CASE AUTH/2198/1/09

PRIMARY CARE TRUST v SOLVAY

Patient identification programme

The assistant medical director of a primary care trust (PCT) complained that a service provided to a general practitioner by Solvay had led to the inappropriate prescribing of Omacor (omega 3-acid ethyl esters 90).

The complainant explained that the GP had met the Solvay representative who promoted Omacor. The GP thought that patients would benefit from the medicine and he signed an agreement with Solvay which provided an unconditional financial grant to audit patients with cardiovascular risk factors and review their long term management. The agreement named a nurse who would do the audit. The GP had been introduced to the nurse by the Solvay representative and although he might have been shown a protocol by the nurse no copies were kept and so nothing was known about it. The GP thought the nurse was identifying patients who had a history of cerebrovascular or coronary heart disease or hypertension or abnormal lipids. The nurse had access to the medical records, identified 'suitable' patients and put Omacor on repeat prescriptions. The GP signed the prescriptions and the letters explaining why the medicine was prescribed. The complainant did not know if the GP was offered any inducement.

The complainant submitted that the matter raised concerns about the nurse and the GP; it had also identified issues relating to Solvay's promotion of Omacor. Breaches of the Code were alleged.

The detailed response from Solvay is given below.

The Panel considered that it was not necessarily unacceptable for pharmaceutical companies to sponsor audits in general practice. The supplementary information to the Code prohibited switch programmes but genuine therapeutic reviews which aimed to ensure that patients received optimal treatment following clinical assessment were acceptable. The decision to change or commence treatment must be made for each individual patient by the prescriber and every decision to change an individual's treatment must be documented with evidence that it was made on rational grounds.

The Panel noted Solvay's submission that it had given the GP unconditional grants to audit patients at increased cardiovascular risk to review their therapy between November 2006 and June 2007. Approximately £1,700 had been given to cover the cost of a nurse to do the audits. As part of the agreement the GP was offered template letters to recall patients for review. It was not clear whether all the patients prescribed Omacor following the audit met the licensed indications.

The Panel noted that the details of that audit were unknown to Solvay. It appeared that the company had no way of knowing if it was paying for a clinically robust audit. This was unacceptable. In the Panel's view, pharmaceutical companies sponsoring third parties, particularly individuals, must be reasonably confident that their proposed activities were clinically sound and complied with the Code. In addition to funding and agreeing that the audit be performed by an external healthcare practitioner, Solvay had, in letters to the GP, stated that the audit would be performed by a named nurse. Solvay had, in effect, provided the nurse to do the audit who the company understood had some expertise in similar audits. Again the Panel considered that this was unacceptable; if the company was recommending staff to carry out the audit it should be sure that they had the necessary expertise. In the Panel's view, by introducing the nurse to the practice, Solvay had to assume some responsibility for her actions.

The Panel was concerned about the representative's role. Although Solvay stated that the representative had sought authority for financial support to be given, it appeared that no regional sales manager or healthcare development manager had discussed the project with the GP as recommended in guidance issued to the field force. The representative had provided the GP with the contact details of the nurse and had arranged for the GP to sign the agreement regarding the support to be provided by Solvay. The representative had delivered the cheque which represented the fee to be paid to the nurse for conducting the audit. In the Panel's view the delivery of cheques to doctors by representatives in this way gave a very poor impression; it might be perceived by some to be an inducement to prescribe the company's products given the prime role of a representative was to promote medicines.

The Panel noted Solvay's involvement with the audit and subsequent therapy review and considered that it was inextricably linked to it. The company had given the GP approximately £1,700 but had had no oversight of the protocol; it had, in effect, provided a nurse to do the audit although it appeared to have no evidence that she was suitably experienced to be able to conduct the audit or knowledge of what she was going to do. The Panel considered that the vague arrangements which existed were wholly unacceptable; the arrangements were such that Solvay had no way of ensuring that the grant which it had given to the GP would be used for an appropriate purpose. The Panel considered that the arrangements were such that they did not constitute a bona fide medical and

educational good or service. The Panel ruled a breach of the Code.

The Panel noted that data provided by the complainant showed that the prescribing of Omacor in the practice in question greatly exceeded the prescribing of Omacor in the other practices in the area. The Panel further noted that shortly after receiving each letter from Solvay regarding the provision of more money (November 2006, January, April and June 2007) prescribing of Omacor in the practice in question increased. The Panel also noted the complainant stated that following the meeting with the representative the GP considered his patients would benefit from Omacor and he signed an agreement with Solvay. The Panel noted its concerns about the role of the representative. The Panel considered that on the balance of probabilities the delivery of cheques by a representative in association with an unacceptable service amounted to an inducement to prescribe Omacor in breach of the Code. The Panel had no evidence that the grants constituted the disguised promotion of Omacor. No breach of the Code was ruled in that regard.

The Panel was very concerned about the overall arrangements set out above. The Panel further considered that given its involvement in the process, Solvay's failure to assume any responsibility for the audit which it facilitated meant that the conduct of employees had fallen short of competent care such as to bring discredit upon or reduce confidence in the pharmaceutical industry. A breach of Clause 2 was ruled.

The Panel was extremely concerned that Solvay appeared to have no procedures in place for ensuring that grants given to facilitate general practice audit were spent on valid audits/therapy reviews and the like. The Panel was also concerned that Solvay would recommend third parties to perform the audits/reviews, without knowing their relevant qualifications or experience to perform such tasks, but take no responsibility for their actions. The Panel decided to report Solvay to the Code of Practice Appeal Board in accordance with Paragraph 8.2 of the Constitution and Procedure. In accordance with Paragraph 7.1 of the Constitution and Procedure, the Panel further required Solvay to suspend the provision of grants for patient identification programmes and the like such that no new agreements were signed.

Solvay accepted all of the Panel's rulings of breaches of the Code.

The Appeal Board was very concerned that Solvay had provided grants in the form of cheques via its representative to the GP on four separate occasions. The Appeal Board considered that it was inappropriate for a representative to hand over money to a doctor. The company had no processes to enable it to check that the money was used to pay a nurse to conduct an audit and how long that would take or that the audit itself was appropriate. Further there was no assessment of the first audit before providing a cheque to the same doctor for the next audit. The Appeal Board did not accept that the payment to the doctor was unconditional as submitted by Solvay. It was provided for a specific reason – ie an audit. The Appeal Board was further concerned that the nurse, introduced to the GP by Solvay and employed by him to undertake the patient identification programme, had not been assessed by the company with regard to her ability to carry out the task for which she was to be paid. There was a failure of management.

The Appeal Board further noted that there appeared to be a marked consequential increase in the prescribing of Omacor by the GP concerned and it queried whether, as a result, patients had been put at risk.

The Appeal Board decided in accordance with Paragraph 11.3 of the Constitution and Procedure to require an audit of Solvay's procedures in relation to the Code to be carried out by the Authority. The audit should be conducted as soon as possible. On receipt of the audit report the Appeal Board would consider whether further sanctions were necessary. In addition the Appeal Board decided that Solvay should be publicly reprimanded.

Upon receipt of the audit report the Appeal Board noted with concern that some of Solvay's policies still needed to be changed so as to ensure compliance with the Code. The Appeal Board decided, in accordance with Paragraph 11.3 of the Constitution and Procedure, to require a further audit of Solvay's procedures in relation to the Code to be carried out by the Authority. The audit should be conducted in November 2009 when the Appeal Board expected Solvay's standard operating procedures (SOPs) to be completed. On receipt of that audit report the Appeal Board would consider whether further sanctions were necessary. In accordance with Paragraph 13.6 of the Constitution and Procedure the Appeal Board decided that an interim case report should be published on the PMCPA website.

Upon receipt of the re-audit report the Appeal Board noted that Solvay had made much improvement since the audit on 5 June 2009. The Appeal Board decided that on the basis that the recommendations from the re audit were either implemented or ongoing no further action was required.

The assistant medical director of a primary care trust (PCT), complained about a patient identification programme sponsored by Solvay Healthcare Limited in 2006.

COMPLAINT

The complainant explained that the PCT had recently investigated inappropriate Omacor (omega

3-acid ethyl esters 90) prescribing in a local general practice. The product was prescribed for 122 patients none of whom met its licensed indications.

The complainant did not know if the doctor was offered any inducement to prescribe Omacor to these patients. Nothing was known about the protocol used by the nurse to identify 'suitable' patients or whether this came from Solvay. There were serious concerns about the professional behaviour of the nurse in relation to this incident, and Solvay's role in introducing her to the practice was unclear.

The complainant provided details of events. The named GP had met the Solvay representative who promoted Omacor. The GP thought that patients would benefit from the medicine and he signed an agreement with Solvay. This provided an unconditional financial grant to audit patients with cardiovascular risk factors and review their long term management. The agreement named a nurse who would do the audit. The GP stated that he had been introduced to the nurse by the Solvay representative and although he might have been shown a protocol by the nurse no copies were kept. The GP thought the nurse was identifying patients who had a history of cerebrovascular or coronary heart disease or hypertension or abnormal lipids. The nurse was given access to the medical records, identified 'suitable' patients and put Omacor on repeat prescriptions. The GP signed the prescriptions and the letters explaining why the medicine was prescribed.

The complainant stated that the nurse selected hypertensives without heart disease and patients with normal triglycerides for treatment with Omacor. A number of nursing concerns were listed by the complainant.

With regard to Solvay the complainant was concerned that the company introduced the nurse to the practice, the nurse recommended by Solvay identified 122 patients as suitable for Omacor when none met the licensed indications, there were concerns about her professional competence and the PCT was unable to obtain a copy of the protocol for review.

The complainant submitted that whilst the findings had raised concerns about the GP, it had also identified issues relating to Solvay's promotion of Omacor. Breaches of Clauses 2, 12, 18.1 and 18.4 of the 2008 edition of the Code were alleged.

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Grants to facilitate the patient identification programme at issue had been made in 2006-2007 thus the provisions of the 2006 edition of the Code applied. The requirements of the clauses cited by the complainant had not changed from 2006 to 2008 but there had been some re-numbering so that the equivalent clauses in 2006 were 2, 10, 18.1 and 18.4. This case was considered under the requirements of the 2006 Code using the 2008 Constitution and Procedure.

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RESPONSE

Solvay noted that the complaint referred to an unconditional grant which it had made to support a patient identification programme in 2006 at a GP surgery. The company noted that little evidence had been presented to support the allegations against Solvay and the independent nurses who undertook the audit at the request of the GP. Solvay was disappointed that a complaint had been made as it had twice written to the PCT to try to explain the nature of a patient identification programme and the involvement of Solvay in such an audit.

1 Alleged promotion of Omacor outside its licensed indications.

The licensed indications for Omacor were:

> 'Post Myocardial Infarction
> Adjuvant treatment in secondary prevention after myocardial infarction, in addition to other standard therapy (e.g. statins, anti-platelet medicinal products, beta-blockers, ACE inhibitors).
>
> Hypertriglyceridaemia
> Endogenous hypertriglyceridaemia as a supplement to diet when dietary measures alone are insufficient to produce an adequate response:
> - type IV in monotherapy,
> - type IIb/III in combination with statins, when control of triglycerides is insufficient.'

Solvay noted that from the PCT's report into this incident, of 122 patients alleged to have been prescribed Omacor outside its licensed indication, 23.7% had a past history of myocardial infarction and 71.4% of patients had abnormal levels of triglyceride prior to starting Omacor (section 7 - Identifying patients). Solvay disagreed with the PCT's statement that none of these patients met the licensed indications.

Solvay had always ethically promoted Omacor within its licensed indications. A copy of the Omacor detail aid used in 2006 was provided. The sales team was trained to the highest standards and was fully aware of its obligations under the Code. The representative concerned was very experienced and had been with Solvay for many years. There had been no complaints from either primary or secondary care health professionals in his area about the manner in which Omacor was promoted. Solvay strenuously denied any suggestions that Omacor had been promoted outside its licensed indication; it therefore denied any suggestions of a breach of Clause 3.

2 Alleged inducement

Solvay stated that it provided an unconditional grant to the GP, following a request for help to audit patients at increased cardiovascular risk to review their therapy. Four payments were made to the GP, totalling £1,700, to pay for 64 hours of nurse resource for an audit programme reviewing the cardiovascular risks of his patients. Solvay understood that the audits looked at different areas of cardiovascular risk and analysis of the practice's performance against quality outcome framework (QoF) targets.

Solvay provided the standard operating procedure (SOP) from 2006 for the field force, which defined the management of patient identification programmes. Solvay also enclosed the agreement letter, signed by the GP, which clearly stated that the funding provided was an unconditional grant from Solvay to support an audit of patients with cardiovascular risk factors. The letter clearly stated that no Solvay employee would be involved in the audit, that the nurses conducting the audit were external to Solvay, and that the payments were solely to fund the nurse resource to conduct the audit. Solvay believed that the payments were fair market value for an experienced nurse's time. Solvay therefore denied that these payments were in breach of Clause 18.1.

Similar audits had provided a broad ranging review of cardiovascular patients to identify untreated adverse risk profiles. This would include both lifestyle changes, for example smoking cessation and weight reduction, together with a therapeutic review eg whether patients reached clinically accepted targets for management of hypertension or lipid lowering. The SOP and the signed letter of agreement with the GP required that patients identified during the audit would be subsequently reviewed by the GP for any appropriate clinical decisions. Solvay noted that no other outcomes of the audit, apart from changes in Omacor prescribing, had been investigated or presented in the PCT report.

Nurses, who were independent of Solvay, conducted the audit; there was no formal relationship between the nurses and Solvay. The nurses were not, and never had been, employees of Solvay. The company could not find any records for any payments to the named nurses, suggesting a formal relationship, over the last five years in its detailed financial records. The company was able to provide the names of the nurses involved from the original letters of agreement with the GP. Solvay provided two names and submitted that it understood that they were local practice nurses with some expertise in similar audits. The nurses were employed by the GP directly and any contracts, training and definition of their role and responsibilities would be between them and the practice. In conclusion, Solvay only provided an unconditional grant and in consequence it did not have a protocol nor could it provide any other details of the nurses who conducted the audits.

Solvay was confident that the audit programme managed by the GP was consistent with a genuine therapy review programme as defined in the supplementary information to Clause 18.4. Solvay did not accept that genuine therapeutic review programmes could be considered under Clause 12 as a form of disguised promotion.

Solvay was proud to work in partnership with the NHS and strongly denied that its conduct was in breach of Clause 2.

In response to a request for further information, Solvay submitted that generic template letters were provided to the GP by its medical representative. Examples of these letters were included in the standard operating procedures for the field force.

Neither Solvay nor its employees, including the representative played any role in the composition or production of the patient letter used by the GP. The representative had not previously seen a copy of the patient letter submitted by the complainant or any document resembling it. That letter was plainly entirely different in purpose, content and style to the generic template letters Solvay provided.

In response to the GP's request for assistance (see below), Solvay's representative introduced a nurse by providing her name and telephone number to the doctor. The telephone number Solvay held no longer appeared to be current.

After attending a meeting which discussed the treatment of patients with cardiovascular risk factors, the GP told the representative that he wished to carry out an audit. The GP asked Solvay for financial assistance and logistical support in identifying someone who might be able to help carry out the audit. As regards the logistical support, the representative provided the GP with the telephone number for the nurse and submitted a request to his manager to support the audit financially in accordance with the company's SOP. Authority was given for this financial support. The representative thereafter arranged for the GP to sign the agreement with Solvay and visited the doctor to deliver the cheque representing the fee to be paid to the nurse for her time in conducting the audit.

The representative had no other involvement with the audit; he did not recommend to the GP that he be supported, and did not solicit a request for support from him.

Solvay supported the GP with four audits to identify patients with cardiovascular risk factors between November 2006 and July 2007. Four payments were made totalling £1,700, to pay for a total of 64 hours of audit time. In this context, Solvay noted its earlier reference to the second of two named individuals who it erroneously stated was a nurse in its letter of 29 January 2009, as Solvay understood that she was a practice manager.

Solvay had provided unconditional grants to support patient identification programmes to a number of other medical practices across the UK. More than 320 unconditional grants were made in 2007 and 2008, spread evenly over those two years. Solvay was not aware of any complaints being made about the provision of these grants.

To the best of Solvay's knowledge, given the time available and based on the information which it had obtained from its representative and regional manager, the nurse had been involved in around 12 audits which had been supported by Solvay in 2007/2008. Solvay was attempting to check this against copies of the agreements which it held.

For the sake of clarity, it was important to note that Solvay provided financial support to the GP for a records audit only, which it described as a patient identification programme. The purpose of this exercise was to enable the GP to identify patients with various cardiovascular risk factors. Solvay would expect this to consist purely of a computer and/or paper records search resulting in a list of names. The GP decided how the search would be conducted and what information he wished to extract from his patients' records. Solvay's financial support, and any other involvement, ended at that point.

Solvay had offered the GP, and other doctors, template letters inviting patients identified as a result of the search to see their GP, but it did not know if the GP at issue used Solvay's letters. Solvay did not provide financial or any other support thereafter for any therapeutic review that the GP at issue might decide to conduct following the Solvay supported audit. The agreement with the GP clearly recorded the distinction between the audit supported by Solvay and any therapeutic review that the GP might wish to carry out. Solvay, therefore, had no involvement whatsoever in any protocol followed by the GP in making management decisions for his patients. It was clear, nevertheless, from the agreement and the template letters that Solvay understood that the GP intended to call back patients before reviewing their management or making any decisions on treatment.

PANEL RULING

The Panel considered that it was not necessarily unacceptable for pharmaceutical companies to sponsor audits in general practice. The supplementary information to Clause 18.4, Switch and Therapy Review Programmes, stated that switch programmes, whereby pharmaceutical companies paid for, or facilitated, patients' medicine being simply changed from medicine A to medicine B were prohibited under the Code. Such arrangements would be seen as companies in effect paying for prescriptions. Genuine therapeutic reviews, however, which aimed to ensure that patients received optimal treatment following clinical assessment were a legitimate activity for a pharmaceutical company to support and/or assist. The decision to change or commence treatment must be made for each individual patient by the prescriber and every decision to change an individual's treatment must be documented with evidence that it was made on rational grounds.

The Panel considered that irrespective of a company's degree of involvement and whether the independent service provider, such as an audit nurse, was appointed by the pharmaceutical company or directly by the service recipient the pharmaceutical company should still be able to demonstrate that any medical and educational goods and services which it provided or facilitated complied with Clause 18.4 and its supplementary information. The parties' roles and responsibilities should be abundantly clear and records kept.

The Panel noted that the letters from Solvay to the GP in question referred to supporting '… your audit of your patients with cardiovascular risk factors'. This was inconsistent with its description of its service (in the penultimate paragraph of its response) as an audit to identify patients with various cardiovascular risk factors. The letter from Solvay to the complainant referred to supporting '… a practice audit to identify patients with cardiovascular disease who may not have been on optimal medical treatment'. The letter from Solvay to the Authority referred to 'a patient identification programme'. The Field Force Working Guidance referred to both. Solvay submitted that it had given the GP four unconditional grants for help to audit patients at increased cardiovascular risk to review their therapy between November 2006 and June 2007. In all, the doctor had been given approximately £1,700 which was to cover the cost of a nurse to do the audit. The letters to the GP further noted that Solvay understood that 'following the audit the practice will carry out a therapeutic review of the patients and decide on appropriate continued management of the patients so identified'. The Panel noted Solvay's initial submission that its Field Force Working Guidance and the signed letter of agreement with the GP required that patients identified during the audit would be subsequently reviewed by the GP for any appropriate clinical decisions. In response to a request for further information, however, Solvay drew a distinction between the audit and any therapeutic review which the GP might subsequently wish to carry out. The Panel noted that as part of the agreement the GP was offered generic template letters to recall patients for review.

The Panel considered that the letter to patients provided by the practice was unacceptable as far as the Code was concerned. However the letter provided bore no resemblance to the templates included in the Solvay Field Force Working Guidance. The Panel considered that it was not clear whether patients prescribed Omacor following the audit met the licensed indications or not although, from the information provided, it appeared that at least some of them would have done.

The Panel disagreed with Solvay's description of the grant as 'unconditional'; the money had been granted for the specific (conditional) purpose of supporting an audit of patients with cardiovascular risk factors. The Panel noted that the details of that audit were unknown to Solvay. It appeared that the company had no way of knowing if it was paying for a clinically robust audit or not. This was unacceptable. In the Panel's view, pharmaceutical companies sponsoring third parties, particularly individuals, must be reasonably confident that their proposed activities were clinically sound and complied with the Code. In addition to funding and agreeing that the audit be performed by an external healthcare practitioner, Solvay had, in each of the four letters to the doctor, stated that the audit would be performed by a named nurse. Solvay had, in effect, provided the nurse to do the audit who the company understood had some expertise in similar audits. Again the Panel considered that this was unacceptable; if the company was recommending staff to carry out the audit it should be sure that they had the necessary expertise. In the Panel's view, by introducing the nurse to the practice, Solvay had to assume some responsibility for her actions.

With regard to the provision of nursing staff the Panel was concerned to note that Solvay had initially named two individuals but had later stated that this was an error in that one of those named was understood to be a practice manager. Nonetheless the final letter from Solvay to the GP (13 June) had the nurse's name crossed out and the assumed practice manager's name written in by hand. There was no information as to who had changed the letter or who had conducted the final audit.

Field Force Working Guidance (SOP SHL C33) issued by Solvay gave guidance on the provision of unconditional medical grants for audit of care in patients in general practice. The guidance stated that if asked for financial assistance with a patient identification audit in the relevant therapeutic area eg coronary heart disease/cardiovascular disease that might encompass patients who had had a previous myocardial infarction, hypertension, lipid abnormalities and stroke, representatives could tell health professionals that Solvay was able to offer help. The guidance, however, did not refer to the company reviewing the proposed audit protocol so as to ensure that it was supporting a valid audit. The guidance also noted that Solvay could provide an external agent to perform the audit and, if requested, template letters that the surgery could use in order to recall patients to review their therapy.

The Panel was concerned about the representative's role in the audit at issue. Although Solvay stated that the representative had sought authority for financial support to be given, it appeared that no regional sales manager or healthcare development manager had discussed the project with the GP as recommended in the Field Force Working Guidance. The representative had provided the GP with the contact details of a nurse who would conduct the audit and had arranged for the GP to sign the agreement regarding the support to be provided by Solvay. The representative had delivered the cheque which represented the fee to be paid to the nurse for conducting the audit. In the Panel's view the delivery of cheques to doctors by representatives in this way gave a very poor impression; it might be perceived by some to be an inducement to prescribe the company's products given the prime role of a representative was to promote medicines.

The Panel noted Solvay's involvement with the audit and subsequent therapy review and considered that it was inextricably linked to it. The company had given the GP approximately £1,700 but had had no oversight of the protocol; it had, in effect, provided a nurse to do the audit although it appeared to have no evidence that she was suitably experienced to be able to conduct the audit or knowledge of what she was going to do. The Panel considered that the vague arrangements which existed were wholly unacceptable; the arrangements were such that Solvay had no way of ensuring that the grant which it had given to the GP would be used for an appropriate purpose. The Panel considered that the arrangements were such that they did not constitute a bona fide medical and educational good and service. The Panel ruled a breach of Clause 18.4 of the Code.

The Panel noted that data provided by the complainant showed that the prescribing of Omacor in the practice in question greatly exceeded the two highest Omacor prescribing practices in the local PCT and that the other 60 or so practices in the area prescribed almost negligible amounts of this medicine. The Panel further noted that shortly after receiving each letter from Solvay regarding the provision of more money (November 2006, January, April and June 2007) prescribing of Omacor in the practice in question increased. The Panel also noted the complainant stated that following the meeting with the representative the doctor considered his patients would benefit from Omacor and he signed an agreement with Solvay. The Panel noted its concerns about the role of the representative and the delivery of cheques to the doctor by the representative. The Panel considered that on the balance of probabilities such payment by a representative in association with an unacceptable service amounted to an inducement to prescribe Omacor in breach of Clause 18.1. The Panel had no evidence that the grants constituted the disguised promotion of Omacor. No breach of Clause 10.1 was ruled.

The Panel was very concerned about the overall arrangements set out above. The Panel further considered that given its involvement in the process, Solvay's failure to assume any responsibility for the audit which it facilitated meant that the conduct of employees had fallen short of competent care such as to bring discredit upon or

reduce confidence in the pharmaceutical industry. A breach of Clause 2 was ruled.

The Panel was extremely concerned that Solvay appeared to have no procedures in place for ensuring that grants given to facilitate general practice audit were spent on valid audits/therapy reviews and the like. The Panel was also concerned that Solvay would recommend third parties to perform the audits/reviews, without knowing their relevant qualifications or experience to perform such tasks, but take no responsibility for their actions. The Panel decided to report Solvay to the Code of Practice Appeal Board in accordance with Paragraph 8.2 of the Constitution and Procedure. In accordance with Paragraph 7.1 of the Constitution and Procedure, the Panel further required Solvay to suspend the provision of grants for patient identification programmes and the like such that no new agreements were signed.

COMMENTS FROM SOLVAY ON THE REPORT

Solvay stated that it had reflected very carefully on the Panel's findings. It had investigated the matter thoroughly and examined its policies and practices relating to similar programmes. The company took its responsibilities as a pharmaceutical company very seriously and always sought to comply with the Code. The company regretted very much that this case had arisen and had led to the Panel ruling that a programme intended to benefit patients and the NHS did not comply with the Code.

Solvay submitted that the patient identification programmes which it sponsored were conceived and, so far as it understood, were executed as audits, stopping short of a consultation and any clinical decision making. Such an audit was essentially a snapshot recording an existing state of affairs rather than an analysis of what should be happening. An audit was an essential preliminary to a therapy review and, of its nature, was an activity which benefitted patients and the NHS. Once the GP had the information from the audit he could decide how to use it. A therapy review would be an obvious second step, but the value in the audit was in the extraction of information which might be used for planning, appraisal and public health purposes, quite apart from its use in the initiation of individual changes of therapy.

Many companies, including Solvay, had sponsored audits, but did not wish or think that it was proper to become involved in a doctor's clinical decision making or prescribing because their own products might feature in those decisions. Solvay designed the patient identification programmes in good faith and with the best of intentions to try to provide the sort of useful audit service which it believed would benefit the NHS and patients. The company had considered that such audits were less likely to give rise to concerns under the Code because they stopped short of becoming involved with therapeutic decisions or protocols, the full responsibility for which remained, as Solvay thought proper, with the GP. Solvay's reading of the Code and previous cases had supported it in this belief.

Following receipt of the Panel's rulings Solvay was carrying out a thorough and urgent review of all of its procedures to ensure that the very important lessons derived from the ruling were learnt and put into practice by all staff. Solvay noted, however, that some of the most concerning aspects that had emerged – such as the letter sent to patients and the quality of the GP's subsequent prescribing decisions – occurred after the completion of the company sponsored audit and were matters over which Solvay had no control.

Solvay stated that the points it made in mitigation did not qualify its respect and support for the Authority and its acceptance of the Panel's rulings. The company repeated that it regretted the matter had come before the PMCPA and its ongoing commitment to compliance with the Code.

At the consideration of the report Solvay's representatives stated that Solvay had not intended to offer any inducement to prescribe Omacor, it considered the payments to be unconditional grants. The representatives apologised for being found in breach of the Code.

The representatives stated that the patient identification programme at issue had ceased in February 2009. Since then a review of the company's standard operating procedures and a further training programme for staff involved in Code issues had been commissioned. The revised standard operating procedures were due to be completed by May 2009 and staff training by June 2009. External Code consultants had been employed.

In addition all sales staff and head office staff involved with the Code had been trained on the Code in December 2008.

APPEAL BOARD CONSIDERATION

The Appeal Board was very concerned that Solvay had provided grants in the form of cheques via its representative to the GP on four separate occasions. The Appeal Board considered that it was inappropriate for a representative to hand over money to a doctor. The company had no processes to enable it to check that the money was used to pay a nurse to conduct an audit and how long that would take or that the audit itself was appropriate. Further there was no assessment of the first audit before providing a cheque to the same doctor for the next audit. The Appeal Board did not accept that the payment to the doctor was unconditional as submitted by Solvay. It was provided for a specific reason – ie an audit. The Appeal Board was further concerned that the nurse, introduced to the GP by Solvay and employed by him to undertake the patient identification programme, had not been assessed by the company with regard to her ability to carry out the task for which she was to be paid. There was a failure of management.

The Appeal Board further noted that there appeared to be a marked consequential increase in the prescribing of Omacor by the GP concerned and it queried whether, as a result, patients had been put at risk.

The Appeal Board decided in accordance with Paragraph 11.3 of the Constitution and Procedure to require an audit of Solvay's procedures in relation to the Code to be carried out by the Authority. The audit should be conducted as soon as possible. On receipt of the audit report the Appeal Board would consider whether further sanctions were necessary. In addition the Appeal Board decided that Solvay should be publicly reprimanded.

APPEAL BOARD FURTHER CONSIDERATION

The audit was conducted in June 2009. The Appeal Board was concerned to note that the audit report demonstrated that Solvay had clearly lacked processes to ensure compliance with the Code. Further policy changes were still required. The Appeal Board thus decided, in accordance with Paragraph 11.3 of the Constitution and Procedure, to require a further audit of Solvay's procedures in relation to the Code to be carried out by the Authority in November when it expected Solvay's standard operating procedures (SOPs) to be completed. On receipt of that audit report the Appeal Board would consider whether further sanctions were necessary.

In accordance with Paragraph 13.6 of the Constitution and Procedure the Appeal Board decided that an interim case report should be published on the PMCPA website.

Upon receipt of the report of the November 2009 re audit the Appeal Board noted that Solvay had made much improvement since the audit in June 2009. The Appeal Board decided that on the basis that the recommendations from the re audit were either implemented or ongoing no further action was required.

Complaint received	**14 January 2009**
Undertaking received	**10 March 2009**
Appeal Board consideration	**23 April 2009**
Interim case report published	**1 June 2009**
Appeal Board consideration	**23 July 2009**
Case completed	**9 December 2009**