

VOLUNTARY ADMISSION BY TESARO

Failure to certify material before use

Tesaro UK voluntarily admitted that seven promotional items had not been certified in their final form before being distributed to the field force.

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 Tesaro.

Tesaro submitted that the final printed copy of the material had not been checked to ensure that it matched the previously approved final electronic version.

The detailed response from Tesaro is given below.

The Panel noted Tesaro's admission that the seven items were only certified in their electronic form before the printed versions were given to its representatives for use. The Panel thus ruled a breach of the Code in relation to each item as acknowledged by Tesaro. In the Panel's view, a robust certification procedure underpinned self-regulation. It was unclear why the printed form had not been submitted for checking but reassuring that this was picked up by the relevant signatory and was the subject of a voluntary admission. The Panel noted that once it knew of the error Tesaro had taken steps to prevent its reoccurrence. The Panel considered that failing to check the final form of seven printed items meant that Tesaro had failed to maintain high standards and a breach of the Code was ruled.

Tesaro UK voluntarily admitted that in February 2018 an internal email identified that seven hard copy promotional items for Zejula (niraparib) might have been distributed to the field team before certification of their final form. Zejula was indicated in the treatment of certain epithelial ovarian, fallopian tube, or primary peritoneal cancers.

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 Tesaro.

VOLUNTARY ADMISSION

Tesaro submitted that the final printed copy of the material had not been checked to ensure that it matched the previously approved final electronic version. The hard copy materials still requiring final form signature were located.

Subsequently, a meeting between two senior employees and the nominated final signatory concluded this was a breach of the Code and a voluntary disclosure to the PMPCA was recommended under Clauses 9.1 and 14.1. An immediate internal review was conducted where a Corrective and Preventive Action (CAPA) plan was devised. A priority

recall notification was sent to the regional business manager's teams requesting the return of all materials.

A review of the database for all hard copy materials was conducted to ensure this was an isolated incident and all promotional items were certified in final form. The review established that the only items contravening the Code were the seven items previously identified. All recalled materials were reviewed and corrective measures implemented.

Tesaro stated that additional steps being implemented as part of the CAPA included retraining all personnel involved in the copy approval process (class-room training), with regular review sessions in place.

Tesaro was asked to respond to Clauses 9.1 and 14.1 of the Code.

RESPONSE

Tesaro submitted that in February 2018 an internal email identified that seven promotional (hard copy materials) might have been distributed to the field team prior to certification of their final form. The incident was first recognised in a call between the company's final medical signatory and product business manager, where the medical signatory claimed to have not seen the final form of materials after their initial electronic certification.

In short, the final printed copy of the material had not been checked to ensure that it matched the previously approved final electronic version, in breach of Clause 14.1.

An immediate internal review was conducted and a CAPA Plan devised.

A priority recall notification was sent to the regional teams requesting return of all seven materials.

Tesaro stated that a review of the database for all hard copy materials was conducted to ensure this was an isolated incident and all promotional items were certified in final form. The review established that the only items contravening the Code were the seven items already identified.

Within four working days of identifying the issue all recalled materials were reviewed for certification based on their final hard copy form.

An internal investigation into the breach revealed that the error occurred due to an oversight by a member of staff delegating jobs to a junior colleague who did not fulfil the required actions before material distribution. This was a failure of the business to maintain high standards, as required by Clause 9 of the Code.

In order to correct this issue and ensure continued high standards were maintained, a CAPA plan had been executed, which included:

- retraining of all personnel involved in the copy approval process (class-room training), with regular review sessions in place. So, the importance of correct certification was communicated to the business
- institution of an interim secondary check upon job archiving to match physical certificates with corresponding hard copy items.

PANEL RULING

The Panel noted that Clause 14.1 stated that promotional material must not be issued unless its final form, to which no subsequent amendments will be made, had been certified by one person on behalf of the company in the manner provided for by this clause. The supplementary information to Clause 14.1 stated that when certifying material where the final form was to be printed companies could certify the final electronic version of the item to which no subsequent amendments would be made. When such material was printed the company must ensure

that the printed material could not be used until any one of the company's signatories had checked and signed the item in its final form. In such circumstances the material would have two certificates and both must be preserved.

The Panel noted Tesaro's admission that the seven items were only certified in their electronic form before the printed versions were given to its representatives for use. The Panel thus ruled a breach of Clause 14.1 in relation to each item as acknowledged by Tesaro. In the Panel's view, a robust certification procedure underpinned self-regulation. It was unclear why the printed form had not been submitted for checking but reassuring that this was picked up by the relevant signatory and was the subject of a voluntary admission. The Panel noted that once it knew of the error Tesaro had taken steps to prevent its reoccurrence. The Panel considered that failing to check the final form of seven printed items meant that Tesaro had failed to maintain high standards and a breach of Clause 9.1 was ruled.

Complaint received **9 February 2018**

Case completed **31 May 2018**