

VOLUNTARY ADMISSION BY BOEHRINGER INGELHEIM

Failure to certify the final form of promotional material

Boehringer Ingelheim voluntarily admitted a breach of the Code in that a recent review of materials showed that a number of job bags had not received an extra signature to confirm that the certified electronic material matched the final printed hard copy.

In accordance with Paragraph 5.6 of the Constitution and Procedure, the Director treated the matter as a complaint.

The detailed response from Boehringer Ingelheim is given below.

The Panel noted that Boehringer Ingelheim, in its initial letter referred to 'a number' of promotional job bags which showed that the final printed copy of the material had not been checked to ensure that it matched the previously approved final electronic version. The Panel was disappointed that the company had not revealed the extent of the matter at the outset; just over 1 in 3 of a sample of nearly 275 job bags were affected (103). The problem appeared to be widespread. Nonetheless, Boehringer Ingelheim had subsequently checked the material and found that in all cases the final form matched that which had been electronically approved. However, the Code required the printed material to be checked against the electronic copy before use and this had not happened. Breaches of the Code were ruled including that high standards had not been maintained.

Boehringer Ingelheim Limited voluntarily admitted a breach of the Code with regard to the certification of promotional material.

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 Boehringer Ingelheim.

VOLUNTARY ADMISSION

Boehringer Ingelheim stated that a recent review of materials showed that a number of hard copy job bags had not received an extra signature to confirm that the electronic material, which had been viewed and certified in Zinc, matched the final printed hard copy of the material as required by the supplementary information to Clause 14.1 which stated that, 'When such material is printed the company must ensure that the printed material cannot be used until any one of the company's signatories has checked and signed the item in its final form. In such circumstances the material will have two certificates and both must be preserved'.

Boehringer Ingelheim submitted that it had since checked all the job bags and found that in all cases the final form matched that which was certified

electronically. Boehringer Ingelheim voluntarily admitted a breach of Clause 14.1.

Boehringer Ingelheim submitted that following review of the job bags it changed its approval process and communicated this to staff to prevent a reoccurrence of this breach of the Code.

Boehringer Ingelheim was asked to provide the Authority with any further comments in relation to the requirements of Clauses 9.1 and 14.1.

RESPONSE

Boehringer Ingelheim submitted that it had conducted a full review of a sample of approximately 275 hard copy job bags and found 103 which did not comply with the supplementary information to Clause 14.1. All of these job bags had been correctly certified in Zinc and in each case there was no difference between the final electronic copy and the physical item. However, Boehringer Ingelheim accepted that these job bags did not comply with the Code.

Boehringer Ingelheim stated that to correct the issue it had:

- 1 Immediately issued a deviation to the existing standard operating procedure (SOP) and now required a physical certificate to be attached to the printed material. The importance of correct certification had been communicated to the business.
- 2 Instituted a process for hard copy job bags to be checked before materials were used.
- 3 Instituted an interim secondary check by the healthcare compliance function before archiving hard copy job bags.
- 4 Instituted quarterly monitoring of a sample of job bags, including hard copy job bags.

With regard to Clause 9, Boehringer Ingelheim submitted that by not ensuring that this final action in the certification process took place, it acknowledged that it had not maintained high standards in this instance.

PANEL RULING

The Panel noted that Boehringer Ingelheim, in its initial letter to the Authority, had referred to 'a number' of promotional job bags which showed that the final printed copy of the material had not been checked to ensure that it matched the previously approved final electronic version to which no subsequent amendments would be made. The Panel was disappointed that the company had not revealed

the extent of the matter at the outset; over 1 in 3 of a sample of nearly 275 job bags were affected (103). The problem appeared to be widespread. Nonetheless, Boehringer Ingelheim had subsequently checked the material and found that in all cases the final form matched that which had been electronically approved. However, the Code required the printed material to be checked against the electronic copy before use and this had not happened in a sizeable proportion of cases. A breach of Clause 14.1 was ruled. The Panel considered that the failure to certify the final printed

form of the material meant that high standards had not been maintained; a robust certification procedure underpinned self-regulation. A breach of Clause 9.1 was ruled. The Panel noted that once it knew of the error, Boehringer Ingelheim had taken steps, including amending its SOP, to ensure that final printed copies of material were certified in future.

Complaint received **6 July 2016**

Case completed **8 August 2016**
