

CASE AUTH/2717/5/14 VOLUNTARY ADMISSION BY ROCHE

Number of pages of advertising

Roche voluntarily admitted that that an edition of the British Journal of Haematology (BJH) bore advertising for MabThera (rituximab) on four pages. 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 Roche.

Roche explained that it was informed by its media buying agency that due to the inadvertent inclusion of a two page MabThera bound-in card by the printing house, two separate double page advertisements for MabThera appeared in the May-II edition of BJH.

The detailed response from Roche is given below.

The Panel noted that Roche's printing agency had in error included two double page advertisements for MabThera in the May-II edition of the BJH; one appeared on the inside and outside back cover and the other appeared in the form of a double sided bound-in card. The Panel noted that the double sided bound-in card was originally supplied for publication in the June-I edition of BJH. Correct details about the publication dates had been provided to both the media buying agency and the printers.

The Panel noted that the printers had accepted responsibility for the error. Nonetheless, it was an accepted principle under the Code that pharmaceutical companies were responsible for the acts or omissions of those who worked on their behalf. In the Panel's view, Roche had been let down by the printers. That four pages of the journal bore advertising for MabThera was a clear breach of the Code as acknowledged by Roche; the Panel ruled accordingly.

Roche Products Ltd voluntarily admitted that an edition of the British Journal of Haematology (BJH) bore advertising for MabThera (rituximab) on four pages. 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 Roche.

VOLUNTARY ADMISSION

Roche explained that it was informed by its media buying agency that due to the inadvertent inclusion of a two page MabThera bound-in card by the printing house, two separate double page advertisements for MabThera appeared in the 19 May edition of BJH.

Roche noted that inclusion of four pages of advertising for a product in a journal was in breach of the requirement that no issue of a journal may bear advertising for a particular product on more than two pages.

Roche stated that the advertisements were certified separately as required by Clause 14.1 and were never intended to appear together in the same publication. A letter from the printing house explained that it was the result of human error by one of its client service representatives. The representative in question had been counselled and understood the severity of the issue and a secondary detailed checklist had since been implemented to make certain that no errors of that description would occur again. All information would be double checked against the checklist going forward and all client representatives had been coached on the extra procedure.

Roche accepted overall responsibility for the actions of any third party acting on its behalf and therefore acknowledged a breach of Clause 6.3. Roche noted that it was committed to the appropriate use of medicines, protecting the safety of patients and strove to maintain high standards in the ethical promotion of its medicines. As such the company and its employees understood the strict requirements of UK medicines regulations and the Code. On discovering the issue, the matter was appropriately escalated to senior management and a thorough investigation carried out to understand the root cause of the issue.

Roche worked with the agency and publisher to understand the full facts so that it could identify any necessary preventative actions to prevent future reoccurrence. When writing to confirm that the matter would be taken up under the Code, the Authority asked Roche to provide any further comments it might have in relation to Clause 6.3.

RESPONSE

Roche submitted that an advertisement for MabThera subcutaneous (sc) was planned to be included in the May-II edition of the BJH. The advertisement position was the outside back cover with the prescribing information on the inside back cover. A separate two page advertisement, taking the form of a bound card, was planned to be included in the next edition, June-I. Due to human error, the bound card was included in the May-II edition meaning that there were four pages of MabThera sc advertising in one edition. Both advertisements (ref RXUKMABO00662e and RXUKMABO00662f) had been separately certified and were never intended to appear in the same edition. Roche submitted that the parties involved were the media buying agency, the publishing company for BJH, printers of the bound card and the printing agency.

Roche submitted that its standard operating procedure (SOP) on approval and certification stated 'A contract and a project confirmation form (where applicable) must be in place with any third party used in the production of materials or involved in activities that come within the scope of the ABPI Code of Practice. All parties involved in the production of such materials/activities, working on Roche's behalf or under Roche's instruction, must be fully aware of any procedural requirements in those contracts/project confirmation forms (PCF) as well as the requirements of this SOP'. As stated within the SOP, it was standard practice within Roche to have both a contract and project confirmation form in place with each third party supplier. All contracts included provisions for both the third party supplier with whom Roche was directly contracting and any subcontractors with whom the third party supplier engaged to carry out activities on its behalf. A copy of the master service agreement (msa) with the media buying agency provided by Roche stated that the agency would perform the services under the agreement and under any project confirmation, in compliance with all applicable national and international laws, rules, regulations, the Code and industry guidelines as amended from time to time.

Roche provided a detailed chronology of events. As a result of its investigation, Roche noted that the inclusion of the MabThera bound-in card intended for the June-I issue in the May-II issue was due to human error at the printers. Roche submitted that the root causes of the breach were as follows:

- 1 The bound-in card intended to be included in the May-II edition was late arriving at the printers. The Roche bound-in card had already arrived at the printers ready for use in the June-I issue. The client services representative at the printer wrongly assumed that the Roche bound-in cards were to be included in the May-II edition. The 'make up' was not checked by the client services representatives in order to confirm which bound-in card should be included.

2 There was no second check performed by the printers prior to mass-printing and collation of the journal, nor prior to journal distribution. 3 There was a second check performed by the publishers but this was an online check only of the regular journal pages and hence only included review of non-bound-in pages. Therefore the publishers would not identify the presence of an incorrect bound card. Roche explained that preventative actions included the following:

1 The printers had implemented a revised workflow and secondary detailed checklist, a copy of which was provided, in an attempt to ensure no similar errors would occur again. Roche provided copies of the previous process and highlighted the points at which extra line management checks would be implemented to avoid any future issues. Further information provided by Roche showed the previous paperwork and the two extra pieces of paperwork which were now required as a final safeguard. All information would be double checked against the aforementioned paperwork going forward. Additionally, all client services representatives had been trained on the new procedure.

2 Roche would communicate the breach internally to all relevant employees and request that all franchise teams inform all agencies involved with journal advertisements of the breach and ask them to review their own processes to ensure that a similar breach could not occur. In response to a query from the case preparation manager, Roche explained that its standard agency contract contained provisions requiring the agency to comply with the Code and required each agency to be trained in Code aspects relevant to their work. All contracts contained provisions regarding subcontractors in that they must also conform to the same requirements. The media buying agency's contract contained all those provisions. Roche submitted that as stated in its previous correspondence, it was committed to the appropriate use of medicines and protecting the safety of patients and strove to maintain high standards in the ethical promotion of its medicines and as such the company and its employees understood the strict requirements of UK medicines regulations and the Code.

PANEL RULING

The Panel noted that Roche's printing agency had in error included two double page advertisements for MabThera in the May-II edition of the BJH; one appeared on the inside and outside back cover and the other appeared in the form of a double sided bound-in card. The Panel noted that the double sided bound-in card was originally supplied for publication in the June-I edition of BJH. Correct details about the publication dates had been provided to both the media buying agency and the printers. The Panel noted from an email provided by Roche, that the printers had accepted responsibility for the error. Nonetheless, it was an accepted principle under the Code that pharmaceutical companies were responsible for the acts or omissions of those who worked on their behalf. In the Panel's view, Roche had been let down by the printers. That four pages of the journal bore advertising for MabThera was a clear breach of Clause 6.3 as acknowledged by Roche; the Panel ruled accordingly.

Complaint received 23 May 2014

Case completed 1 July 2014