MEDIA/DIRECTOR v ROCHE

Newspaper article about Herceptin

An article entitled 'The selling of a wonder drug' which appeared in the g2 supplement to The Guardian on 29 March criticized Roche's promotion of Herceptin (trastuzumab). In accordance with established practice the matter was taken up by the Director as a complaint under the Code.

The article alleged that Roche, or its public relations agency, tried to use a patient as part of its marketing strategy. It was also alleged that Roche organized a think tank for journalists paying each £250 for their time and giving them dinner in an expensive restaurant. The journalists were asked for their opinions on how best Roche could get stories into the media about its medicine for breast cancers that had spread to the bones.

The Panel noted that the article referred to a conversation between a named breast cancer patient and the spokeswoman from Roche who was reported as stating '… we're running a big campaign to promote Herceptin …' and 'Either we could find funding for Herceptin or … there would be fees for appearances [at seminars]'. Roche denied that it or its agency ever offered the patient a financial incentive to become involved or arranged access to treatment or asked her to promote Herceptin or speak at seminars. The Panel noted Roche's submission that its public relations agency had had a short conversation with the patient to ask her if she was interested in being involved in a disease awareness programme for breast cancer patients; the patient had already talked publicly about her disease. The Panel noted that the accounts differed significantly and there was little evidence. The Panel did not accept that the information before it was such as to show unequivocally that Roche had attempted to recruit the patient to promote Herceptin, that it had promoted Herceptin to her or that it had encouraged her such that she would ask her doctor to prescribe Herceptin. No breach of the Code was ruled.

The Panel noted that Roche had organised a media 'think tank' in March 2006. The Code did not prohibit such activity. Information made available directly or indirectly to the public about medicines such as via the press had to comply with the Code. The article stated that the journalists were asked how best the company could get stories in the media about its medicine for breast cancers that had spread to the bone. Roche stated that it was not the purpose of the meeting to get journalists to support a campaign for Herceptin. The aim was for the journalists to be used in an advisory capacity to talk about metastatic bone pain and breast cancer and cancer capacity within the NHS. It was to help Roche understand what journalists needed, what interested them and how to provide them with the right information. Roche did not provide information for publication. Confidentiality agreements were signed. [Note: Roche subsequently admitted that, due to an error, confidentiality agreements had not in fact been signed on this occasion.]

The Panel noted that again the accounts differed. Roche had not provided information to the journalists for publication, it had sought advice from them. On the basis of the information before it, the Panel considered that the activity did not constitute advertising prescription only medicines to the general public nor did it consider that information about medicines had been made available to the public either directly or indirectly. Thus the Panel ruled no breach of the Code.

With regard to the actual meeting the Panel noted that the supplementary information to the 2006 Code specifically stated that meetings for journalists had to comply with the Code. This was a requirement newly introduced into the 2006 Code. The relevant requirements of the 2003 Code only applied to hospitality provided to health professionals or appropriate administrative staff. The Panel noted that during the period 1 January 2006 to 30 April 2006, no activity could be regarded as being in breach of the 2006 Code if it failed to comply with its provisions only because of requirements newly introduced. Thus the Panel ruled no breach of the Code.

The Panel noted its rulings of no breach of the Code above and considered that, in consequence, there thus could, *inter alia*, be no breach of Clause 2 of the Code.

The journalist did not appeal but stated that contrary to Roche's submission, she had not been asked to sign a confidentiality agreement. Roche was asked to comment.

Roche stated that contrary to its response to the complaint, it had subsequently discovered that confidentiality agreements had not been signed by journalists. This only came to light because it investigated the point raised by the journalist in her letter to the Authority in which she commented upon, but did not appeal, the Panel's ruling.

The matter was referred to the Appeal Board which noted that the Code did not require confidentiality agreements to be signed. The Appeal Board was extremely concerned that Roche had stated that confidentiality agreements had been signed by journalists when this was not so; by stating that confidentiality agreements were signed when they were not, Roche had implied that by writing the article the journalist in question had breached a confidentiality agreement. The Appeal Board

considered this matter to be of the utmost seriousness. It was unacceptable to present assumptions as fact. It was of paramount importance that submissions to the Authority were checked for accuracy as the effectiveness of self regulation relied upon the integrity of the information provided by pharmaceutical companies. Roche had failed to provide accurate information to the Panel.

The Appeal Board decided in accordance with Paragraph 11.3 of the Constitution and Procedure that the Authority should carry out an audit of Roche's procedures in relation to the Code. In addition the Appeal Board decided to publicly reprimand Roche.

Upon receipt of the audit report the Appeal Board was concerned about arrangements for a meeting outside the UK and the management of the standard operating procedures. The Appeal Board decided that Roche should be reaudited in June/July 2007. The reaudit should include an update on the relationship between the UK and Head Office.

An article entitled 'The selling of a wonder drug' which appeared in the g2 supplement to The Guardian on 29 March criticized Roche's promotion of Herceptin (trastuzumab). In accordance with established practice the matter was taken up by the Director as a complaint under the Code.

COMPLAINT

The article alleged that Roche, or its public relations agency, tried to use a patient as part of its marketing strategy. It was also alleged that Roche organized a think tank for journalists paying each £250 for their time and giving them dinner in an expensive restaurant. The article also stated that the journalists were asked for their opinions on how best the company could get stories into the media about its medicine for breast cancers that had spread to the bones.

When writing to Roche, the Authority asked it to respond in relation to Clauses 2, 9.1, 20.1, and 20.2 of the 2003 edition of the Code.

RESPONSE

Roche stated that it had never set out to promote Herceptin to the public or encourage members of the public to request the medicine by name. The breast cancer patient named in the article had been approached by Roche's public relations agency shortly after her appearance in The Observer on 22 May 2005 in which she talked about her HER2 positive breast cancer. The patient was asked if she would be interested in becoming involved in a project that was being considered (but never actually completed) at the time called 'HER right to know'. This project was about a general disease awareness in women diagnosed with breast cancer ie awareness of specific diagnostic tests that should be conducted on their tumour.

In the interests of balance and integrity, the awareness would have involved all diagnostic tests that should be conducted, such as HER2, PR (progesterone receptor) and ER (estrogen receptor) and not an individual test or any specific treatment. As the conversation with the patient, when she said that she was not interested in taking part, was short, Roche's agency was unable to outline the full scope of this planned activity. No pressure was placed on the patient to participate in the project when she said she was not interested. Roche noted that 'HER right to know' had not developed, as the company considered that it had been superseded by a Department of Health (DoH) campaign to ensure that every breast cancer patient had access to a HER2 test.

Roche had decided to invite the patient to participate in the programme because of her previous willingness to appear in The Observer talking about her breast cancer and as a guest on television and radio discussion programmes. Roche stated that neither it nor its agency ever offered her a financial incentive to become involved, or arranged access to the treatment, or asked her to promote Herceptin or speak at seminars.

Roche stated that the telephone call had been misrepresented in the g2 article and the allegation that Roche was 'running a big campaign to promote Herceptin' was untrue. Indeed Roche's approach was more accurately represented in this article by the patient who stated that it had provided facts when asked but that Roche 'did not help her campaign at all', and 'they don't want any involvement with the campaign'.

In response to the issue of safety and efficacy that was discussed in the article, Herceptin was licensed in metastatic breast cancer in 2000. Herceptin was appropriate for the 1 in 5 breast cancer patients who had amplification of the HER2 gene.

Four independent studies had been conducted in the use of Herceptin in adjuvant disease. In April 2005 the National Cancer Institute announced the first in a series of results for Herceptin use in the adjuvant setting showing a 52% reduction in the risk of breast cancer relapse in HER2 positive patients. Three weeks later the Breast International Group made an unplanned presentation to the American Society of Clinical Oncology (ASCO) announcing the HERA data, from a pre-planned interim analysis. Data from these trials received an extremely strong response from ASCO attendees, who included mainly oncologists, but also members of UK patient organisations. Post ASCO, it was clear that the data had had a high impact globally, with oncologists around the world changing practice ahead of an official licence. The data were subsequently published as two separate papers and an editorial in the New England Journal of Medicine in October 2005. This issue of the journal included the two pivotal studies, and an editorial which included a comment that some patients might be cured. This was the most prestigious journal in the world, and none of the comments in it were influenced by Roche. It was this publicity and the extraordinary results of these

studies which had led to the unprecedented public and media awareness leading onto the issue of access to treatment. It was not due to a campaign organised by Roche as alleged.

In line with Clause 20.2 information about these new data and publications was communicated to the media via press releases, copies of which were provided. Roche had also sent these press releases to relevant patient organisations, so they had factual and accurate information to enable them to answer media calls that they received. Roche also answered further factual questions from these charities, such as questions about cost, on request.

Given the strength of the data, the strong clinical support for Herceptin, the patient group support for the medicine and the media environment (eg Kylie Minogue's recent breast cancer diagnosis) the news was widely covered. The newspapers continued their interest in the medicine and breast cancer. Over this time, Roche answered many media queries and responded to questions. On occasion the company had also had to send out separate press statements to clarify facts and correct mis-reporting. However Roche had also refused interviews with media and participation in TV programmes so as to avoid fuelling the media debate around Herceptin – especially at a time when Roche's regulatory submissions were being made.

Roche noted that the article in The Guardian referred to a survey to see how many of the women who were suitable were getting Herceptin which was then given to a cancer charity. The data to which the journalist referred was developed in 2002 following the NICE approval of Herceptin in metastatic disease. A robust algorithm was developed, and by using Roche sales data, implementation of NICE guidance across cancer networks was audited. Over a period of about 12 months leading experts, clinicians and finally patient organisations including the cancer charity were informed of this data within private discussions, and the outcomes discussed. There was major interest and eventually Roche agreed that the charity could use the data at its meeting in October 2003. Roche noted that it had provided the charity with the complete data set and support from its PR agency, but had had no direct involvement with the press activity that followed. It was clearly stated in the main body of the press release that the data had been supplied by Roche.

The NICE implementation audit was still widely used today. Roche updated the data approximately every 6 months and continued to share it with all interested parties. Given that implementation of NICE guidance was of major importance to many, the audit had been used or referred to in numerous external presentations, and cited as a model of best practice.

Roche noted that, further to the reference in The Guardian article to the funding of the charity, a letter from the charity in April 2006 clarified that, contrary to what had been reported, it received 7% of funding from pharmaceutical companies (of which only 0.26% was from Roche), and not the 31% that had been inaccurately reported.

Roche further noted that the article suggested that the company hoped to get support from patient groups, opinion leaders and journalists. In this regard Roche organised a media 'think tank' on 6 March 2006 but not with the purpose of getting journalists to support a campaign for Herceptin. The aim of the event was to bring about ten journalists together in an advisory capacity to talk about metastatic bone pain and cancer capacity within the NHS. The 'think tank' was devised to help Roche understand what journalists needed, what interested them and how to provide them with the right information. Roche reiterated that this advisory meeting was not to talk about Herceptin. It was usual for companies to consult a wide range of audiences to understand their knowledge of diseases and their impact on patients and society. When seeking strategic insight from these parties it was standard practice for confidentiality agreements to be signed, and for honoraria to be offered for participants' time, expertise and expenses. Roche submitted that the event complied with the Code.

Roche provided the invitation, agenda, and presentations from the evening. All the journalists signed confidentiality agreements which confirmed that Roche was not providing them with information that it wanted them to publish. [Note: Roche subsequently admitted that, due to an error, confidentiality agreements had not in fact been signed on this occasion.] In recognition of their time and professional expertise attendees were offered an honorarium of £200 (not £250 as reported in The Guardian). In all communication it was clearly stated that their attendance was requested for their counsel and expert contribution to the meeting discussions. The event was held in central London at a total cost per head of £50.

Invitations were sent to health correspondents at a range of media outlets. The author of the article at issue attended the meeting and the dinner which followed. She was invited because The Guardian was a respected newspaper, and like all newspapers guarded its independent reputation. In particular the author was known to take an investigative approach which Roche decided would give it a wider insight on the specific needs of a wide range of journalists and the media's needs. There was no intention to secure media coverage from the information provided at this event and indeed none to date had appeared which was not surprising in view of the confidentiality agreement. [Note: As indicated above Roche subsequently admitted that confidentiality agreements were not signed.]

Roche considered it conducted responsible activities that adhered to the Code, and did not compromise the impartiality and integrity of patient groups. Roche considered that its actions had not discredited the industry (Clause 2), that high standards had been maintained (Clause 9.1) and that it had not advertised a prescription only medicine to the general public (Clause 20.1). Similarly, information released by the company to the media was factual and presented in a balanced way; Roche had never sought to encourage members of the public to ask their doctor for a specific medicine (Clause 20.2).

PANEL RULING

The Panel noted that the published article referred to the conversation between a named breast cancer patient and the spokeswoman from Roche who was reported as stating '… we're running a big campaign to promote Herceptin …' and 'Either we could find funding for Herceptin or … there would be fees for appearances [at seminars]'. Roche denied that it or its agency ever offered the patient a financial incentive to become involved or arranged access to treatment or asked her to promote Herceptin or speak at seminars. The Panel noted Roche's submission that its public relations agency had contacted the patient to ask her if she was interested in being involved in a disease awareness programme for breast cancer patients; she had already talked publicly about her disease. Roche had submitted that the conversation was short. The Panel noted that the accounts differed significantly and there was little evidence. The Panel did not accept that the information before it was such as to show unequivocally that Roche had attempted to recruit the patient to promote Herceptin, that it had promoted Herceptin to her or that it had encouraged her such that she would ask her doctor to prescribe Herceptin. No breach of Clauses 20.1 and 20.2 was ruled.

The Panel noted that Roche had organised a media 'think tank' on 6 March 2006. The Panel noted that the Code did not prohibit pharmaceutical companies from consulting with journalists about the media or the placing of stories etc. Information made available directly or indirectly to the public about medicines such as via the press had to comply with the Code. The article stated that the journalists were asked how best the company could get stories in the media about its medicine for breast cancers that had spread to the bone. Roche stated that it was not the purpose of the meeting to get journalists to support a campaign for Herceptin. The aim was for the journalists to be used in an advisory capacity to talk about metastatic bone pain and breast cancer and cancer capacity within the NHS. It was to help Roche understand what journalists needed, what interested them and how to provide them with the right information. Roche did not provide information for publication. Confidentiality agreements were signed. [Note: Roche subsequently admitted that, due to an error, confidentiality agreements had not in fact been signed on this occasion.]

The Panel noted that again the accounts differed. Roche was not providing information to the journalists for publication, it was seeking advice from them. On the basis of the information before it, the Panel considered that the activity did not constitute advertising prescription only medicines to the general public nor did it consider that information about medicines had been made available to the public either directly or indirectly. Thus the Panel ruled no breach of Clauses 20.1 and 20.2.

With regard to the actual meeting the Panel noted that the supplementary information to Clause 20.2 of the 2006 Code specifically stated that meetings for journalists had to comply with Clause 19 of the Code. This was a requirement newly introduced into the 2006 Code. The requirements of Clause 19 in the 2003 Code only applied to hospitality provided to health professionals or appropriate administrative staff. The Panel noted that during the period 1 January 2006 to 30 April 2006, no activity could be regarded as being in breach of the 2006 Code if it failed to comply with its provisions only because of requirements newly introduced. Thus the Panel ruled no breach of Clause 19.1.

The Panel noted its rulings of no breach of the Code above and considered that, in consequence, there thus could be no breach of either Clause 9.1 or Clause 2.

The journalist did not appeal but subsequently noted that contrary to Roche's submission, she had not been asked to sign a confidentiality agreement. Roche was asked to comment and in a letter stated that contrary to its response to the complaint, the company had subsequently discovered that confidentiality agreements had not been signed by journalists. This only came to light because it investigated the point raised by the journalist in her letter to the Authority in which she commented upon, but did not appeal, the Panel's ruling.

The Authority referred the matter to the Appeal Board which decided to consider the matter formally.

APPEAL BOARD CONSIDERATION

The Appeal Board noted the submission from Roche that confidentiality agreements had not been signed on this occasion due to human error. Roche apologised for the error. Three similar 'think tanks' had already taken place where confidentiality agreements had been signed. Roche assumed that confidentiality agreements had therefore been signed at the meeting in question. The company had not verified this assumption before submitting its response to the complaint.

An external public relations (PR) agency had administered the meeting. Roche explained that typically at the outset of the meeting the PR agency would hand out confidentiality agreements to be signed which it would then collect and keep. At the three previous meetings a Roche employee had personally overseen the distribution and collection of these forms. This had not happened at the meeting at issue. Roche had a block contract with the PR agency which was then customised for each meeting by a project affirmation form. Roche could not confirm if that form specified the requirement for confidentiality agreements.

The Appeal Board noted that the Code did not require confidentiality agreements to be signed. However if a company was going to ask attendees to sign confidentiality agreements this should be made clear in advance so that invitees knew what was expected.

The Appeal Board was very concerned that by stating that confidentiality agreements were signed when they were not, Roche had implied that by writing the article

the journalist in question had breached a confidentiality agreement. It had subsequently come to light that this was not so. The Appeal Board considered this matter to be of the utmost seriousness. It was unacceptable to present assumptions as fact. It was of paramount importance that submissions to the Authority were checked for accuracy as the effectiveness of self regulation relied upon the integrity of the information provided by pharmaceutical companies. Roche had failed to provide accurate information to the Panel. This would have been easily avoided.

The Appeal Board decided in accordance with Paragraph 11.3 of the Constitution and Procedure to require an audit of Roche's procedures in relation to the Code to be carried out by the Authority. The audit would focus in particular upon Roche's relations with third parties, PR agencies, patient groups and its processes for responding to the Authority. In addition the Appeal Board publicly reprimanded Roche.

Upon receipt of the audit report the Appeal Board was concerned about arrangements for a meeting outside the UK and the management of the standard operating procedures. The Appeal Board decided that Roche should be reaudited in June/July 2007. The reaudit should include an update on the relationship between the UK and Head Office.

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