

HEAD OF MEDICINES MANAGEMENT AT A HEALTH BOARD v BAYER

Recruitment of patients for market research

The head of medicines management at a health board complained about an email sent by a market research recruitment agency inviting a hospital consultant to recruit patients for a market research project. The email stated that the agency was working on behalf of a pharmaceutical company looking particularly at stroke prevention in patients with non valvular atrial fibrillation treated with any one of four anticoagulants. Contact with patients would be via a 15 minute interview and an honourarium would be paid to patients and physicians would receive a 'finder's fee' per qualifying patient.

The complainant stated that companies should not offer inducements to health professionals for any action that was not appropriate (in this case passing on patients' details and breaking confidentiality).

The complainant explained that whilst the health board accepted that it might be possible for consultants to avoid breaking patient confidentiality, the email did not make that clear. The health board was concerned that inexperienced health professionals might break patient confidentiality and misuse NHS time and resources.

The market research agency stated that it was working on behalf of Bayer.

The detailed response from Bayer is given below.

The Panel noted that the required that market research activities must not be disguised promotion. Supplementary information to the Code referred to the guidelines from the British Healthcare Business Intelligence Association (BHBI). The Panel considered that market research had to be conducted for a *bona fide* purpose. If market research was ruled to be disguised promotion any payment was likely to be in breach of the Code. In addition, the company should be mindful of the impression created by the invitation to participate in the survey and description therein of any payment.

The complainant was concerned that the finder's fee was an inducement to break patient confidentiality. There was no mention in the materials regarding patient confidentiality. The Panel considered that health professionals would be well aware of their obligations with regard to patient confidentiality. The complainant also referred to possible misuse of NHS time and resources. The Panel considered that health professionals responding to the request would be responsible for ensuring that they followed relevant NHS policies and procedures. There was no evidence that NHS time and resources had been misused.

The email in question asked health professionals to contact the agency if interested in helping recruit patients. Such health professionals would be provided with letters to give to patients who would then contact the agency direct. The patients had to have been taking one of four treatments for at least three months; one was Bayer's medicine and the other three were competitors'. The Panel thus considered that there was no incentive to change a patient's medication to Bayer's product or to increase prescribing of it for new patients. The health professional would not pass on patient details to the agency. The finder's fee would only be paid in relation to patients who completed the survey.

Although there was no allegation that the market research was disguised promotion, in order to consider the allegations, the Panel had to address this point first. On the information before it, the Panel did not consider that the survey was disguised promotion of Xarelto and, as a consequence, it was not unreasonable to pay health professionals. The Panel noted the allegations about the payment offered and its comments above and ruled no breach of the Code in this regard.

The Panel noted that the email did not mention patient confidentiality and did not consider that the method of identifying and enrolling patients was inappropriate. The position was clearer on receipt of the further information about the arrangements, which would be sent to interested health professionals, than from the email in question. Given all the circumstances, the Panel ruled no breach of the Code including no breach of Clause 2.

The head of medicines management at a health board, complained on behalf of the health board about an email received by one of his/her consultant/ cardiologist from a market research agency inviting him/her to recruit patients for a market research project.

The email subject referred to 'Finders Fee for recruitment of patients with AF [atrial fibrillation]'. The email went on to describe the agency as an international market research company that was working on behalf of an international pharmaceutical company which wanted to speak to patients diagnosed with non valvular atrial fibrillation being treated for stroke prevention to understand more about their treatment and dosing regimen.

Potential respondents were to be over 19 and receiving one of four named treatments for at least 3 months. Xarelto (rivaroxaban) Bayer's product was one of the treatments listed with its dose as was Lixiana (edoxaban), Eliquis (apixaban) and Pradaxa

(dabigatran). Xarelto's indications included the prevention of stroke and systemic embolism in adult patients with non valvular atrial fibrillation with one or more risk factors.

The email included details of the study including that the telephone interview would take 15 minutes and that an honorarium of £30 for patients and a physician fee of £50 per qualifying patient was offered. Interested health professionals were to contact the agency for further details.

COMPLAINT

The complainant noted that although the agency was a market research company, the Code stated that pharmaceutical companies were responsible for the activities and materials that market research companies carried out on their behalf. The complainant stated that companies should not offer inducements to health professionals for any action that was not appropriate (in this case passing on patients' details and breaking confidentiality).

The complainant explained that whilst the health board accepted that it might be possible for consultants to avoid breaking patient confidentiality by first contacting their patients to gain their consent before passing on their details to the agency, the email did not make that clear. The health board was concerned that inexperienced health professionals might break patient confidentiality and misuse NHS time and resources.

In response to a request from the case preparation manager, the agency identified the relevant pharmaceutical company as Bayer.

When writing to Bayer, the Authority asked it to bear in mind the requirements of Clauses 2, 7.2, 9.1 and 18.1 of the Code.

RESPONSE

Bayer acknowledged that it was an established principle that market research must be carried out in such a way as to not contravene the Code and in accordance with the requirements of Clause 12.2, market research material must be examined. The British Healthcare Business Intelligence Association (BHBIA) code and the Legal and Ethical Guidelines for Healthcare Market Research were also relevant.

Bayer submitted that the payment offered to health professionals participating in the market research was £50 per patient who met the selection criteria and successfully completed an interview. The fee was calculated on the assumption that each physician would contact an average of six patients, in order to find one who was willing to take part in the study; each referral typically took around 5-10 minutes, therefore physicians would spend approximately 30 minutes on each patient who was recruited to take part in the study. This value was consistent with Bayer's fair market value table for the amount of work undertaken by health professionals and as such was not considered to be an inducement or an inappropriate payment. It was also important to note that the market research material referred to

all of the available direct oral anticoagulants (DOACs) with their respective licensed doses for stroke prevention in non valvular atrial fibrillation. There was no reference to Bayer and no emphasis placed on its products. Therefore it was not an inducement to prescribe any specific product and as such the activity was not in breach of Clause 18.1.

Bayer submitted that the email in question outlined the patient group of relevance to the market research, and requested that health professionals interested in recruiting patients contact the agency project manager. The email did not request patient information of any kind to be passed on. The instruction was very clear and therefore not in breach of Clause 7.2.

Bayer recognised that market research material must be examined. The email in question was sent by the agency without approval by Bayer. Bayer enclosed a copy of the communication which was intended for health professionals with evidence of examination by Bayer.

The emails between Bayer and the market research agency 22 November 2016 and the subsequent email of the same date between the market research agency and the recruitment agency, enclosing the health professional and patient letter stating they were approved by the UK and that recruitment could commence was provided.

Bayer confirmed that to date 42 health professionals had responded to the email and five had been paid the qualifying fee.

Bayer provided copies of the communication intended for health professionals and the letter that was provided to participating health professionals to pass on to patients. The letter contained details of how those patients could contact the market research recruitment agency. Bayer also provided the patient screening questionnaire that was used by the recruitment agency.

Bayer was disappointed that the email that was sent out to the health professional was not the version that it had examined. The emails from 22 November 2016 were very clear in this regard. Bayer was investigating the matter and in the interim further recruitment of health professionals had been put on hold. However, Bayer submitted that the email that was sent to the health professionals from the recruitment agency would have been approvable had it been put forward for examination and as such had not compromised patient safety. Therefore, Bayer submitted that high standards had nevertheless been maintained and refuted a breach of Clause 9.1.

Bayer submitted that the matter did not bring the industry into disrepute and therefore a breach of Clause 2 was not warranted.

PANEL RULING

The Panel noted that the email in question was from a market research recruitment agency whereas Bayer was working with another agency in relation to the survey. It appeared that market

research agency contracted the recruitment agency to help with recruitment. It was not clear why the recruitment agency had not used the agreed email. The differences between the two included listing the products strength and doses. In any event Bayer was responsible under the Code for its third party arrangements.

The only requirement in the Code that specifically mentioned market research was Clause 12.2 which provided that market research activities, clinical assessments, post-marketing surveillance and experience programmes, post-authorization studies (including those that were retrospective in nature) and the like must not be disguised promotion. They must be conducted with a primarily scientific or educational purpose. The supplementary information to Clause 12.2 referred to the BHIA Guidelines. The Panel considered that market research had to be conducted for a *bona fide* purpose. If market research was ruled to be disguised promotion contrary to Clause 12.2, any payment was likely to be in breach of Clause 18.1. In addition, the company should be mindful of the impression created by the invitation to participate in the survey and description therein of any payment.

The complainant was concerned that the finder's fee was an inducement to break patient confidentiality. There was no mention in the materials regarding patient confidentiality. The Panel considered that health professionals were responsible for patient confidentiality and would be well aware of their obligations in this regard. The complainant also referred to possible misuse of NHS time and resources. The Panel considered that health professionals responding to the request would be responsible for ensuring that they followed relevant NHS policies and procedures. There was no evidence that NHS time and resources had been misused.

The email in question asked health professionals to contact the third party agency if interested in helping

recruit patients. Such health professionals would be provided with letters to give to patients who would then contact the market research agency directly. The patients had to have been taking one of four treatments for at least three months; one was Bayer's medicine and the other three were competitors'. Given these conditions, the Panel considered there was no incentive to change patient's medication to Bayer's product or to increase prescribing of it for new patients. The health professional would not pass on patient details to the third party agency. The finder's fee would only be paid in relation to patients who completed the survey.

The Panel noted that there was no allegation that the market research was disguised promotion and thus the company had not addressed the point. However, in order to consider the allegations, the Panel had to address this point first. On the information before it, the Panel did not consider that the survey was disguised promotion of Xarelto and, as a consequence, it was not unreasonable to pay health professionals. The Panel noted the allegations about the payment offered and its comments above and ruled no breach of Clause 18.1 of the Code in this regard.

The Panel noted that the email did not mention patient confidentiality and did not consider that the method of identifying and enrolling patients was inappropriate. The position was clearer on receipt of the further information about the arrangements, which would be sent to interested health professionals, than from the email in question. Given all the circumstances, the Panel ruled no breach of Clauses 7.2, 9.1 and 2.

Complaint received **25 May 2017**

Case completed **31 July 2017**