CASE AUTH/2023/7/07

TEACHING PRIMARY CARE TRUST PHARMACIST v PFIZER

Champix GP Referral Aid

A pharmacist at a teaching primary care trust (PCT) complained about a Champix (varenicline) GP referral aid issued by Pfizer. The referral aid was comprised of a pad of tear-off letters which were completed by providers of a smoking cessation service including community pharmacists and other health professionals, and handed to the patient to give to their GP.

The complainant noted that the letter referred patients to their GP from the pharmacy and recommended that Champix be prescribed. The complainant did not believe that a community pharmacist would have access to the necessary clinical information needed to make this recommendation. She was particularly concerned by a section of the letter, which stated, 'In cases where the patient has epilepsy or a history of psychiatric illness, the clinical justification for recommending Champix is described below…'. This seemed a wholly inappropriate way of promoting a prescription only medicine.

The Panel noted that the GP referral letter was headed 'Smoking cessation therapy' and began by giving the patient's personal details. The letter explained that the patient was receiving a support programme from the local stop smoking service and that 'Following consultation, we recommend that in order to help them give up smoking, the therapy of choice is varenicline tartrate (Champix)'. Details of the dosage regimen were given. The GP was also advised that the patient had been encouraged to enrol in the LifeREWARDS programme (www.myliferewards.co.uk). The letter continued 'To ensure that Champix is suitable for this patient, we have already checked the following' and listed a number of clinical parameters under the headings 'Motivated to quit', 'Contraindictions' and 'Warning/precautions'. The final parameter under 'Warning/precautions' was 'Does the patient have a history of psychiatric illness?' followed by a highlighted blue box which read 'In cases where the patient has epilepsy or a history of psychiatric illness, the clinical justification for recommending Champix is described below', and was followed by space for completion by the smoking cessation adviser or health professional. Pfizer submitted that the letter was completed by smoking cessation advisers, pharmacists who provided a smoking cessation service or other health professionals.

The Panel noted that the role of smoking cessation advisers might include discussion of treatment including prescription only medicines such as Champix. Whilst the comments and recommendations made by the adviser would be relevant the Panel noted that the final prescribing decision lay with the GP.

The Panel noted the complainant's general allegation that the letter was a wholly inappropriate way of promoting a prescription only medicine. The Panel was extremely concerned about the content of the referral letter and its provision to patients. The Panel considered that the description of Champix as 'the therapy of choice' was an exaggerated claim. It implied a special merit, quality or property which could not be substantiated. A breach of the Code was ruled.

The Panel noted that the Champix summary of product characteristics (SPC) stated in the special warnings/precautions for use section that 'smoking cessation whether with or without pharmacotherapy has been associated with the exacerbation of underlying psychiatric illness (eg depression). Care should be taken with patients with a history of psychiatric illness and patients should be advised accordingly'.

Whilst the Panel noted the role of the smoking cessation advisers it queried whether the person completing the referral form would know enough about a patient's psychiatric history to determine the clinical justification for recommending Champix. It was unclear whether they would have access to the patient's medical notes and patients might be reluctant to disclose such information.

The Panel considered that the letter would leave the patient with the unequivocal impression that Champix was the most suitable therapy and this wholly undermined the GP's ability to make a subsequent independent prescribing decision. The Panel considered that the letter clearly promoted Champix. Further a statement, 'Prescribing information for Champix can be found at the back of this document. For more information, please contact your local Pfizer representative' appeared at the bottom of the letter. It was unacceptable to provide patients with material that promoted prescription only medicines. The letter implied that the prescribing decision had already been made and that the role of the GP was to do no more than rubber stamp the recommendation to prescribe Champix. This was unacceptable. The Panel noted that the patient would already have been told about the LifeREWARDS support programme and encouraged to join it; according to the home page of the website referred to in the letter the programme was only open to those who had already been prescribed Champix.

The Panel considered that the referral letter and its provision to patients did not maintain high standards and reduced confidence in and brought discredit upon the pharmaceutical industry. Breaches of the Code, including a breach of Clause 2, were ruled.

The Panel noted its rulings above and in accordance with Paragraph 7.1 of the Constitution and Procedure decided that if there were subsequently an appeal by Pfizer it would require Pfizer to suspend use of the material pending the final outcome.

The Panel considered that the content of the letter and its provision to patients was inappropriate as described above. The undermining of the patient/GP relationship was an extremely serious matter. The Panel decided to report Pfizer to the Code of Practice Appeal Board in accordance with Paragraph 8.2 of the Constitution and Procedure for it to decide whether further sanctions were warranted.

Upon appeal by Pfizer, the Appeal Board noted that smoking cessation advisers ranged from health professionals such as pharmacists and nurses to ex smokers. Although the latter could not be considered health professionals as defined in the Code they could, in certain circumstances, be considered as appropriate administrative staff. The role of smoking cessation advisers might include discussion of treatments including prescription only medicines. Whilst the comments and recommendations made by the advisers might be relevant the Appeal Board noted that the final prescribing decision lay with the prescriber such as the GP.

The Appeal Board was extremely concerned about the content and use of the referral letter. Pfizer expected health professionals to use various methods to send the referral letter to the GP without it being seen by the patient including sealing it in an envelope for the patient to deliver. This account differed from Pfizer's response to the Panel which implied that the letter was given, open, to a patient to hand to their GP. In the Appeal Board's view it was inevitable that some patients would see the letter.

The Appeal Board considered that the description of Champix as 'the therapy of choice' was an exaggerated claim. It upheld the Panel's ruling of a breach of the Code.

The Appeal Board supported the Panel's comments with regard to the smoking cessation advisor's clinical knowledge and thus their ability to recommend Champix for patients with a history of psychiatric illness. Further, the letter only referred to end stage renal disease and did not refer to moderate or severe renal impairment which according to the SPC required dose reduction.

The Appeal Board further agreed that the letter would wholly undermine the GP's ability to make an independent prescribing decision. The letter clearly promoted Champix. It was unacceptable to provide promotional material to patients about prescription only medicines.

The Appeal Board considered that advising patients that Champix was the therapy of choice and encouraging them to enrol in a support programme which was only available to Champix patients implied that the GP was to do no more than rubber stamp the recommendation to prescribe Champix; a refusal to do so would be highly likely to damage the GP/patient relationship. This was unacceptable. The Appeal Board considered that the referral letter and its provision to patients did not maintain high standards and reduced confidence in and brought discredit upon the pharmaceutical industry. The Appeal Board upheld the Panel's rulings of breaches of the Code, including a breach of Clause 2.

With regard to the Panel's report under Paragraph 8.2 of the Constitution and Procedure, the Appeal Board was concerned that as the letter was provided in the form of a tear-off pad a large number of them could still be being used. Whilst noting that the materials were no longer distributed by Pfizer the Appeal Board decided nonetheless to require Pfizer to recover the GP referral aids in accordance with Paragraph 11.3 of the Constitution and Procedure.

A pharmacist at a teaching primary care trust (PCT) complained about a Champix (varenicline) GP referral aid (ref SCE021) issued by Pfizer Limited. The referral aid was comprised of a pad of tear-off letters which were completed by providers of a smoking cessation service (smoking cessation advisers) including community pharmacists and other health professionals and handed to the patient to give to their GP.

COMPLAINT

The complainant noted that the letter referred patients to their GP from the pharmacy and recommended that Champix be prescribed.

The complainant did not believe that a community pharmacist would have access to the necessary clinical information needed to make this recommendation. She was particularly concerned by a section near the bottom of the letter, which stated, 'In cases where the patient has epilepsy or a history of psychiatric illness, the clinical justification for recommending Champix is described below…'. This seemed a wholly inappropriate way of promoting a prescription only medicine.

When writing to Pfizer, the Authority asked it to respond in relation to Clauses 2, 7.10 and 9.1 of the Code.

RESPONSE

Pfizer stated that the Champix GP referral aid was a pad of tear-off letters for use by the smoking cessation advisers, pharmacists who provided a smoking cessation service, and other health professionals during the appointment with the patient. By using the checklist provided the patient was assessed by the health professional. The tear-off letter was then given to the patient and they were advised to give it to their

GP at their next appointment. This review would help the GP when (s)he examined the patient.

This process also confirmed that the local stop smoking services had seen the patient and referred them to the GP. This ensured that the stop smoking service was being used properly, and further ensured that these patients would continue to receive the behavioural support from the service, which formed an important part of the smoking cessation treatment approach with Champix.

The complainant was particularly concerned by the section in the letter that read, 'In cases where the patient has epilepsy or a history of psychiatric illness, the clinical justification for recommending Champix is described below…'. This section was included so as to show that the smoking cessation adviser had taken the appropriate medical history, and that appropriate discussion had taken place with the patient. These were then noted on the letter so as to prompt and remind the GP that before making the final decision to prescribe or not, they should again discuss these medical conditions with the patient and then make their own clinical judgement.

The GP referral letter was intended to be used by pharmacists, smoking cessation advisers and other health professionals who were fully trained in providing such a service, and were aware of the importance of recording information about epilepsy and psychiatric conditions before recommending a specific treatment to aid their patients stop smoking. This information would then help the GP to decide, using their clinical judgement, what to do.

Pfizer considered that throughout it had behaved in an open and honest manner. It had not promoted Champix outside its marketing authorization and had complied with both the spirit and the letter of the Code. On the basis of the facts provided above, the company considered that it had not breached any clause of the Code and it was confident that its conduct had been of a high standard throughout.

PANEL RULING

The Panel noted that the GP referral letter was headed 'Smoking cessation therapy' and began by giving the patient's personal details. The letter explained that the patient was receiving a support programme from the local stop smoking service and that 'Following consultation, we recommend that in order to help them give up smoking, the therapy of choice is varenicline tartrate (Champix)'. Details of the dosage regimen were given. The GP was also advised that the smoking cessation adviser or health professional had 'encouraged this patient to enrol in the LifeREWARDS programme (www.myliferewards.co.uk)'. The letter continued 'To ensure that Champix is suitable for this patient, we have already checked the following' and listed a number of clinical parameters under the headings 'Motivated to quit', 'Contraindictions' and 'Warning/precautions'. The final parameter under 'Warning/precautions' was 'Does the patient have a history of psychiatric illness?' followed by a highlighted blue box which read 'In cases where the patient has epilepsy or a history of psychiatric illness, the clinical justification for recommending Champix is described below', and was followed by space for completion by the smoking cessation adviser or health professional. The Panel noted that the referral letter was handed to the patient to provide to his/her GP.

Pfizer explained that the letter was completed by smoking cessation advisers, pharmacists who provided a smoking cessation service or other health professionals. The Panel noted that the role of smoking cessation advisers might include discussion of treatment including prescription only medicines such as Champix. Whilst the comments and recommendations made by the smoking cessation advisers would be relevant the Panel noted that the final prescribing decision lay with the GP.

The Panel noted the complainant's general allegation that the letter was a wholly inappropriate way of promoting a prescription only medicine. The Panel was extremely concerned about the content of the referral letter and its provision to patients for them to hand to their GP.

The Panel considered that the description of Champix as 'the therapy of choice' was an exaggerated claim. It implied a special merit, quality or property which could not be substantiated. A breach of Clause 7.10 was ruled.

The Panel noted that Section 4.4 of the Champix summary of product characteristics (SPC), special warnings and precautions for use, stated that 'smoking cessation whether with or without pharmacotherapy has been associated with the exacerbation of underlying psychiatric illness (eg depression). Care should be taken with patients with a history of psychiatric illness and patients should be advised accordingly'.

Whilst the Panel noted the role of the smoking cessation advisers it queried whether the person completing the referral form would have access to sufficient information about a patient's psychiatric history to determine the clinical justification for recommending Champix. It was unclear whether they would have access to the patient's medical notes and patients might well be reluctant to disclose such information.

The Panel considered that the letter would leave the patient with the unequivocal impression that Champix was the most suitable therapy and this wholly undermined the ability of the GP to make a subsequent independent prescribing decision. The Panel considered that the letter clearly promoted Champix. Further a statement, 'Prescribing information for Champix can be found at the back of this document. For more information, please contact your local Pfizer representative' appeared at the bottom of the letter. It was unacceptable to provide promotional material to patients about prescription only medicines. The letter gave the impression to patients that the prescribing decision had already been made and that was not

necessarily so. The overall tone implied that the role of the GP was to do no more than rubber stamp the recommendation to prescribe Champix. This was unacceptable. The Panel noted that the patient would already have been told about the LifeREWARDS support programme and encouraged to join it; according to the home page of the website referred to in the letter the programme was only open to those who had already been prescribed Champix. The Panel considered that the referral letter and its provision to patients did not maintain high standards and reduced confidence in and brought discredit upon the pharmaceutical industry. Breaches of Clauses 2 and 9.1 were ruled.

The Panel noted its rulings above and in accordance with Paragraph 7.1 of the Constitution and Procedure decided that if there were subsequently an appeal by Pfizer it would require Pfizer to suspend use of the document pending the final outcome.

The Panel considered that the content of the letter and its provision to patients was inappropriate as described above. The undermining of the patient/GP relationship was an extremely serious matter. The Panel decided to report Pfizer to the Code of Practice Appeal Board in accordance with Paragraph 8.2 of the Constitution and Procedure for it to decide whether further sanctions were warranted.

APPEAL BY PFIZER

Pfizer stated that in November 2006, the GP referral aid was pre-vetted by the Medicines and Healthcare products Regulatory Agency (MHRA) prior to the launch of Champix in December 2006. The objective of the item was outlined as it was intended to be used – 'a letter to recommend patients for Champix on a named patient basis from non-prescribers to ensure they are suitable for treatment'. After reviewing the referral aid, the MHRA did not object to its use.

The GP referral aid was a pad of tear-off letters for use by health professionals specifically where they wished to recommend a Champix prescription for a particular patient, after discussion with that patient and consideration of all available treatment options.

Stop smoking services were provided via a variety of routes including NHS local stop smoking services via pharmacies that had set themselves up to provide a stop smoking service to the community, and at GP practices often by trained nurses. Regardless of the route that the patient followed after consultation they were usually recommended a course of action that might include pharmacological therapy along with behavioural support. The recommended therapy might include a prescription only medicine (such as Champix), or nicotine replacement therapy which was available with or without prescription. As the majority of smoking cessation advisers (with the exception of some nurse and independent prescribers) were unable to prescribe medicines, they in turn referred patients to a GP who would then evaluate them, the suitability of any recommended treatment and make any relevant prescribing decision. If the adviser had prescribing powers, they could simply prescribe the chosen treatment.

Pfizer submitted that as the route to a prescription in smoking cessation was more complex than most other therapy areas, the smoking cessation advisers used referral letters such as the GP referral aid at issue to aid this process; the letters were meant to be used after the patient and adviser had discussed all treatment options. If it was decided that Champix was the best option for that particular patient then the adviser would use the referral aid in order to record important information that would aid the GP to make the final prescribing decision. It was designed to ensure that the health professional was prompted to consider important contraindications and special precautions/warnings for Champix to help ensure appropriate prescribing. As from previous experience with other oral smoking cessation therapies it was important to ensure that a complete history of epilepsy and psychiatric history was recorded as either of these conditions might be exacerbated either by the therapy itself or by the effects of stopping smoking. As 'epilepsy' and 'history of psychiatric illness', were listed as warning/precautions to the use of Champix, the referral aid had a highlighted box to ensure that the smoking cessation adviser documented any important information gathered from the patient consultation that would help the GP make the ultimate prescribing decision.

As the GP referral aid referred to Champix by name stating its indication and dosage, Pfizer considered it to be a promotional item and therefore included the prescribing information as required by Clause 4.1. Smoking cessation advisers, like other health professionals, used various routes for sharing confidential patient information with other health professionals, such as email/post/fax or delivery of sealed envelopes via the patient. It was not Pfizer's responsibility to tell health professionals how to enter into such confidential dialogue. Pfizer expected good professional practice to be maintained at all times.

The GP referral aid could be used as a tool by health professionals who were providing a smoking cessation service after they had completed their consultation with the patient and considered all relevant therapies. If Champix was then considered as a treatment option the referral aid then acted as an aide memoire by highlighting key questions and special precautions/warnings relating to Champix.

With regard to the Panel's query about whether the person completing the GP referral aid would have access to sufficient information about a patient's psychiatric history to determine the clinical justification for recommending Champix, and that a patient's medical notes might not be accessible or that patients might be reluctant to disclose such information, Pfizer submitted that stop smoking services were an integral part of the UK health system to provide patients with information about the support available to help them stop smoking. Smoking cessation advisers were health professionals who were generally considered to be experts in their line of work. Patients were often

referred to them by GPs for expert smoking cessation advice, support, and information about treatment options. The smoking cessation advisers evaluated the best treatment for their patients on a case by case basis. For some treatments patients might be passed back to their GP with a recommended treatment (which might include both non-prescription and prescription medicines). The GP then evaluated this assessment, and normally prescribed as appropriate following consultation with the patient. Specifically highlighting potential areas warnings/precautions such as epilepsy or a history of psychiatric illness, alerted the prescriber to the fact that Champix might be unsuitable for a particular patient. The GP referral aid supported the rational and clinically appropriate use of Champix.

Only where the smoking cessation adviser believed a Champix recommendation was appropriate, would the referral letter go to the GP for consideration. Pfizer did not expect any referral aids to be seen by patients, and it would never encourage or endorse this. Smoking cessation advisers, like other health professionals, used various routes for the careful exchange of confidential information with other health professionals, such as email/post/fax/sealed envelope via the patient. This was supported by various PCT guidance documents as to how referrals should be sent (examples were provided). Although not specific to smoking cessation, the guidance stipulated that referral letters handed to patients should be in sealed envelopes. Pfizer had no reason to believe that this process was not followed by smoking cessation advisers, and therefore submitted that patients would not possibly see a copy of the referral aid in question

Pfizer acknowledged that it could have been clearer on this issue in its response when it stated that the GP referral aid was handed to the patient after its completion by a health professional. However, Pfizer had no reason to believe that the health professional would not use standard practice and therefore fully expected the letter to be sealed in an envelope before being handed to the patient (if it was not sent directly to the patient's GP).

It was common practice for stop smoking services to discuss with patients the types of therapies available to help them to stop smoking. During these discussions the main objective was to evaluate what would be the best treatment option for that particular patient. When both the patient and adviser agreed on a certain treatment then that was considered the 'therapy of choice' for that particular patient and it was for these reasons that the term 'therapy of choice' was included in the referral aid; it did not imply a special merit, quality or property as noted by the Panel.

As previously stated, the main objective of the discussions between the patient and the smoking cessation adviser was to evaluate what would be the best treatment option and support programme for that particular patient. The patient would normally be told that the decision to prescribe certain treatments, such as Champix, rested with the GP. The referral aid did not state that the GP must prescribe Champix nor did Pfizer believe that the smoking cessation advisers advocated this. GPs received referral letters from many health professionals other than smoking cessation advisers, in which recommendations were made regarding treatment, but the final decision to act upon the recommendation rested with the GP who would consider other important factors from the patient's history and medical notes and prescribe the medicine considered to be the most appropriate for that patient.

Pfizer noted the Panel's concerns about the reference to the LifeREWARDS programme in the referral aid. LifeREWARDS was a personalized behavioural support programme created by Pfizer and was available only to Champix patients. Similar support programmes were offered by other companies providing smoking cessation products. All treatment options along with associated behavioural support programmes were evaluated and discussed with the patient. When Champix was recommended as a treatment option then the advisers would discuss the associated LifeREWARDS support programme with the patient as an optional form of behavioural support.

Pfizer noted that as detailed in Section 1 of the National Institute for Health and Clinical Excellence (NICE) guidance for Champix, the second recommendation stated that 'varenicline should normally be prescribed only as part of a programme of behavioural support'. The NICE guidance further elaborated in Section 4.4 that 'varenicline should normally only be provided in conjunction with counselling and support, but that if such support is refused or is not available, this should not preclude treatment with varenicline'. Pfizer submitted that it was important that smoking cessation advisers knew about LifeREWARDS as an additional help and support for patients trying to stop smoking. The odds of successfully quitting increased if the patient had access to a behavioural support programme along with pharmacological treatment (Coleman *et al* 2004). Discussing LifeREWARDS with the patient at this early stage helped ensure that they knew about the full treatment package available with Champix. The LifeREWARDS support programme was an optional behavioural modification programme that complimented the support that was provided by the stop smoking advisers.

Pfizer submitted that after the completion of the referral aid the smoking cessation advisers should inform patients that it was only a recommendation and that the GP would always have the final decision. The referral aid was not for the patient to see or read but a document that was sent from one health professional to another. The GP would then decide after taking into consideration all related aspects whether to agree with the recommendation or to choose an alternate course of action. This did not imply that patients would demand Champix, and it did not undermine the patient/GP relationship for reasons mentioned above.

In conclusion, Pfizer submitted that it had not breached Clauses 2, 7.10 or 9.1 and it was confident that its conduct, which was open and honest, had been of a high standard throughout. Pfizer submitted that it had complied with both the spirit and the letter of the Code.

COMMENTS FROM THE COMPLAINANT

The complainant disputed Pfizer's submission that smoking cessation advisers were health professionals. Many did not have a health qualification, although they would have had some specific training in smoking cessation. Even if health professionals completed the form (as would be the case with community pharmacists) they still would not have had access to the patient's medical records and would therefore not confidently know whether the patient had a history of psychiatric illness. How likely would a patient be to disclose this information? The form would be slightly more acceptable if it stated, 'Please check that this patient does not have a history of psychiatric illness or epilepsy before prescribing'. The fact that it actually stated, 'In cases where the patient has epilepsy or a history of psychiatric illness, the clinical justification for recommending Champix is described below' made this a completely different scenario. The complainant could not imagine what sort of justification a pharmacist (or even more worryingly a smoking cessation adviser who was not a health professional) would give. Where would the clinical liability lie if a GP prescribed based on this recommendation?

The complainant considered Pfizer to be rather naïve when it stated that it did not expect any referral aids to be seen by patients, and that it did not believe that patients would possibly see a copy of the referral aid. If the smoking cessation adviser or pharmacist was to obtain information about psychiatric illness, epilepsy, breast feeding, renal disease etc and was seen to be completing a form, then the patient would know what this was for and would know that the GP was being asked to prescribe Champix.

Pfizer quoted guidance from another PCT regarding how referrals should be sent ie in a sealed envelope. The complainant alleged that this guidance was not related to smoking cessation services or to community pharmacy and applied to GP referral letters to secondary care, which was an entirely different situation. If a random selection of community pharmacists were asked what they would do with the referral form it was likely that they would just hand it to the patient. There was nothing on the form to suggest otherwise.

The complainant noted that Pfizer appealed on the basis that, in cases when both the patient and adviser agreed to certain treatment, then it submitted that this was considered the 'therapy of choice'. In the absence of a prescriber during the consultation, the complainant alleged that a decision could not be made that this was the therapy of choice. A more appropriate form of wording might have been that Champix was 'a suitable option' or similar.

The complainant noted the Panel had considered that the letter implied that the prescribing decision had already been made. Pfizer had disputed this, insisting that the patient would understand that the final decision rested with the GP. Given that the patient had to give full medical details to the pharmacist or smoking cession adviser, the complainant alleged that the patient was very likely to assume that the GP would prescribe. This undermined the GP's ability to make a subsequent independent prescribing decision and undermined the relationship between the patient, the GP and the pharmacist.

The complainant noted that Pfizer's appeal seemed to rest upon extolling the values of LifeREWARDS, although this was not actually disputed in the complaint. The Panel had noted that LifeREWARDS was only open to those already prescribed Champix and that it was therefore inappropriate for it to be mentioned before prescribing had occurred. The complainant stated that the mention of LifeREWARDS at this stage actually reinforced the impression that the GP was expected to rubber stamp the decision to prescribe Champix.

The complainant noted that the Panel had considered that the GP would not have any other choice as the patient would demand Champix and this would undermine the patient/GP relationship. The complainant noted Pfizer's appeal was on the basis that the patient would not have seen the referral, would understand that this was only a recommendation and that the final decision rested with the GP. For all the reasons above, the complainant did not consider this to be an accurate reflection of what would happen.

The GP would be in a very difficult situation if they decided not to prescribe. Champix carried a black triangle status and some GPs might consider that it was not in the best interests of the patient to prescribe, which was their clinical right. However, this would cause tension between the GP and the patient, who already had a high expectation that Champix would be prescribed. It was also likely to cause tension between GPs and local community pharmacists if referrals were made using this form.

In conclusion, the complainant alleged that Pfizer had acted in breach of Clauses 2, 7.10 and 9.1 as ruled by the Panel. The complainant found nothing in Pfizer's appeal to alter the facts and change her view.

APPEAL BOARD RULING

The Appeal Board noted that the referral letters were to be completed by smoking cessation advisers. The advisers ranged from health professionals such as pharmacists and nurses to previous smokers who had stopped smoking. Although the latter could not be considered health professionals as defined in Clause 1.4 they could, in certain circumstances, be considered as appropriate administrative staff (Clause 1.1). The role of smoking cessation advisers might well include discussion of treatments including prescription only medicines such as Champix. Whilst the comments and recommendations made by the smoking cessation advisers might be relevant the Appeal Board noted that the final prescribing decision lay with the prescriber such as the GP.

The Appeal Board was extremely concerned about the content and use of the referral letter. Pfizer expected

health professionals to use various methods to send the referral letter to the GP without it being seen by the patient including sealing it in an envelope for the patient to deliver. This account differed from Pfizer's response to the Panel which implied that the letter was given, open, to a patient to hand to their GP. In the Appeal Board's view it was inevitable that some patients would see the letter.

The Appeal Board considered that the description of Champix as 'the therapy of choice' was an exaggerated claim. It implied a special merit, quality or property which could not be substantiated. A breach of Clause 7.10 was ruled. The appeal on this point was unsuccessful.

Section 4.4 of the Champix SPC, special warnings and precautions for use, stated that 'smoking cessation whether with or without pharmacotherapy has been associated with the exacerbation of underlying psychiatric illness (eg depression). Care should be taken with patients with a history of psychiatric illness and patients should be advised accordingly'.

Whilst the Appeal Board noted the role of smoking cessation advisers it queried whether those completing the referral form would have access to sufficient information about a patient's psychiatric history to determine the clinical justification for recommending Champix. It was unclear whether they would have access to the patient's medical notes and patients might well be reluctant to disclose such information. Further, the letter only referred to end stage renal disease and did not refer to moderate or severe renal impairment which according to the SPC required dose reduction.

The Appeal Board considered that the completion of the letter by the smoking cessation adviser would give the patient the unequivocal impression that Champix was the most suitable therapy and wholly undermine the GP's ability to make a subsequent independent prescribing decision. The letter clearly promoted Champix. It was unacceptable to provide promotional material to patients about prescription only medicines.

The Appeal Board considered that advising patients that Champix was the therapy of choice and encouraging them to enrol in the LifeREWARDS support programme (which was only available to Champix patients) implied that the role of the GP was to do no more than rubber stamp the recommendation to prescribe Champix. If the GP then refused to prescribe Champix this would be highly likely to damage the GP/patient relationship. This was unacceptable. The Appeal Board considered that the referral letter and its provision to patients did not maintain high standards and reduced confidence in and brought discredit upon the pharmaceutical industry. The Appeal Board upheld the Panel's rulings of breaches of Clauses 2, and 9.1. The appeal was unsuccessful.

With regard to the Panel's report under Paragraph 8.2 of the Constitution and Procedure, the Appeal Board was concerned that as the letter was provided in the form of a tear-off pad a large number of them could still be being used. Whilst noting that the materials were no longer distributed by Pfizer the Appeal Board decided nonetheless to require Pfizer to take steps to recover the GP referral aids in accordance with Paragraph 11.3 of the Constitution and Procedure.

Complaint received	**18 July 2007**
Case completed	**18 October 2007**