

# VOLUNTARY ADMISSION BY BAYER

## Breach of undertaking

Bayer voluntarily advised the Authority that a leaflet which ought to have been withdrawn pursuant to the provision of the undertaking in Case AUTH/1813/3/06 had subsequently been displayed at an exhibition stand at The British Association of Urological Surgeons (BAUS) conference on 29 June.

The Director decided that as the matter related to a breach of undertaking it was sufficiently serious for it to be taken up and dealt with as a complaint under the Code.

The Panel considered that an undertaking was an important document. It included an assurance that all possible steps would be taken to avoid similar breaches of the Code in the future. It was very important for the reputation of the industry that companies complied with undertakings.

The Panel noted that the leaflet in question had been dispatched for use at BAUS prior to Bayer being advised of the Panel's ruling in Case AUTH/1813/6/06. Further to the provision of the undertaking on 30 May the leaflet was subsequently displayed in error at BAUS on 29 June. Other material sent to BAUS and caught by the undertaking was not similarly displayed.

The Panel queried whether an email dated 9 June instructing staff about the withdrawal of the material was adequate. It began 'As a result of a complaint from Lilly and following discussions with the ABPI code of practice, Bayer have agreed to remove all reference to ...'. It was not clear from the email that Bayer was required to withdraw the material as a result of a ruling of a breach of the Code; by stating that Bayer had agreed to withdraw the material it appeared that such action was a result of informal discussions between it, Lilly and the 'ABPI code of practice'. It was beholden upon companies to ensure that the information they gave to their employees about materials ruled in breach of the Code was clear. Nonetheless the email listed the leaflet as one of thirteen items that were to be withdrawn with immediate effect.

The Panel considered that, despite Bayer's submission that failure to withdraw the leaflet was an oversight, the company had breached its undertaking. A breach of the Code was ruled which was accepted by the company. The Panel further considered that Bayer had not maintained high standards and had brought discredit upon, and reduced confidence in, the pharmaceutical industry. Breaches of the Code were ruled which were upheld upon appeal, including the Panel's ruling of a breach of Clause 2. The Code of Practice Appeal Board also decided to require an audit of Bayer's procedures in relation to the Code.

Upon receipt of the audit report and Bayer's comments upon it the Appeal Board noted that there was much work to be done by Bayer on its standard operating procedures. This was a matter of urgency. Taking all the circumstances into account the Appeal Board decided that Bayer should be reaudited in July 2007.

Bayer plc, Pharmaceutical Division, voluntarily advised the Authority that a leaflet (ref 6LEVI13) which ought to have been withdrawn pursuant to the provision of the undertaking in Case AUTH/1813/3/06, had subsequently been displayed at an exhibition stand at The British Association of Urological Surgeons (BAUS) conference on 29 June 2006.

## COMPLAINT

The Director decided that as the matter related to a breach of undertaking it was sufficiently serious for it to be taken up and dealt with as a complaint under the Code. Bayer was asked to respond in relation to Clauses 2, 9.1 and 22 of the Code.

## RESPONSE

Bayer explained that the inadvertent use of the leaflet following on from its undertaking to withdraw all materials incorporating the 10 minute claim at issue in Case AUTH/1813/3/06 was a complete oversight. Nevertheless Bayer agreed that such an omission constituted a breach of Clauses 2, 9.1 and 22.

Promotional materials for the stand were despatched to the exhibitor managing the stand at BAUS in early May, prior to the Panel's ruling on the 10 minute claim on 19 May and prior to the company's undertaking to no longer use materials containing the 10 minute claim dated 30 May.

Prior to attending BAUS, Bayer knew that some items it had planned to use could no longer be displayed on the stand eg reprints of Montorsi *et al* (2004) (10 minute study) and a poster containing the 10 minute claim. The staff manning the stand failed to realise that the leaflet at issue also contained the 10 minute claim and therefore should not have been used. In error, it was displayed on the stand. As a result of this error, procedures were now in place to ensure that no materials appeared on a stand without approval of key personnel.

Bayer provided copies of its relevant standard operating procedure (SOP) which it submitted was adequate. The problem in this instance was non-

adherence to the SOP which it was confident would not happen again.

Bayer also provided a copy of an email announcing the withdrawal of, *inter alia*, the leaflet at issue as a result of the ruling in Case AUTH/1813/3/06.

## PANEL RULING

The Panel considered that an undertaking was an important document. It included an assurance that all possible steps would be taken to avoid similar breaches of the Code in the future. It was very important for the reputation of the industry that companies complied with undertakings.

Case AUTH/1813/6/06 concerned Levitra and the SortEDin10 campaign; breaches of the Code were ruled, *inter alia*, in relation to promotion of the efficacy of Levitra 10 minutes after dosing.

The Panel noted that the leaflet in question had been dispatched for use at BAUS prior to Bayer being advised of the Panel's ruling in Case AUTH/1813/6/06. Further to the provision of the undertaking on 30 May the leaflet was subsequently displayed in error at BAUS on 29 June. Other material sent to BAUS and caught by the undertaking was not similarly displayed.

The Panel queried whether the email dated 9 June instructing staff about the withdrawal of the material was adequate. It began 'As a result of a complaint from Lilly and following discussions with the ABPI code of practice, Bayer have agreed to remove all reference to ...'. The email did not refer to any rulings of the Panel and so it was not clear that Bayer was required to withdraw the material as a result of a ruling of a breach of the Code; by stating that Bayer had agreed to withdraw the material it appeared that such action was a result of informal discussions between it, Lilly and the 'ABPI code of practice'. It was beholden upon companies to ensure that the information they gave to their employees about materials ruled in breach of the Code was clear. Nonetheless the email listed the leaflet as one of thirteen items that were to be withdrawn with immediate effect.

The Panel considered that, despite Bayer's submission that failure to withdraw the leaflet was an oversight, the company was in breach of its undertaking and had not maintained high standards. Breaches of Clauses 2 and 9.1 were ruled. The failure to withdraw the leaflet had brought discredit upon, and reduced confidence in, the pharmaceutical industry; a breach of Clause 2 was ruled.

## APPEAL BY BAYER

Bayer submitted that the Panel's decision to treat this as a serious breach and so invoke Clause 2 of the Code was unreasonable. The consequences of the ruling, especially the requirement to publish Bayer as having 'brought discredit upon and reduced confidence in the

pharmaceutical industry' were disproportionate. The 'discovery' by a Lilly employee that one of sixteen withdrawn promotional pieces was inadvertently displayed at one meeting was not comparable to serious breaches of the Code, especially recent examples of breaches of Clause 2. Nor did the company consider that it should be regarded as having failed to maintain high standards (Clause 9.1) for a single omission of a minor nature.

Bayer submitted that following receipt of the Panel's ruling in Case AUTH/1813/3/06, it was made very clear to employees that all materials in which the claim in question was used had to be withdrawn immediately. The instruction was in accordance with Bayer's SOP. On reviewing another SOP about the withdrawal of promotional materials no longer compliant with the Code, Bayer had decided to add that the '[Marketing Manager] will be responsible for checking additional distribution routes for the materials in question and preventing any usage'. This would deal with the situation arising in this case.

Bayer submitted that in this case, sixteen such items were identified, including the leaflet at issue. In one instance, this single piece was inadvertently displayed at a congress. All of the materials for this congress had been ordered for distribution prior to the Panel ruling but during the process of intercepting these materials, the company which was building the exhibition stand on Bayer's behalf overlooked the leaflet in question. This was subsequently identified by an employee of Lilly who approached Bayer about this oversight. In discussion with Lilly, Bayer agreed to voluntarily admit a breach of the Code to the Authority. Bayer had accepted that the undertaking given not to utilise these pieces further had been breached and also that this was not a trivial issue.

Bayer submitted that the Panel's ruling of breaches of Clauses 2 and 9.1 was out of proportion, especially with the decision to name and shame the company as bringing discredit upon the industry by this regrettable administrative oversight. If the Appeal Board upheld a breach of Clause 2, then it asked that consideration be given not to require such a breach to be publicised in the medical and pharmaceutical press on the basis that published breaches of Clause 2 were usually related to deliberate flouting of the Code.

Bayer referred to a number of past cases which concerned breaches of Clauses 2 and 9.1 of the Code.

## APPEAL BOARD RULING

The Appeal Board noted from Bayer's representatives that the leaflet in question together with a number of other items had been dispatched for use at BAUS prior to Bayer being advised of the Panel's ruling in Case AUTH/1813/6/06. The agency responsible for setting up the stand at the BAUS meeting on 29 June was subsequently supplied with a list of items which were not to be used at the meeting. The leaflet at issue was missing from that list. A Bayer employee was responsible for ensuring that no materials in breach of

the undertaking were displayed on the stand. However, approximately 50 copies of the leaflet at issue were placed on the stand of which approximately 10 were taken. Bayer could not provide exact figures.

The Appeal Board was concerned that material had not been withdrawn as a result of the undertaking. No date for final withdrawal of material had been given in the email from Bayer instructing staff about the withdrawal of material. Bayer's representatives submitted that it relied upon its field force and regional managers to return items. The Appeal Board considered this process inadequate.

The Appeal Board noted from the Bayer representatives that Lilly had written to Bayer on 19 July to advise it that the leaflet at issue had been found on the exhibition stand; the voluntary admission was dated over six weeks later on 1 September. The letter from Lilly had not been provided by Bayer. Bayer's representatives submitted that the delay in sending the company's voluntary admission to the Authority was due to intercompany communications concerning this and other matters. The Appeal Board considered this explanation to be inadequate.

The Appeal Board considered that Bayer's email of 9 June instructing staff to withdraw material was inadequate. It began 'As a result of a complaint from Lilly and following discussions with the ABPI code of practice, Bayer have agreed to remove all reference to ...'. The email did not refer to any rulings of the Panel and so it was not clear that Bayer was required to withdraw the material as a result of a ruling of a breach of the Code; by stating that Bayer had agreed to withdraw the material it appeared that such action was a result of informal discussions between it, Lilly and the 'ABPI code of practice'. It was beholden upon companies to ensure that the information they gave to their employees about materials ruled in breach of the Code was clear. The Appeal Board considered that the email sought to downplay the situation. Nonetheless the email listed the leaflet as one of thirteen items that were to be withdrawn with immediate effect.

The Appeal Board considered that an undertaking was

an important document. It included an assurance that all possible steps would be taken to avoid similar breaches of the Code in the future. It was very important for the reputation of the industry and of self-regulation that companies complied with undertakings.

The Appeal Board noted that Bayer had accepted the Panel's ruling of a breach of Clause 22. In failing to withdraw the leaflet, the company had not maintained high standards. The Appeal Board upheld the Panel's ruling of a breach of Clause 9.1. The failure to withdraw the leaflet had brought discredit upon, and reduced confidence in, the pharmaceutical industry. The Appeal Board upheld the Panel's ruling of a breach of Clause 2. The appeal was unsuccessful.

The Appeal Board was concerned that Bayer's original voluntary admission was not a full and fair account of all the circumstances, and further it was concerned about the apparent failings in Bayer's procedures to comply with undertakings given in respect of the Panel's rulings. The Appeal Board was also concerned that the email of 9 June was inadequate. The Appeal Board decided in accordance with Paragraph 10.4 of the Constitution and Procedure to require an audit of Bayer's procedures in relation to the Code.

#### **CONSIDERATION OF THE AUDIT REPORT BY THE APPEAL BOARD**

Upon receipt of the audit report and Bayer's comments upon it the Appeal Board noted that there was much work to be done by Bayer to produce, implement and train out standard operating procedures. This was a matter of urgency. Taking all the circumstances into account the Appeal Board decided that Bayer should be reaudited in July 2007.

<b>Proceedings commenced</b>	<b>4 September 2006</b>
<b>Undertaking received</b>	<b>18 December 2006</b>
<b>Appeal Board consideration</b>	<b>22 February 2007</b>