HEALTH PROFESSIONALS v BOEHRINGER INGELHEIM

Online survey

Three complaints were received relating to an on-line survey about stroke prevention in atrial fibrillation. The matter was taken up with Boehringer Ingelheim in the UK as the survey was commissioned by its parent company Boehringer Ingelheim International GmbH. The complainants were a head of medicines management (Case AUTH/2565/11/12), a primary care trust medicines management lead (Case AUTH/2566/11/12) and a general practitioner (Case AUTH/2567/11/12).

The complainants had all been invited, by email, to participate in the survey. The selection criteria for the survey as outlined in the invitations included firstly, patients that were previously treatment naïve who had started on therapy (warfarin, Pradaxa (dabigatran) or Xarelto (rivaroxaban, Bayer's product)) in the last three months and secondly patients who were on warfarin, Pradaxa or Xarelto and who switched to a different therapy (warfarin, Pradaxa or Xarelto) in the last three months. The email stated that to complete the study, including two online patient forms, would take around 60 minutes and an honorarium of £70 was offered.

The complainant in Case AUTH/2565/11/12 was concerned at the possibility of a £5 payment for switching to a certain branded medicine.

The complainant in Case AUTH/2566/11/12 alleged that the survey was in breach of the Code and noted that he/she was not a member of the healthcare advisory board referred to in the email.

The complainant in Case AUTH/2567/11/12 queried whether the email complied with the Code or study methodology.

The detailed response from Boehringer Ingelheim is given below.

The Panel considered that the rulings set out below applied equally to all three complaints.

The Panel noted it was an established principle under the Code that UK companies were responsible for the acts and omissions of their overseas affiliates that came within the scope of the Code. The survey had been used in the UK and therefore it came within the scope of the UK Code.

The only requirement in the Code that specifically mentioned market research stated that, *inter alia*, such activities must not be disguised promotion. They must be conducted with a primarily scientific or educational purpose. The supplementary information referred to the British Healthcare Business Intelligence Association (BHBIA) Legal and Ethical Guidelines for Healthcare Market Research. The Panel noted that market research had to be conducted for a *bona fide* purpose. If market research was ruled to be disguised promotion, any payment was also likely to be in breach. A company should be mindful of the impression created by the invitation to participate in the survey and description therein of any payment.

The Panel noted that, to help it develop its business strategy, Boehringer Ingelheim GmbH had commissioned a third party to conduct an international survey about prescribing practices. The survey was conducted from July to December 2012. The third party subcontracted another company to conduct the UK fieldwork and this organisation had, itself, subcontracted another company to recruit by telephone. It was an established principle under the Code that pharmaceutical companies were responsible for work undertaken by third parties on their behalf. Thus Boehringer Ingelheim was responsible for the activities of the third party and all those subcontracted.

The Panel noted that the request for proposal document sent by Boehringer Ingelheim referred to a general market research plan which was likely to lead to a series of market research studies.

The Panel noted that at the formal kick off meeting about the survey between the third party and its subcontractor in September 2012, project objectives and survey administration details (programming) were discussed by telephone and were not documented in writing. The hard copy version of the survey provided by Boehringer Ingelheim included programming and other instructions. There was no written instruction about how the survey should be communicated to potential participants.

The invitation was written and approved by the company subcontracted by the third party. The Panel was concerned about the lack of input and/or approval by Boehringer Ingelheim of the invitation. In the Panel's view Boehringer Ingelheim should have, at the very least, satisfied itself that the invitations were not promotional.

The Panel noted that the survey itself was detailed and included screening questions about participants' roles and activities. There were detailed questions about non-valvular atrial fibrillation (NVAF) and treatment with Pradaxa and Xarelto. After completing general questions, participants were asked about a specific patient. The Panel considered that the survey focussed on the condition and general requirements about treatment. It did not focus on Boehringer Ingelheim's product.

The Panel noted that whilst the £70 payment, for completion of the survey and two patient forms, did not seem unreasonable given the submission that

the estimated time for completion was 60 minutes, the Panel was nonetheless concerned about the description of the payments in the email invitations.

The emails in Cases AUTH/2565/11/12 and AUTH/2566/11/12 were very similar but all three were different to that provided by Boehringer Ingelheim which did not have 'GBP' inserted both in the subject and email heading, and did not refer to the provision of gift vouchers. Gift vouchers were referred to in the email in question in Case AUTH/2567/11/12. The Panel made its rulings on the invitations provided by the complainants.

The email invitations in Cases AUTH/2565/11/12 and AUTH/2566/11/12 were very similar. They referred to the recipients' membership of a healthcare advisory board. The subject heading read 'Earn 70 GBP GBP honorarium: Stoke Prevention' and the invitation was headed 'Online study for 70 GBP'. Participants were asked to complete the survey and a minimum of two and a maximum of 10 patient forms. Additional honoraria of £15 were offered per additional patient form completed. Participants were '… incentivized with an extra hono of 5 GBP for each Switched to Pradaxa or Switched to Xarelto PRFs [patient record forms] completed'.

The email in question in Case AUTH/2567/11/12 was similar. The email bore a different subject heading '[details of the subcontractor] Online Study on Stroke Prevention in Non-Vascular Fibrilation'. There was no reference to membership of an advisory board. The payment was described as 'a £70 cheque or a £70 Amazon.co.uk gift certificate'. This invitation did not make it clear that the maximum of 10 patient record forms included the 2 completed within the main survey. In addition the ordering of paragraphs was such that three paragraphs detailing payments appeared at the beginning of the email before the patient selection criteria whereas in the emails to the other complainants and that provided by Boehringer Ingelheim the order was reversed. This email also included '… incentivized with an extra hono of 5 GBP for each Switched to Pradaxa or Switched to Xarelto PRFs completed'.

The Panel queried whether the disproportionate emphasis on payment in all the emails was appropriate given the need to ensure that the material was non-promotional. Both the subject title and email heading referred to the £70 honoraria in Cases AUTH/2565/11/12 and AUTH/2566/11/12 and in addition throughout the invitations at issue in Cases AUTH/2565/11/12 and AUTH/2567/11/12 all references to honoraria were emboldened and, in the Panel's view, were designed to catch the reader's eye.

The Panel was concerned that an additional £5 incentive was offered for each form for patients who had been switched to Pradaxa or Xarelto. The Panel noted Boehringer Ingelheim's submission that the numbers of such patients in the UK was small and thus payment of the incentive would aid collection of data in these patient types. It further submitted that the overall payment was reasonable. The Panel considered that offering an extra payment for identifying certain patients in a market research study was not necessarily a breach of the Code providing there was a *bona fide* need for such data, the overall payment was reasonable and the overall arrangements including the description of the payment did not render the arrangements promotional.

The Panel noted that the survey was retrospective but there was a small theoretical possibility that health professionals could switch patients on learning that an extra £5 would be paid. In order to do this Boehringer Ingelheim submitted that prescribers would need to recall patients to an anticoagulant service, explain details of the switch and obtain agreement to switch. There would need to be sufficient time for each patient's warfarin to be stopped and their blood clotting rate rechecked until it reached a certain level before they could be started on Pradaxa. The doctor would then have to complete the survey. The Panel noted that the emails in Cases AUTH/2565/11/12 and AUTH/2566/11/12 clearly referred to the survey being on patients that the doctor had seen in the last three months. This was mentioned three times and underlined in these emails before the statement 'On top of that you'll be incentivized with an extra hono[rarium] of 5GBP for each Switched to Pradaxa or Switched to Xarelto PRFs completed'.

The email in Case AUTH/2567/11/12 was slightly different. The emboldened sentence 'On top of that you will be incentivized with an extra hono[rarium] of £5 for each Switched to Pradaxa or Switched to Xarelto PRFs completed' gave more visual emphasis to the incentivisation payment. Whilst noting that the first paragraph referred to participating in 'an online study on The Stroke Prevention in Non Valvular Atrial Fibrillation treated in the last 3 months' this sentence was not grammatically correct. Towards the end of the email a description of the patient selection criteria included the statement 'in the last 3 months' twice.

The Panel was concerned that the reference to the 'Switched to Pradaxa' or 'Switched to Xarelto PRFs' might be seen as offering a payment for switching. In this regard it was particularly concerned about the email in Case AUTH/2567/11/12. It queried whether such an offer would be an inducement to prescribe which was prohibited under the Code.

Taking all the circumstances into account, the Panel did not consider that the survey itself was promotional and thus it could not be argued that its nature in this regard was disguised. No breach was ruled. Similarly, and noting its finding that the survey was non-promotional the Panel did not consider that the level of payment was inappropriate, nor given the retrospective nature of the study that the level of payment otherwise amounted to an inducement to prescribe, no breach was ruled on these narrow points.

The Panel was, however, very concerned about the disproportionate emphasis on payment in the subject title and body of the emails as described above. In addition, the reference to the incentivized payments was a standard paragraph which in Case AUTH/2567/11/12 was emboldened. A reader

glancing at the email might get the impression that a £5 honorarium was payable in relation to each patient switched to Pradaxa or Xarelto. Indeed this was the complainant's impression in Case AUTH/2565/11/12. Such an impression was unacceptable. The Panel was also concerned about the apparent lack of control exercised over the content of the invitations. High standards had not been maintained and a breach was ruled.

Noting its rulings above and on balance, the Panel did not consider that the circumstances warranted a ruling of a breach of Clause 2 which was used as a sign of particular censure and reserved for such use.

The Authority received three complaints relating to an on-line survey about stroke prevention in atrial fibrillation. Following contact with the market research company which emailed details of the survey the matter was taken up with Boehringer Ingelheim Limited in the UK as the survey was commissioned by its overseas parent company Boehringer Ingelheim International GmbH. The complainants were a head of medicines management (Case AUTH/2565/11/12), a quality and medicines management lead at a primary care trust (PCT) (Case AUTH/2566/11/12) and a general practitioner (Case AUTH/2567/11/12).

The complainants had all been invited, by email, to participate in the survey which was about patients with non-valvular atrial fibrillation. The selection criteria for the survey as outlined in the invitations were firstly, patients that were previously treatment naïve who had started on therapy (warfarin, Pradaxa (dabigatran) or Xarelto (rivaroxaban, Bayer's product)) in the last three months; secondly patients who were on warfarin, Pradaxa or Xarelto and who switched to a different therapy (warfarin, Pradaxa or Xarelto) in the last three months; thirdly, that patients should not be enrolled in a clinical trial. The email stated that to complete the study, including two online patient forms, would take around 60 minutes for which an honorarium of £70 was offered.

Pradaxa was indicated for primary prevention of venous thromboembolic events in adults who had undergone elective total hip replacement surgery or total knee replacement surgery. It was also indicated for prevention of stroke and systemic embolism in adults with non-valvular atrial fibrillation (NVAF) with one or more of certain risk factors.

Xarelto 10mg was indicated for the prevention of venous thromboembolism (VTE) in adults undergoing elective hip or knee replacement surgery. Xarelto 15mg and 20mg were indicated to prevent stroke and systemic embolism in adults with NVAF with one or more named risk factors. It was also indicated for the treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) and prevention of DVT and PE in adults.

Case AUTH/2565/11/12

COMPLAINT

The complainant was concerned at the possibility of a £5 payment for switching to a certain branded medicine.

Case AUTH/2566/11/12

COMPLAINT

The complainant alleged that the survey was in breach of Clause 18.1 and noted that he/she was not a member of the healthcare advisory board referred to in the email.

Case AUTH/2567/11/12

COMPLAINT

The complainant, who had discussed the survey with his local pharmaceutical advisor and a partner in the practice who was a prescribing lead for a primary care trust (PCT), queried whether the email, which was sent to his/her practice, complied with the Code or study methodology.

When writing to Boehringer Ingelheim, the Authority asked it to respond to each complaint in relation to Clauses 2, 9.1, 12.2 and 18.1.

RESPONSE

Boehringer Ingelheim submitted that the market research survey in question was commissioned by Boehringer Ingelheim Headquarters, Boehringer Ingelheim International GmbH, as a global project that was conducted from July to December 2012 in Germany, the US, Canada, Spain, Japan, Brazil and the UK.

Boehringer Ingelheim GmbH noted that the basis for the three complaints related to disguised promotion of a medicine and the attempt to induce, or inducement of, physicians to switch to a particular medicine. However, the invitation to the market research survey, and the survey itself, requested only retrospective information, ie, information relating to past prescribing practices of physicians invited to participate. Thus, no physicians were induced or incentivised to prescribe any patients a particular medicine as a consequence of the survey. Accordingly, Boehringer Ingelheim considered that there had been no breach of the Code.

Boehringer Ingelheim explained that Boehringer Ingelheim GmbH commissioned a third party agency to conduct the market research survey in question as part of a commercial assessment relating to prescribing practices, in order to help Boehringer Ingelheim GmbH develop its business strategy for Pradaxa. The survey was developed by the third party in response to Boehringer Ingelheim GmbH's request for proposal, and was described in the project proposal. The survey was subsequently approved by Boehringer Ingelheim GmbH. Boehringer Ingelheim GmbH and the third party had a master services agreement in place under which the market research work was governed. The third party subcontracted another company to conduct the fieldwork for this market research project. There was no direct contract between Boehringer Ingelheim GmbH and the company subcontracted by the third party. The company subcontracted by the third party did not know Boehringer Ingelheim GmbH was the project sponsor (as per standard policy) until the

PMCPA disclosure. Copies of Boehringer Ingelheim GmbH's request for proposal, the third party's corresponding project proposal, and relevant master services agreements and contracts were provided.

The company subcontracted by the third party created the invitation letter and reimbursement structure, and used the invitation to recruit physician respondents from its healthcare advisory board. As members of the British Healthcare Business Intelligence Association (BHBIA) the subcontracted company conducted market research in the UK in accordance with the BHBIA Legal and Ethical Guidelines for Healthcare Market Research, October 2011; the company confirmed that all staff working on this survey had completed BHBIA training.

Boehringer Ingelheim referred to Section 8 of the BHBIA guidelines which set out the key principles and guidelines relating to the recruitment and reimbursement of market research participants. Boehringer Ingelheim submitted that the invitation emailed to potential participants incorporated all the elements required to comply with the BHBIA guidelines including clear, unambiguous information about the research study, information about what exactly their participation would entail, together with a direct statement about the reimbursement offered.

Boehringer Ingelheim GmbH submitted that the honorarium offered for completion of the survey fell within the BHBIA's definition of market research 'reimbursement', which stated that to encourage participation in a market research study reimbursement should be: kept to a minimum level; proportionate to the amount of time involved and appropriate to the respondent type and the nature of the task(s).

Boehringer Ingelheim GmbH was confident that the wording of the invitation and the survey was sufficiently clear that the questions asked related only to past prescribing practices finished at the time of the interview and therefore would not have induced any participant to prescribe a particular medicine.

Boehringer Ingelheim explained that the survey was conducted to help understand the prescribing drivers for physicians in terms of NVAF anticoagulant treatment. In July 2012, Boehringer Ingelheim GmbH's Pradaxa global brand team identified a number of key business questions about the NVAF market and Pradaxa in particular that needed to be answered for brand planning. In essence, these questions centred around understanding more about physicians' decision making in the NVAF market, how this had evolved, how the new oral anticoagulant class and individual products were being perceived, and how that perception was likely to further evolve with increasing competition within the market.

No target lists of physicians were used in the UK. Neither Boehringer Ingelheim GmbH nor the third party identified any lists of physicians for the purposes of recruiting specific target physicians in the UK. The subcontracted company had an existing group of UK health professionals, the healthcare advisory board, which was used together with some supplemental telephone recruiting. This meant physicians who might not be on the advisory board were recruited and proactively provided their email to receive study invitations. There was not a separate invitation for these physicians.

No physician-identifying information of any kind was provided to Boehringer Ingelheim GmbH.

The survey asked participants to recall their decisions to change people between medicines in the previous 3 months. After entering the survey, via the link on the invitation letter, the participants were asked 'Doctor, you previously stated that you can recall information about at least one NVAF patient of the following patient types and that you have treated the following number of NVAF patients in the last 3 months'. Once survey respondents agreed that they could recall such patients, they were asked to complete the survey based on memory of a patient (no identifiers were requested nor opportunities given to provide such identifying information).

The healthcare advisory board was comprised of physicians and other health professionals who shared their opinions and views on a variety of health issues by participating in opinion surveys delivered via a variety of channels, including the Internet.

Boehringer Ingelheim explained that the company subcontracted by the third party had recruited respondents using many different recruitment sources and methodologies including special recruitment campaigns or techniques and offline methods for physicians or healthcare practitioners in hard-to-reach geographical locations. Examples were provided.

When respondents were recruited to the healthcare advisory board, it was made very clear that they had joined an opinion survey community and that they would be asked periodically to participate in online research. They were also given a link to terms and conditions when they registered and had to actively agree to abide by these before participating. A link to the subcontracted company's privacy policy was referenced on the registration page and on the terms and condition page for each study.

All recruited members had completed a 'double' opt-in process. After registration, each new member received a confirmation email which described community membership and provided instructions for continuing membership as well as the option to opt-out.

Boehringer Ingelheim submitted that 34 physicians received the honorarium with additional incentive for completing recall charts for patients they saw in the past 3 months who were moved from one medicine to another. There were 54 recall charts for which this additional honorarium was paid. The maximum number of patient charts that could be completed within the survey was 10; and so the maximum amount of additional reimbursement for

these 10 charts for information about patients previously switched to Pradaxa or Xarelto would be £50.

Boehringer Ingelheim noted that the survey did not ask for patients to be switched from one therapy to another. Switching patients was not Boehringer Ingelheim GmbH's intent; on the contrary the objective was to understand why patients might have been switched in the past. The additional £5 for the information on a concluded switch to Pradaxa or Xarelto was intended to be paid to learn more about the motivation of the health professional and the circumstances of the case, but not to induce any switch – indeed, this would not be possible because the switch had already been completed.

Boehringer Ingelheim GmbH believed that the invitation letter clearly inquired about the past actions of the physicians invited to participate in the survey. The survey (including the invitation at issue) asked about prescribing decisions that were made within the three months before the invitation was sent. In that regard Boehringer Ingelheim noted that the phrase 'the last 3 months' was used three times in the invitation letter and was emboldened and underlined to emphasise that the information sought related to patients that had already been switched independently of the study. The additional honorarium offered as reimbursement for information was to be provided to respondents only in respect of information they provided about prescribing decisions made in the three months preceding the date of the survey request. It was neither the company's intention nor its expectation that any patients were switched by prescribers as a result of this survey, and to its knowledge that was the case.

In summary, Boehringer Ingelheim GmbH did not intentionally attempt or design the survey to induce or incentivise any physician to prescribe Pradaxa, nor switch patients to Pradaxa. In addition the objective of the survey was not intended to be disguised promotion in any way. Indeed, the three most commonly prescribed oral anticoagulants in the UK (warfarin, Xarelto and Pradaxa) were all mentioned equally in the invitation. Furthermore, the PMCPA's letter with details of the complainants' declarations of interest revealed that at least one of the complainants 'had no idea' which company was involved. This disclosure would therefore call into question the assertion that this market research survey was disguised promotion. The objective of the survey was to seek further information about the factors that drove physicians to make the decisions about prescribing oral anticoagulants.

Boehringer Ingelheim acknowledged the complainants' concerns, but it appeared that they might have misinterpreted the purpose of the study based on the wording of the invitation. Boehringer Ingelheim GmbH believed that the wording of the invitation letter was clear that additional honorarium was to be provided to respondents only in respect of information relating to prescribing decisions made in the three months before the survey request. In addition, the enclosed documentation indicated that Boehringer Ingelheim GmbH's objective for this market research was not to induce or incentivise the prescribing of Pradaxa; nor was it to use the market research as disguised promotion. However, Boehringer Ingelheim GmbH submitted that it would invest additional efforts in future to ensure that the risk of similar misinterpretation of its market research materials would not occur again.

In conclusion, Boehringer Ingelheim GmbH did not believe that the conduct of the market research study in question was in breach of Clauses 2, 9.1, 12.2 and 18.1. The company refuted any allegations of misconduct made by the complainants and believed that the evidence provided demonstrated that high standards in relation to healthcare market research had been maintained.

In response to a request for further information, Boehringer Ingelheim clarified that the market research survey was part of a wider market research project and commercial assessment commissioned by Boehringer Ingelheim International GmbH in order to help develop its business strategy for Pradaxa.

Boehringer Ingelheim submitted that a briefing was provided during a formal kick off call between the third party and the company subcontracted by the third party in September 2012. Project objectives and survey administration details were discussed by telephone and were not documented in writing. A copy of the survey, which included the programming instructions given by the third party to its subcontractor, as well as the survey objectives were provided.

While the subcontracted company carried out the survey in the UK it, in turn, subcontracted another company to do some additional telephone recruiting using the same script (see below). This company was a member BHBIA and all team members had successfully completed their BHBIA training before conducting any telephone recruiting for this survey.

Boehringer Ingelheim noted that Clause 12.2 referred, *inter alia*, to market research activities and stated that these must be conducted with a primarily scientific or educational purpose. Boehringer Ingelheim considered that market research was different from these other activities since it was not inherently clinically scientific or educational. Nonetheless, the purpose of this market research survey was scientific and educational, albeit from a business intelligence analysis perspective rather than a clinical perspective: to help Boehringer Ingelheim GmbH to understand the factors that drove physicians to make prescribing decisions in the treatment of NVAF.

The Boehringer Ingelheim GmbH request for proposal document described the five key questions that the Pradaxa Global team wanted to answer to help develop its 2013 marketing strategy. This market research project was commissioned to help Boehringer Ingelheim GmbH answer these questions, which underpinned the objectives of the wider market research project, of which this survey was one workstream.

Boehringer Ingelheim submitted that in all market research studies, many of those invited to participate did not respond and when it was believed that it would be harder to meet quotas needed for testing significance in the sample, then an additional honorarium might be used as a way to gain additional responses. For example:

- When conducting qualitative or quantitative market research with several physician specialties, it might be challenging to meet the minimum required sample of a particular specialty. Increasing honoraria to that specialty group for participation (of course staying within fair market value) might be acceptable.

- When conducting quantitative market research and one patient type or target sample quota was lagging, adding an additional honorarium to get closer to the required response for statistical analysis for that segment was a standard practice (again, staying within reasonable fair market value).

This approach was in line with the BHBIA Legal & Ethical Guidelines for Healthcare Market Research:

' 8.26 If there is evidence to suggest that the standard reimbursement will not be successful, e.g. if past experience proves that a respondent type is particularly difficult to recruit because they belong to an exceptionally small universe; then it is possible to amend the reimbursement but it should not be excessive in relation to the task(s) required.'

Boehringer Ingelheim stated that all patient types were of equal importance in this survey. The reality was that the new oral anticoagulants (Pradaxa and Xarelto) were in the UK market for significantly less time than in other countries (due to a later launch date in the UK) and hence the potential numbers of such patients were relatively small and such patients were harder to locate. Therefore, the idea of the additional £5 honoraria was implemented to encourage physicians who had already made the prescribing decision and had such a patient to provide recall information for that type of patient (instead of, or in addition to other patient types they could provide information for).

Specifically, an additional £5 honorarium was offered for the patients switched from warfarin to Pradaxa or Xarelto within the last 3 months to aid the collection of these patient types as it was anticipated that they would be limited in number.

In summary Boehringer Ingelheim submitted that increasing honoraria, within fair market value, was a standard market research tool to reach meaningful quota of responses within a survey. No quota in this survey was deemed 'more valuable' (nor was that atypical in market research). The additional honorarium offered was to increase the likelihood of achieving an adequate number of samples for more difficult quota areas and not to influence prescribing practice.

Boehringer Ingelheim stated that in order for health professionals 'to read the email invitation, switch patients then complete the survey' as suggested by the PMCPA, they would first need to recall patients to an anticoagulant service, explain the details of the switch and obtain each patient's agreement to be switched. There would then need to be sufficient time for each patient's warfarin to be stopped and each patient's International Normalised Ratio (INR) [measurement of time for blood to clot compared to an average] to be rechecked until it fell below 2.0, before he/she could be started on Pradaxa.

The market survey in question was only available for clinicians in the UK to complete from 19 October to 1 December 2012 and so any health professionals switching patients from warfarin to Xarelto or Pradaxa would only be able to do so between those two dates. Given the detailed process described above, Boehringer Ingelheim believed it would be extremely unlikely for this type of switch to happen especially given that the only reimbursement for such a switch would be a maximum additional sum of £50 (if 10 patients had been switched from warfarin to Pradaxa or Xarelto).

Boehringer Ingelheim stated that if Boehringer Ingelheim GmbH's intended to incentivise health professionals to switch patients to Pradaxa as alleged, then it would be illogical and counterproductive to offer the same additional honorarium for switches to another company's product, Xarelto. The intentions of this Boehringer Ingelheim GmbH market research survey and the wording of the invitation email were never for health professionals to switch patients to Pradaxa based on this survey.

Boehringer Ingelheim submitted that 111 UK physicians participated in the survey, and no UK specific conclusions were drawn in the resulting market research report (as this was a global project being run in several countries). Instead, the general report was used to educate Boehringer Ingelheim about prescribers' decision-making process and thus helped to inform the Boehringer Ingelheim GmbH global marketing strategy for the coming year. Boehringer Ingelheim noted that the request for proposal from Boehringer Ingelheim GmbH was for the wider global market research project as a whole rather than for just the survey in question.

Boehringer Ingelheim submitted that the healthcare advisory board was not a Boehringer Ingelheim initiative. It was an initiative of the company subcontracted by the third party and was accessible only to that company and its affiliates and no other third parties. Physicians did not receive any fees or honoraria payments just for subscribing to the healthcare advisory board. Honoraria payment was provided only on completion of online surveys, and only for those for which the health professionals were eligible. There were more than 70,000 members of the healthcare advisory board.

Boehringer Ingelheim stated that 8,917 physicians were contacted by email recruitment via the healthcare advisory board and an additional 1,200

physicians outside of the healthcare advisory board community were emailed to participate. A further 175 physicians outside of the healthcare advisory board community were contacted via telephone to participate in the online survey.

Details of the telephone script that would have been used were provided as follows: GPs would have been offered an honorarium of £70 as per the original email invitation.

> 'Hello Dr .....,
>
> It's ..... calling from [the name of the subcontractor] and we are conducting a 60 minute online study on the **Management and therapy preferences for treatment of Stroke Prevention in Non-Valvular Atrial Fibrillation** with an incentive payment of £100. Is this something that would be of interest?
>
> I do have some questions that I need to ask to make sure that you fit criteria. Are you okay to go through these with me now?.'

Boehringer Ingelheim submitted that it was made aware of the overall global market research project in July 2012 but was not operationally involved; the global project dated from July to December 2012. The survey was one workstream of a global market research project. Work relating to this survey commenced in the UK in October 2012.

Boehringer Ingelheim GmbH considered that the wording of the invitation letter was clear that the additional honorarium was to be provided to survey respondents only in respect of information relating to prescribing decisions made in the three months preceding the date of the survey request. The objectives outlined in the request for proposal indicated that Boehringer Ingelheim GmbH's intention for the wider market research project and the specific study in question was not to induce or incentivise the prescribing of Pradaxa; nor was it to use the market research as disguised promotion. Therefore Boehringer Ingelheim GmbH did not believe that the conduct of the market research study in question was in breach of Clauses 2, 9.1, 12.2 or 18.1.

PANEL RULING

The Panel noted that it had received three separate complaints about the survey and invitations. It considered that the rulings set out below applied equally to all three complaints.

The Panel noted Boehringer Ingelheim's submission that the market research survey in question was commissioned by Boehringer Ingelheim's overseas headquarters, Boehringer Ingelheim International GmbH. It was an established principle under the Code that UK companies were responsible for the acts and omissions of their overseas affiliates that came within the scope of the Code. The survey had been used in the UK and therefore the survey came within the scope of, and had to comply with, the UK Code.

The Panel noted Boehringer Ingelheim's submission that the survey was in line with the BHBIA Legal and Ethical Guidelines for Healthcare Market Research, October 2011 Edition. The role of the Panel was to consider the complaints in relation to the ABPI Code. It had no role in deciding whether the survey was in line with the BHBIA Guidelines.

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 BHBIA 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 Panel noted Boehringer Ingelheim's submission that Boehringer Ingelheim GmbH had commissioned a third party to conduct the international survey as part of its commercial assessment about prescribing practices to help the company develop its business strategy. The survey was conducted from July to December 2012. The third party engaged another company to conduct the fieldwork for the survey in the UK. In turn this organisation subcontracted another company to do some additional telephone recruiting. It was an established principle under the Code that pharmaceutical companies were responsible for work undertaken by third parties on their behalf. Thus Boehringer Ingelheim was responsible for the activities of its third party and all those subcontracted.

The Panel noted that the request for proposal document sent by Boehringer Ingelheim explained that Boehringer Ingelheim needed to answer some very important questions relating to prescribing habits. It referred to a general market research plan which was likely to lead to a series of market research studies.

The Panel noted that a formal kick off meeting about the survey between the third party and its subcontractor took place in September 2012. Project objectives and survey administration details (programming) were discussed over the telephone and were not documented in writing. The hard copy version of the survey provided by Boehringer Ingelheim included programming instructions given by the third party to its subcontractor. The Panel noted that these written instructions contained information on the survey background, objectives, methodology and some general survey notes. There was no written instruction about how the survey should be communicated to potential participants.

Boehringer Ingelheim's response included a letter from the company subcontracted by the third party to the third party which explained that the invitation was written and approved by the company subcontracted by the third party. The Panel was concerned about the lack of input and/or approval by Boehringer Ingelheim of the invitation. In the Panel's view Boehringer Ingelheim should have, at the very least, satisfied itself that the invitations were not promotional.

In Cases AUTH/2565/11/12 and AUTH/2566/11/12 the emails in question had been sent by the company subcontracted by the third party to members of its healthcare advisory board. The complainant in Case AUTH/2566/11/12 stated that he/she was not a member of the healthcare advisory board. Boehringer Ingelheim did not know the identity of the complainant and thus could not comment on this. The email in Case AUTH/2567/11/12 had been sent by another group which appeared to be connected to the company subcontracted by the third party.

The Panel noted that the survey itself was detailed and included screening questions about participants' roles and activities. There were detailed questions about NVAF and treatment with Pradaxa and Xarelto. After completing general questions participants were then asked about a specific patient. The Panel considered that the survey focussed on the condition and general requirements about treatment. It did not focus on Boehringer Ingelheim's product.

The Panel noted that whilst the £70 payment, for completion of the survey and two patient forms, did not seem unreasonable given the submission that the estimated time for completion was 60 minutes, the Panel was nonetheless concerned about the description of the payments in the email invitations.

The emails in Cases AUTH/2565/11/12 and AUTH/2566/11/12 were very similar but all three were different to that provided by Boehringer Ingelheim which did not have 'GBP' inserted both in the subject and email heading, and did not refer to the provision of gift vouchers. Gift vouchers were referred to in the email in question in Case AUTH/2567/11/12. The Panel made its ruling on the invitations provided by the complainants.

The email invitations in Cases AUTH/2565/11/12 and AUTH/2566/11/12 were very similar. They referred to the recipients' membership of a Healthcare Advisory Board. The subject heading read 'Earn 70 GBP GBP honorarium: Stoke Prevention' and the invitation was headed 'Online study for 70 GBP'. Participants were asked to complete the survey and a minimum of two and a maximum of 10 patient forms. Additional honoraria of £15 were offered per additional patient form completed. Participants were '… incentivized with an extra hono of 5 GBP for each Switched to Pradaxa or Switched to Xarelto PRFs [patient record forms] completed'.

The email in question in Case AUTH/2567/11/12 was similar. The email bore a different subject heading '[details of the subcontractor]: Online Study on Stroke Prevention in Non-Vascular Fibrilation'. There was no reference to membership of an advisory board. The payment was described as 'a £70 cheque or a £70 Amazon.co.uk gift certificate'. This invitation did not make it clear that the maximum of 10 patient record forms included the 2 completed within the main survey. In addition the ordering of paragraphs was such that three paragraphs detailing payments appeared at the beginning of the email before the patient selection criteria whereas in the emails to the other complainants and that provided by Boehringer Ingelheim the order was reversed. This email also included '… incentivized with an extra hono of 5 GBP for each Switched to Pradaxa or Switched to Xarelto PRFs completed'.

The Panel queried whether the disproportionate emphasis on payment in all the emails was appropriate given the need to ensure that the material was non-promotional. Both the subject title and email heading referred to the £70 honoraria in Cases AUTH/2565/11/12 and AUTH/2566/11/12 and in addition throughout the invitations at issue in Cases AUTH/2565/11/12 and AUTH/2567/11/12 all references to honoraria were emboldened and, in the Panel's view, were designed to catch the reader's eye.

The Panel was concerned that an additional £5 incentive was offered for each form for patients who had been switched to Pradaxa or Xarelto. The Panel noted Boehringer Ingelheim's submission that the numbers of such patients in the UK was small and thus payment of the incentive would aid collection of data in these patient types. It further submitted that the overall payment was reasonable. The Panel considered that offering an extra payment for identifying certain patients in a market research study was not necessarily a breach of the Code providing there was a *bona fide* need for such data, the overall payment was reasonable and the overall arrangements including the description of the payment did not render the arrangements promotional.

The Panel noted that the survey was retrospective but there was a small theoretical possibility that health professionals could switch patients on learning that an extra £5 would be paid. In order to do this Boehringer Ingelheim submitted that prescribers would need to recall patients to an anticoagulant service, explain details of the switch and obtain agreement to switch. There would need to be sufficient time for each patient's warfarin to be stopped and each patient's INR to be rechecked until it fell below 2 before that patient could be started on Pradaxa. The doctor would then have to complete the survey. The Panel noted that the emails in Cases AUTH/2565/11/12 and AUTH/2566/11/12 clearly referred to the survey being on patients that the doctor had seen in the last three months. This was mentioned three times and underlined in these emails before the statement 'On top of that you'll be incentivized with an extra hono[rarium] of **5GBP** for each Switched to Pradaxa or Switched to Xarelto PRFs completed'.

The email in Case AUTH/2567/11/12 was slightly different. The emboldened sentence **'On top of that you will be incentivized with an extra hono[rarium] of £5 for each Switched to Pradaxa or Switched to**

Xarelto PRFs completed' gave more visual emphasis to the incentivisation payment. Whilst noting that the first paragraph referred to participating in 'an **online study on The Stroke Prevention in Non Valvular Atrial Fibrillation treated in the last 3 months'** this sentence was not grammatically correct. Towards the end of the email a description of the patient selection criteria included the statement 'in the last 3 months' twice.

The Panel was concerned that the reference to the 'Switched to Pradaxa' or 'Switched to Xarelto PRFs' might be seen as offering a payment for switching. In this regard it was particularly concerned about the email in Case AUTH/2567/11/12. It queried whether such an offer met the requirements of Clause 18.1 as such a payment would be an inducement to prescribe. Clause 18.1 prohibited inducements to prescribe any medicine. In that regard the Panel did not accept Boehringer Ingelheim's submission that it could not be in breach of Clause 18.1 as the survey paid an extra honorarium for patients switched to a competitor product.

The Panel noted its comments above about the online survey. Taking all the circumstances into account the Panel did not consider that the survey itself was promotional and thus it could not be argued that its nature in this regard was disguised. No breach of Clause 12.2 was ruled. Similarly and noting its finding that the survey was non-promotional the Panel did not consider that the level of payment was inappropriate, nor given the retrospective nature of the study that the level of payment otherwise amounted to an inducement to prescribe, no breach of Clause 18.1 was ruled on these narrow points.

The Panel was, however, very concerned about the disproportionate emphasis on payment in the subject title and body of the emails as described above. In addition, the reference to the incentivized payments was a standard paragraph which in Case AUTH/2567/11/12 was emboldened. A reader glancing at the email might get the impression that a £5 honorarium was payable in relation to each patient switched to Pradaxa or Xarelto. Indeed this was the impression gained by the complainant in Case AUTH/2565/11/12. Such an impression was unacceptable. The Panel was also concerned about the apparent lack of control exercised over the content of the invitations. High standards had not been maintained and a breach of Clause 9.1 was ruled.

Noting its rulings above and on balance, the Panel did not consider that the circumstances warranted a ruling of a breach of Clause 2 which was used as a sign of particular censure and reserved for such use. No breach of Clause 2 was ruled.

Case AUTH/2565/11/12

Complaint received	**19 November 2012**
Process commenced	**4 December 2012**
Case completed	**22 March 2013**

Case AUTH/2566/11/12

Complaint received	**20 November 2012**
Process commenced	**4 December 2012**
Case completed	**22 March 2013**

Case AUTH/2567/11/12

Complaint received	**20 November 2012**
Process commenced	**4 December 2012**
Case completed	**15 March 2013**