Acomplia NICE guidance since the guidance was announced on 25 June 2008. Although the complaint referred to the practice receiving several cards Sanofi-Aventis had assumed that this referred to more than one copy of the mailing in question as no other cards had been sent out.

Use of the reply paid card commenced on 7 July and mailers were sent on a named basis to doctors at the complainant's practice, with a general mailer to 'the pharmacist' on 10 July, by second class post. It was anticipated that these mailers would have arrived at the practice on 14 July. The only record of a card being returned from the practice was dated 15 July and was from a GP, not the complainant. Sanofi-Aventis had no record of a card being returned by the complainant.

Sanofi-Aventis explained that its reply paid cards were sent out by an agency. Each card was coded with a territory number designated by the area to which it was posted. Cards, returned by second class post from the health professional to the agency, were forwarded to the relevant representative. The contract with the agency did not specify a timeframe for this; however it used a weekly dispatch to send the cards to the representatives. When the representatives received the cards, they ordered the materials requested from the company's warehouse on a monthly basis. The materials were then sent to the representative to be delivered to the health professional in question. In this particular instance, the reply paid card from the doctor at the complainant's practice was sent to the appropriate representative on 1 August. This representative would then order items from the warehouse, most likely in their August order, to be delivered to the doctor in the future. There was normally eight to twelve weeks between the health professional returning the reply paid card and him receiving the items requested.

If the health professional indicated that they did not wish to see a representative, the items would be left with the receptionist at the surgery. This was standard policy endorsed by Sanofi-Aventis and the reply paid card made it clear that there was no obligation to see a representative. In addition, all representatives were fully trained and briefed regarding the Code, and in particular, Clause 15.3 relating to not employing inducement or subterfuge to gain an interview and the relevance of this to reply paid cards.

It was not possible to be more specific about the interval between the card being returned and dispatch of the items as this varied. Sanofi-Aventis noted that reply paid cards were sent by second class post and thus treated as low priority by the postal services. This alone could result in significant delays in requests arriving. Additionally, if cards missed either the weekly mail from the agency to the representative, or the monthly order from the representative, delays were inevitable. Beyond this cards might be lost in the post, an event wholly out of the company's control.

From the company's investigation it appeared that the earliest the complainant could have returned the reply paid card was around 14 July. The complaint was received by the Authority on 6 August, a timeframe of less than four weeks. As stated above, however, Sanofi-Aventis did not appear to have received a card from the complainant and it could only assume that it might have been lost in the post.

Sanofi-Aventis added that, to date, it had not received any other complaints about this reply paid card or delivery of items. In addition, Sanofi-Aventis had not had any previous complaints regarding the other reply paid cards. Sanofi-Aventis believed that its processes were reasonable and robust and that a delay of eight to twelve weeks from posting date to receipt of promotional items was not unreasonable given the nature of such items.

In view of the level of quantity and quality of service generally provided to date in these matters and the absence of previous complaints, Sanofi-Aventis believed that this demonstrated that it had maintained high standards and was therefore not in breach of Clause 9.1.

## **PANEL RULING**

The Panel noted Sanofi-Aventis' arrangements for dealing with responses (via reply paid cards) to its mailings. It noted that Sanofi-Aventis had not received the complainant's reply paid card and that the company now assumed that it had got lost in the post. In the circumstances the Panel did not consider that the failure to deliver the requested items to the complainant meant that high standards had not been maintained. No breach of Clause 9.1 was ruled.

## **APPEAL BY COMPLAINANT**

The complainant alleged that it was most convenient that this complaint had been diverted into a failure of the mail delivery services rather than of Sanofi-Aventis, especially as the complainant had returned such cards in the past and yielded no response. In addition, the Royal Mail admitted that, by its own estimates, 99.93% of mail was delivered. In all probability, based on this statistic, the complainant considered that his reply paid card was indeed delivered. The complainant wondered what systems were in place to record delivery of these cards that could be produced to demonstrate failed delivery.

The complainant was further disappointed that in light of such blameless conduct Sanofi-Aventis had, as yet, failed to instruct its local representative to deliver the clinical papers as originally requested or attempted some other means of delivery.

The complainant thought that as Sanofi-Aventis had been accused of failing to respond to a simple reply paid card, it would try to resolve the situation to the satisfaction of the complainant. The complainant considered that perhaps in the future he should return several cards from different post boxes in order to minimise the likelihood of the post being lost.

## **COMMENTS FROM SANOFI-AVENTIS**

Sanofi-Aventis submitted that in response to the complaint it had already outlined how this process operated, but summarised the key points. The original mailer, including the reply paid card, was sent to a list of general practitioners and the pharmacist, with the name and address pre-stamped on the reply paid card. No reply paid card was received by the agency containing the complainant's name or from the pharmacist at this practice. However, a reply paid card was received from one of the named general practitioners at the practice. This particular reply paid card had been forwarded to the local representative to trigger the ordering of the items requested for subsequent delivery to the named GP, according to their instructions.

Although Sanofi-Aventis could understand the complainant's frustration, it had to rely on external agencies for this process to be completed. It was in the company's interest to ensure that items such as clinical papers were provided to clinicians upon request, and Sanofi-Aventis also regretted that in this instance the fulfilment of the request had not been possible. This appeared to be outside the control of the company, as indicated in the original response, and Sanofi-Aventis was not able to make any further submission other than to outline again the facts that had occurred, as above.

Sanofi-Aventis noted that the complainant was disappointed that Sanofi-Aventis had not acted

upon this complaint and sought to deliver the items to him. Sanofi-Aventis would have been more than happy to do this had the complainant contacted the company direct but a complaint to a third party did not represent a *bona fide* request to the company. In the absence of such a direct request there was no desire to respond in what might be considered an unsolicited manner, given that such an action might be considered in breach of the Code. Should the complainant desire a copy of the clinical papers mentioned in the initial complaint, a simple request to the medical information department would be all that was necessary.

## FINAL COMMENTS FROM COMPLAINANT

The complainant noted that his complaint was in respect of Sanofi-Aventis' failure to respond to a reply paid card requesting clinical papers for rimonabant (Acomplia). The card was completed and returned on 9 July and requested that four clinical papers were delivered to the practice along with other items, including a laptop case, that the complainant thought the practice might find useful.

In response to the complaint Sanofi-Aventis had stated that no card was received from the complainant although it confirmed that cards were sent to each of the named doctors and one to 'the pharmacist'. This latter card was the one returned by the complainant.

The complainant noted Sanofi-Aventis' reliance on external agencies and that it regretted that it had failed to fulfil his request in this instance. The complainant was unsure exactly what the term external agencies implied but he had already noted the small amount of mail that was lost annually by Royal Mail. If Sanofi-Aventis was referring to companies that were subcontracted to manage these cards, perhaps a more robust system of management was required.

In addition, the complainant suggested that if Sanofi-Aventis had a genuine reason to regret its failure to fulfil his request then surely it would have instructed its local representative to call on him having been given his details as part of this complaint. Sanofi-Aventis advised that any such contact might be considered an unsolicited approach.

There were several points here that were worthy of further discussion. Firstly, Sanofi-Aventis appeared to be unsure if such an approach would constitute a breach of the Code given that the phrase might be considered as unsolicited was hardly conclusive. Additionally, the fact that the complainant had complained about failure to respond to a card returned via the post surely indicated that his request was not unsolicited. The very fact that he had stated that he had returned a card meant his request was solicited and this was further reinforced by the fact that he had complained about

a failure to respond to his request.

Setting this aside, the complainant noted out that almost all visits from company representatives were unsolicited. A representative could have been dispatched to see him with instructions to apologise for not having responded earlier, explain that no card had been received and offer to correct this if he still desired it. The complainant did not believe that this could have been construed as a breach of the Code.

If this approach had not been appropriate then Sanofi-Aventis could have posted items. Clause 10 of the Code applied to provision of reprints. It stated that these could not be provided unsolicited unless they had been refereed. The supplementary information to Clause 10.1 of the Code stated that, when providing an unsolicited reprint of an article about a medicine, it should be accompanied by prescribing information. Since the main request was for clinical papers (which had been peer reviewed before publication in a journal and therefore refereed before this publication) this implied that the papers could have been mailed directly provided that prescribing information such as a summary of product characteristics was included in the mailing.

In summary, the complainant sympathised that Sanofi-Aventis might not have received his card, however he alleged that this was highly unlikely and he still could not understand the apparent lack of interest in rectifying this situation if indeed Sanofi-Aventis genuinely regretted its failure to fulfil his request. There had been ample time and opportunity to satisfy his original request but this opportunity had not been taken. Events over the last few days had meant that a request to the medical information department for the papers was now moot because the medicine had been withdrawn following recommendations from the European Medicines Evaluation Agency.

## APPEAL BOARD RULING

The Appeal Board noted Sanofi-Aventis' arrangements for dealing with responses (via reply paid cards) to its mailings. It noted Sanofi-Aventis' submission that it had not received the complainant's reply paid card and that the company had assumed that it had got lost in the post. This was disputed by the complainant. However in these circumstances the Appeal Board did not consider that the failure to deliver the requested items to the complainant prior to the submission of the complaint meant that high standards had not been maintained. The Appeal Board upheld the Panel's ruling of no breach of Clause 9.1. The appeal was unsuccessful.

<b>Complaint received</b>	<b>6 August 2008</b>
<b>Case completed</b>	<b>13 November 2008</b>