PRESCRIPTION MEDICINES
CODE OF PRACTICE AUTHORITY

# QUARTERLY REVIEW APRIL 1994

12 Whitehall London SW1A 2DY Telephone 0171-930 9677 Facsimile 0171-930 4554

# PRESCRIPTION MEDICINES CODE OF PRACTICE AUTHORITY

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### Case Reports

A further set of reports of cases settled by the Prescription Medicines Code of Practice Authority (PMCPA) is included in this issue of the Review.

### Allegations in The Sunday Times

For three consecutive weeks in November 1993, allegations appeared in The Sunday Times concerning the activities of pharmaceutical companies. In accordance with the usual practice all of these matters were taken up for investigation as complaints under the Code of Practice for the Pharmaceutical Industry and reports of them are included in this Review (AUTH/90/11/93, AUTH/91/11/93, AUTH/92/11/93 and AUTH/93/11/93).

Two companies, Duphar Pharmaceuticals Limited (AUTH/93/11/93) and Fisons Pharmaceuticals (AUTH/90/11/93), were reprimanded by the Board of Management of The Association of the British Pharmaceutical Industry (ABPI) and suspended from membership. Following an audit of its procedures by the PMCPA, Fisons has since been reinstated by the ABPI Board.

### Implementation of the EC Directive on the Advertising of Medicinal Products for Human Use.

The regulations to implement in the United Kingdom the EC Directive on the advertising of medicinal products for human use are still awaited. Companies will be sent details as soon as the regulations are made.

It may be helpful to remind you how the regulations will affect the content of promotional material.

Full Advertisements Advertisements which comply with Clauses 4.1 and 4.2 of the Eighth Edition of the Code of Practice for the Pharmaceutical Industry (1 January 1993) will comply with the requirements of the forthcoming regulations.

The date upon which the advertisement was drawn up or last revised will be required on all mailings and leavepieces etc but not on full advertisements appearing in journals in respect of which it will be optional.

Abbreviated Advertisements The requirements of Clause 5 of the Eighth Edition of the Code of Practice will continue to apply except that:

a. It will be necessary to include the legal classification, ie, POM, P or GSL;

b. At the present time, it is optional whether an indication for the use of the medicine is included. It is proposed to amend the Code of Practice so as to make the inclusion of at least one indication obligatory. The inclusion of a concise statement as to why the medicine is recommended for the indication or indications given will remain optional.

c. Abbreviated advertisements will have to include any warning which the Medicines Commission, a section 4 committee (usually the Committee on Safety of Medicines) or the licensing authority has required to be included in advertisements relating to the medicine in question.

Audio–Visual Advertisements Prescribing information in relation to audio–visual material which complies with Clause 4.3 of the Eighth Edition of the Code of Practice for the Pharmaceutical Industry will comply with the requirements of the forthcoming regulations.

Promotional Aids The requirements as to the inclusion of information on promotional aids which are set out in Clause 18.3 of the Eighth Edition of the Code of Practice will continue to apply, except that it will no longer be permissible to include the address of the company concerned.

Companies are advised to include the legal category in each abbreviated advertisement as soon as possible, even though technically the inclusion of a legal category is not at present permitted under the current regulations or the current Code of Practice. Until these are both changed, however, the inclusion of a legal category will not be regarded as in contravention of either.

**Proposed New Edition of the Code of Practice for the Pharmaceutical Industry**

Notwithstanding the fact that the advertising regulations have not yet been made, the ABPI hopes to put proposals for amending the Code of Practice for the Pharmaceutical Industry and the Constitution and Procedure for the Prescription Medicines Code of Practice Authority before its Annual General Meeting on 14 April. It is anticipated that the proposals will be sent out towards the end of March.

Agreement on changes would enable a printed version of the Code to be issued to replace the temporary photocopied version which has been in use since the beginning of 1993 pending implementation of the EC Directive.

**Seminars**

An important part of the work of the PMCPA is assisting pharmaceutical companies with the training of their staff in the requirements of the Code of Practice with a view to maintaining high standards. Ten seminars on the Code of Practice open to all companies were held by the PMCPA at the Royal Society of Medicine in 1993 and twenty–two similar seminars were held at individual companies.

Further open seminars take place at the Royal Society of Medicine on:

Wednesday, 27 April 1994 (fully booked)
Thursday, 26 May 1994
Wednesday, 6 July 1994

Seminars can also be arranged for individual companies.

Please ask Miss Emer O' Reilly at the PMCPA for details.

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# CASE REPORTS
# APRIL 1994

*In each case where a breach of the Code was ruled the company concerned gave an undertaking that the practice in question would cease forthwith and that all possible steps would be taken to avoid a similar breach in the future. An undertaking must be accompanied by details of the actions taken to implement that undertaking. The reports refer to the Eighth Edition of the Code, 1 January 1993.*

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CASE AUTH/71/8/93

GENERAL PRACTITIONER V MEMBER COMPANY

Promotion of a prescription only medicine to the public

*Complaint* A doctor complained about the activities of a member company in relation to various materials which concerned a particular condition. The company in question had a product for the treatment of that condition. The materials issued consisted of literature and an audio tape which were provided to the public following requests from listeners to a radio programme and documents which were part of a press briefing. The complainant alleged that the activities were a major public relations exercise to promote a prescription only medicine to the public.

*Response* The company submitted that the information provided following requests from the public was not promotional in nature. Some of the information had been prepared in collaboration with a patient association for the condition concerned. The information prepared by the company was intended to give a reasonably comprehensive review of the condition and to address the concerns of patients. The press briefing documents had formed part of a medical press briefing which had been sent to medical journalists together with a data sheet for the product.

**Panel Ruling** The Code of Practice Panel noted that the materials supplied to the public did not contain any reference to the product by name but did make reference to its therapeutic category. The Panel noted that the press materials did refer to the product by name in a positive manner and that a data sheet had been included.

The Panel examined the requirements of Clause 20 of the Code which concerned information to the general public and decided that on balance the materials were not unacceptable. The Panel therefore ruled there was no breach of the Code.

**Complaint received** **26 August 1993**

**Case completed** **6 January 1994**

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CASES AUTH/72/9/93 AND AUTH/77/9/93

CONSULTANT MICROBIOLOGIST V ROUSSEL LABORATORIES LTD AND PANPHARMA LTD

Mailing on Orelox

*Complaint* A consultant microbiologist, complained about a mailing on Orelox (cefpodoxime) sent by Roussel Laboratories Ltd. The mailing included a reference, by way of a company logo, to Panpharma Limited and the matter had been taken up with both companies.

The complainant drew attention to claims in the mailing that Orelox was "Well tolerated in clinical use" and that "Orelox is significantly better tolerated than co-amoxiclav", which were referenced to a particular study. The complainant referred to a further study which the complainant assumed was an up to date evaluation in which the authors noted that there was "no significant difference between the groups".

*Response* Roussel Laboratories Ltd submitted that in the light of the results of the study quoted by the complainant, it had no reason to reappraise its use of the study to which the claims were referenced. Both studies had been conducted using maximum doses of both products, but only the referenced study was performed with sufficient patients to be able to come to a valid conclusion on tolerance. The lack of a statistically significant difference between the incidence of side-effects with the two products in the second study might simply have been due to too small a sample size. The two groups compared in the referenced study showed markedly different adverse event profiles, in particular those events affecting the gastrointestinal tract where the incidence of diarrhoea was 3.7% and 12.6%, vomiting, 0% and 5.9%, and nausea 0% and 4.4% for Orelox and co-amoxiclav respectively. All of these differences were statistically significant.

The company submitted that it was valid to point out that the referenced study was performed entirely in the UK, whereas the second study was a multi-national study conducted in Germany, France and Italy.

Panpharma Limited although not a member of the ABPI had agreed to comply with the Code. The company did not wish to add to the response submitted by Roussel.

*Panel Ruling* The Code of Practice Panel noted that both the studies were multi-centre and both apparently in general practice which therefore involved problems of comparability between centres and patients, either in the UK or abroad. Neither of the two studies appeared to be peer reviewed but were broadly comparable in approach and the methods adopted.

The Panel noted that the referenced study found statistically significant advantages in the adverse event profile for Orelox compared to co-amoxiclav, whereas the second study concluded that in relation to adverse events there were no significant differences between the groups.

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The Panel did not accept that the second study did not merit consideration. The Panel accepted that the referenced study provided some evidence to show that Orelox was better tolerated than co-amoxiclav but did not accept that the claim "Orelox is significantly better tolerated than co-amoxiclav" was a balanced evaluation of all the available evidence. It was too strong a claim in the light of the evidence. The Panel therefore ruled a breach of Clause 7.2 of the Code.

*Appeal* Roussel Laboratories stated that the mailing had been sent to hospital microbiologists. There were four clinical studies published that compared Orelox with co-amoxiclav in adults, the two studies that had been provided and two additional open studies.

The company acknowledged that three of the four studies, although performed in relatively large numbers of patients, failed to show any statistically significant difference between the adverse event profiles for the two products. The second study failed to show a statistically significant difference between the two comparators. The adverse events were, however, slightly numerically greater in the Orelox group. The two additional studies both showed numerically greater adverse events with co-amoxiclav, but although these differences were larger than those seen in the second study, they failed to reach a statistically significant level. The company submitted that the overall results of the four studies demonstrated a more favourable adverse event profile for Orelox. In this sample of 1012 adult patients, the incidence of adverse events was 18.5% in the co-amoxiclav group and 12.4% for cefpodoxime. The company agreed that although pooling data in this situation could be considered inappropriate, it submitted that it was worthwhile noting that this difference in adverse event profiles was statistically significant.

The company pointed out that the study given as the reference stated that "The results of this study indicated that cefpodoxime proxetil is better tolerated than Augmentin..." and "Significantly more patients treated with Augmentin experienced an adverse event..."

The company submitted that the use of the word "significantly" in the claim at issue was appropriate when referring to a statistically significant result in a communication to a scientific audience.

Panpharma advised that it was linked with Roussel's response.

*Appeal Board Ruling* The Code of Practice Appeal Board accepted that the study given as a reference to the claim was a good quality study. It noted that twice as many patients in the Augmentin group withdrew from the study with significantly more patients discontinuing treatment as a result of an adverse event. The Appeal Board did not accept that the results from the other three studies should be discounted.

The Appeal Board did not accept that it was appropriate to pool the data from the four studies. In this regard it noted that the studies were separate studies with the two additional studies being open studies and the other two studies being double blind.

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The Appeal Board accepted that the study to which the claim was referenced did provide some evidence to show that Orelox was better tolerated than co-amoxiclav but did not accept that the claim "Orelox is significantly better tolerated than co-amoxiclav" was a balanced evaluation of all the available evidence. The use of the word "significantly" meant that it was too strong a claim in the light of the available evidence. The Appeal Board ruled a breach of Clause 7.2 of the Code. The Appeal therefore failed.

**Complaint received** **31 August 1993**

**Case completed** **7 January 1994**

CASE AUTH/83/9/93

COMMUNITY PHARMACIST V GLAXO LABORATORIES LIMITED

Mailings on Imigran Subject

***Complaint*** A community pharmacist complained about a "Dear Pharmacist" letter (ref GHM1265-ALP/September 1993) on Imigran Subject sent by Glaxo Laboratories Limited. The complainant was concerned that the letter recommended that the existing auto-injector stock should be dispensed until exhausted. Prescribing doctors would think that patients would be receiving the new device, Imigran Subject, and this would be incorrect. Secondly, if prescriptions were written as Imigran Subject, it would be against the pharmacists' code of ethics to supply the auto-injector device, as the wrong item would have been supplied. Thirdly, patients would not be able to obtain refills for the older device on ensuing prescriptions and this would cost the NHS more money, as refills were cheaper than full kits.

***Response*** Glaxo Laboratories Limited stated that from 1 October 1993 it would only be supplying the new Subject packs and as soon as old existing auto-injector stocks were exhausted, patients would inevitably be transferred to the new device. The company provided a copy of a "Dear Doctor" letter (ref GHM1251-ALP/September 1993) and pointed out that it specifically requested doctors to prescribe Imigran Injection by writing "Imigran Injection treatment pack 10P" or "Imigran Injection refill pack 10P". It did not encourage doctors to write "Subject" and if a doctor were to prescribe Imigran Subject there was nothing to stop a pharmacist dispensing accordingly. Glaxo pointed out that it would be supplying Subject transfer packs free of charge to all community pharmacists which could be used to transfer patients with a refill pack prescription to the new Subject device and that all of the costs associated with the introduction would be met by Glaxo and not the NHS.

***Panel Ruling*** The Code of Practice Panel noted that Glaxo had been asked to supply details of what doctors had been told and the company had provided the "Dear Doctor" letter referred to above. The Panel noted that there has been no complaint about the "Dear Doctor" letter as such but considered that it came within the scope of the complaint as it was relevant to consider what doctors had been told about the introduction of Imigran Subject.

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The Panel noted that the "Dear Pharmacist" letter recommended that existing auto-injector stocks should be dispensed until exhausted, whereas the "Dear Doctor" letter stated that patients with repeat prescriptions for Imigran would receive the new Subject device when they next visited the pharmacist to collect their prescription. The Panel noted that patients with repeat prescriptions for Imigran would not necessarily receive the Subject device if the pharmacist dispensing the prescription held existing auto-injector stock. The Panel considered that the discrepancy in this regard between the "Dear Doctor" letter and the "Dear Pharmacist" letter was misleading. The Panel therefore ruled a breach of Clause 7.2 of the Code.

The Panel ruled that there had been no breach of the Code in relation to the two other allegations which concerned the pharmacists' code of ethics and the cost of the changeover.

*Appeal* Glaxo submitted that the "Dear Doctor" letter should be considered entirely separately from the letter to pharmacists, in that they had different and specific objectives. The letter to doctors was to make as many doctors as possible aware of the changeover and to minimise the number of prescriptions for the older equipment and refills. The company had taken measures to ensure that stocks of the auto-injector device were reduced during September and had decided that the simplest and most accurate representation of the changeover was to state that patients would be transferred at their next visit to the pharmacy. It submitted that this was factually correct for the majority of cases and extra detail would have resulted in considerable confusion.

*Appeal Board Ruling* The Code of Practice Appeal Board accepted that stocks of Imigran held by pharmacists were unlikely to be high. It noted that the "Dear Doctor" letter stated that "Patients with repeat prescriptions for Imigran Injection will be provided with the new Subject device when they next visit the pharmacist to collect their prescription". The Appeal Board considered that patients with repeat prescriptions for Imigran would not necessarily receive the Subject device if the pharmacist dispensing the prescription held existing auto-injector stock. The "Dear Doctor" letter should have made it clear that existing stocks of the auto-injector were to be used up. The Appeal Board considered that the discrepancy between the "Dear Doctor" letter and the "Dear Pharmacist" letter was misleading and the Appeal Board ruled a breach of Clause 7.2 of the Code. The appeal therefore failed.

**Complaint received** **6 October 1993**

**Case completed** **4 January 1994**

**CASE AUTH/87/10/93**

**DIRECTOR V MEMBER COMPANY**

**Journal advertisement featuring a smoker**

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*Complaint* In accordance with established practice, a letter in the British Medical Journal from a doctor critical of the promotion of a medicine by a member company was taken up as a complaint under the Code of Practice. It was alleged that the illustration in the advertisement of a smoker inferred that if patients took the medicine there was no need for them to modify their smoking practices and that the benefits of the medicine were enhanced by smoking.

*Response* The company concerned pointed out that the advertisement appeared in professional journals for doctors and health professionals and that these groups were very well aware of the dangers of smoking and its effects in the particular condition. The risks of smoking and other relevant factors were depicted in the advertisement in a spectrum of patients.

*Panel Ruling* The Code of Practice Panel noted that the advertisement appeared in a professional publication and the audience would be familiar with the problems associated with smoking. The Panel noted that doctors would probably be advising patients to modify their lifestyles by stopping smoking but there was no guarantee that patients would do so. The Panel did not accept that the advertisement inferred that there was no need for patients to modify their smoking habits if they were taking the medicine or that the benefit of the medicine was enhanced by smoking. The Panel therefore ruled that there was no breach of the Code.

The ruling of the Panel was appealed by the doctor.

*Appeal* The complainant accepted that all health professionals should be very much aware of the hazards of smoking by their patients but this did not imply that they would do anything about it. The complainant queried whether it was ever appropriate to depict smoking in anything other than a negative light. The complainant alleged that the inclusion of smoker in a positive light in a journal for health professionals showed a clear lack of understanding of the issues involved.

The company did not accept that the advertisement depicted smoking in a positive light. The intention was to depict positively the benefits of the medicine among at risk patients.

*Appeal Board Ruling* The Code of Practice Appeal Board did not accept that the inclusion of a smoker in the advertisement was inappropriate as alleged. The Appeal Board therefore rejected the appeal.

**Proceedings commenced** **26 October 1993**

**Case completed** **9 December 1993**

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CASE AUTH/88/10/93

PHARMACEUTICAL ADVISER v MEMBER COMPANY

Mailing on the use of a medical device

*Complaint* A primary care pharmaceutical adviser complained about a "Dear Hospital Pharmacist" letter sent by a member company. The letter concerned the use of a medical device and raised the issue of incompatibility of the device with other companies' products for which a reference was given. The complainant alleged that the letter was misleading because it misrepresented the data in the quoted reference which was concerned with compatibility and not incompatibility.

*Response* The company submitted that the letter was trade information and not within the scope of the Code. The device had been specifically developed and tested for use with the company's own product. The company submitted that the reference quoted was nevertheless appropriate, as it did raise the question of incompatibility.

*Ruling* The Code of Practice Panel did not accept that the letter was trade information and outside the Code as it promoted the supply of a product and included prescribing information. The Panel considered that the quoted reference did raise the issue of incompatibility and therefore decided that the letter was not misleading as alleged. The Panel ruled that there had been no breach of the Code.

**Complaint received** **21 October 1993**

**Case completed** **8 December 1993**

CASE AUTH/90/11/93

DIRECTOR V FISONS

Promotion of Tilade Mint Syncroner and Aerocrom

*Complaint* An article in The Sunday Times, 7 November 1993, criticised the activities of Fisons Pharmaceuticals. In accordance with the usual practice, the matter was taken up under the Code of Practice for the Pharmaceutical Industry. The Sunday Times article focused on three principal matters and these were dealt with as follows:

1. ***Fisons offered doctors under the counter cash payments in return for prescribing its asthma medicines.***

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*Complaint* In the article, a representative was reported as stating that he had been paying bribes to doctors over the last four to five months. Another representative stated that he had been offering doctors £10 for each new patient prescribed Tilade. He had told doctors that they should fill out cards with the initials of the new patient and by returning the card the doctor would then be eligible for the £10 fee.

The Sunday Times provided a copy of the patient record card which was headed "Tilade Mint Syncroner". The Sunday Times also provided a copy of a memorandum from the national sales manager to area sales managers. The memorandum was headed "Sales Performance-Targeting". The article alleged that the memorandum urged area managers to sell Tilade harder and quoted from the memorandum "our current sales performance with Tilade is unsatisfactory ..... This would not be the case if we were generating new patients from target doctors".

*Response* Fisons submitted that it had conducted a detailed audit of sales force expense claims, interviewed sales representatives and area managers and reviewed all the sales force and marketing department correspondence. These failed to reveal any payments which might constitute inducing doctors to prescribe the company's products.

The company submitted that the patient record card was introduced into one sales area on its own initiative. The card was not submitted for approval and the action was totally outside the company's policy and established procedures and disciplinary action had been taken. During its investigation, no evidence was found that this unapproved initiative or any of a similar nature had taken place in other sales areas. The area manager involved and all the sales representatives had vehemently denied that any cash inducement was ever discussed in relation to the card either by them as a group or offered by them as individuals to doctors. One of these quoted in the article, previously a representative within this area, had not responded to the company's approaches and had not therefore been interviewed.

The company had also contacted 360 of the 408 general practitioners who had been visited by members of the area sales team in question since the introduction of the patient record card. All the doctors contacted, save for three, indicated that at no time had any inducement to prescribe a product been offered or paid. In the first instance, the general practitioner said that he was offered £5 per patient to complete the card to cover his administration costs and that the offer of payment was not presented or interpreted as an inducement to prescribe. In the second instance, the doctor stated that he was visited by a sales representative and offered a donation of £100 towards practice funds provided he prescribed Tilade for five patients. The doctor saw the sales representative on a subsequent occasion when he stated that no further mention was made of the inducement.

The representative involved denied that any such inducement was ever offered. The third instance concerned a request for sponsorship of a practice nurse on a training course which had been received by head office and passed to the local representative for discussion with the practice. One of the practice doctors indicated that in the course of this discussion, he felt obliged to prescribe Tilade but no patient numbers were mentioned. No offer of sponsorship was made, only the possibility was discussed. The representative remembered the incident and stated that he took great care to avoid any risk of association of the sponsorship discussion with the sales call. As a result of this, the company had changed its procedures so that all sponsorships were handled centrally by its medical department.

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In a further instance, a general practitioner stated that he was offered a donation of a book token or another similar token to cover administration costs for completion of the patient record card. The doctor stated that the patients would have been treated with Tilade in any event and confirmed that the book token was not offered or taken as an inducement to prescribe. The representative concerned had confirmed that he had offered a book token or book for use by the practice nurse. The book "Atlas of Ophthalmology", valued at approximately £15, was suggested as a possible educational item for the practice nurse and was not intended as payment for the record card.

The company submitted that, unrelated to its investigation, it was brought to its attention that a doctor had been contacted by The Sunday Times. The company itself contacted this doctor who indicated that ne was offered £10 per patient to prescribe Tilade. The doctor believed that the representative was accompanied by the area sales manager but could not be certain. The company's call reporting system had the visit recorded as unaccompanied and the area manager had no recollection of such a visit.

***Panel Ruling*** The Code of Practice Panel examined all the documentation and considered that although the evidence was limited, it did appear that inappropriate inducements had been offered to a few doctors. In this regard, it noted from the company's press release that two employees had been subject to disciplinary proceedings and one of them had been dismissed. The Panel decided that the representatives involved had not maintained a high standard of ethical conduct and ruled that there had been a breach of Clause 15.2 of the Code. The Panel also ruled a breach of Clause 18.1 of the Code because of the representatives' offer of unacceptable benefits to doctors. In addition, the Panel ruled that there had been a breach of Clause 2 as the activities in question were quite unacceptable. Fisons appealed the ruling of a breach of Clause 2 but accepted the other rulings.

***Appeal*** Fisons had not condoned, nor would it ever condone, the payment of financial inducements to doctors in return for prescriptions for its medicines. The company had voluntarily conducted a detailed review of its activities including contacting the individual doctors seen by its representatives. The company had seen no clear pattern which would suggest a co-ordinated, deliberate activity. What it did find were five isolated and distinct cases out of over 400 doctor contacts. The company submitted that these were not the result of any deliberate attempt to unfairly influence doctors but the result of misunderstanding and confusion between doctors and representatives. The company acknowledged that breaches of the Code had occurred but submitted that there was no possibility of anyone believing that such an activity was permissible. Following the investigation it had come to light that some doctors had thought that inducements were being offered when representatives were offering such items as books for the library or training materials. As a consequence the company had changed its procedures.

The company submitted that its finding of no evidence of a co-ordinated campaign aimed at inducing doctors to prescribe was supported by an investigation by the West Midlands Family Health Services Authority (FHSA). The FHSA was reported in the press as having found no evidence of unusual prescribing which could be related to such an activity. The ruling of a breach of Clause 2 was therefore excessively harsh.

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The company stated that the patient record card referred to in the article had been used by the sales area in question. It had been intended as a record card for general practitioners to keep track of patients. The area manager had been disciplined and demoted to a sales representative. The representative named in The Sunday Times article had not been at the original briefing and it was believed that a misunderstanding had occurred.

*Appeal Board Ruling* The Appeal Board noted that financial inducements had been offered for the purposes of sales promotion. The Appeal Board considered that the company's activities had brought discredit upon the pharmaceutical industry and therefore ruled a breach of Clause 2 of the Code. The appeal therefore failed.

2. ***Fisons set up secret "slush funds" to reward GPs who regularly prescribed its medicines.***

*Complaint* The article alleged that a Fisons document, a memorandum from the West Midlands area sales manager to the national sales manager, revealed the existence of a "slush fund" to pay the bribes to doctors. The article reported that the memorandum stated "I will not list the activities for obvious reasons .... we costed the social selling activities and came up with a figure of £2,000 per (representative)". The article stated that the area sales manager later denied writing the memorandum and that the fund was established to pay for free luxury goods, theatre and ballet tickets and golfing breaks. The Sunday Times provided a copy of this memorandum.

*Response* Fisons submitted that the term "social selling" was used to refer to those meetings held by representatives which involved a number of doctors where modest hospitality would be provided. It could not be regarded as a "slush fund" as alleged nor was it used for the purpose claimed. The detailed review of sales force expenses provided no evidence that the budgeted finance was used to provide cash gifts or to buy luxury goods. The company had stated that it would cease to use this term because of the likelihood of misunderstanding. The sum mentioned was to cover the period October to December 1993 and was to be allocated for thirty-nine meetings which had been booked. These meetings were principally video or audio presentations in surgeries, followed by snack refreshments or a meal. The company submitted that the average cost of these was approximately £16 per head.

Fisons submitted that the memorandum from the area sales manager to the national sales manager concerned the sales representatives' area meeting. The company had determined from the area sales manager that the social selling activities referred to were meetings for doctors for which some form of hospitality was provided. The reference to not listing the activities merely reflected that to list all the meetings would not be practical. It did not suggest or imply any inappropriate activities.

The company acknowledged that there had been isolated instances where the entertainment associated with a meeting could be considered inappropriate and this was outside company policy. These included meetings with small groups of doctors at which the hospitality involved included games of golf, cricket matches and visits to concerts or ballet. They reflected a very small proportion of the total promotional expenditure but nevertheless, the company considered that the nature of the hospitality was inappropriate. The representatives concerned had been formally cautioned.

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The company submitted that representatives were made fully aware of their responsibilities under the Code. All representatives received detailed general instructions concerning the conduct of meetings. A sales force policy document which had been issued to all representatives was provided. All meetings held by representatives were subject to approval by the relevant area manager and procedures allowed for oversight by head office.

*Panel Ruling* The Code of Practice Panel noted that there was no evidence that each representative actually had £2,000 available for use as alleged. The evidence was limited but it appeared that the money had been intended to cover a number of meetings involving doctors at which hospitality would be provided and there was nothing to show that it amounted to a "slush fund". The Panel considered that the use of the term "social selling" was most unfortunate. The Panel was sceptical about the exact meaning of the reference in the area sales manager's memorandum to not listing the activities for obvious reasons.

The Panel noted that the company accepted that some inappropriate hospitality and benefits had been given to doctors. The Panel considered that the representatives involved had not maintained a high standard of ethical conduct and ruled there had been a breach of Clause 15.2 of the Code. The Panel also ruled a breach of Clause 18.1 of the Code due to provision of unacceptable benefits to doctors and a breach of Clause 19 because of the provision of unacceptable hospitality. In addition, the Panel ruled that there had been a breach of Clause 2 as the activities in question were quite unacceptable. Fisons appealed the ruling of a breach of Clause 2 but accepted the other rulings.

*Appeal* Fisons acknowledged that the term "social selling" to cover all aspects of promotion to groups of doctors had proved unfortunate. It had been used to describe the change of direction of the company from face to face selling to group selling. The allegation that the company was indulging in widespread inappropriate hospitality was not true. The company's own investigation brought to light nine cases where the activities associated with the meeting may have been inappropriate and even in these cases the hospitality provided was by no means lavish.

The company stated that representatives had £50 a week to spend on group activities which were usually audio-visual meetings for general practitioners at an average cost of £5 - £6 per head for sandwiches or a modest lunch. Before holding a meeting representatives would have to complete a meeting approval form, which included an estimate of the cost, to be approved by their area manager prior to meetings being held. Following the meeting, an expense form would be submitted with the actual cost and receipts for money paid. The new operating procedures required that these two documents were submitted together. Additional funds had been available for the last cycle of the year.

*Appeal Board Ruling* The Appeal Board noted that the company accepted that some inappropriate hospitality and benefits had been given to doctors. The Appeal Board considered that the company's activities had brought discredit upon the pharmaceutical industry and therefore ruled a breach of Clause 2 of the Code. The appeal therefore failed.

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3. ***Fisons offered more than 100 doctors expensive free trips on the understanding they would promise to put new patients on its medicines.***

*Complaint* The article referred to four meetings. Firstly, one to be held in a five star hotel in Portugal in November, where doctors were alleged to be asked to put twenty patients on prescription as a qualification for going on this trip. This trip was to include golf, swimming and tours at Fisons' expense. Secondly, one held in Barcelona in June which cost the company £800 per head. Doctors who had allegedly been encouraged to prescribe Tilade to thirty patients were said to have received a champagne reception and lavish meals at the five-star Princess Sofia, the city's most expensive hotel. Thirdly, a meeting held in Portugal in March for 24 consultants. Fisons was reported as wanting these consultants to become product champions who would influence general practitioners to buy Aerocrom. The consultants were taken on jeep-safaris and allowed free use of hire cars. Representatives were alleged to have been told that they could spend as much as they wanted on the doctors. Finally, a meeting held in Chester in June, where 40 doctors were taken on a three day break to a hotel, costing £130 per night. This involved clay-pigeon shooting, golf, test-driving four wheel drive vehicles, dining on a river show boat in the evening and a wine tasting. Documents in relation to the meetings were provided by The Sunday Times. These included an outline programme and a memorandum from the professional services manager regarding the meeting to be held in Portugal later in the month and a memorandum which stated that "doctors had been invited to Barcelona on the strength of Syncroner sales being forthcoming". It was not clear who this memorandum was from and to whom it was sent.

*Response* Fisons advised that the meeting to be held in Portugal had originally been planned for Barcelona and had been postponed. The company refuted all the allegations relating to this meeting. Fisons submitted that the three meetings which had been held were attended principally by general practitioners, but also by a number of chest physicians. The meetings had been held in relation to the introduction of a new prescription product. Overseas venues were chosen as doctors were more likely to attend. The company submitted that the locations were appropriate given the nature of the event. The company did not accept that the meetings were expensive, the hotel accommodation was standard among a range of good hotels and not out of keeping with what delegates might have been prepared to pay themselves. The total cost of each of the meetings in Portugal and Spain were approximately the same per capita as for the meeting held in Chester. The company submitted that the meetings were not overtly promotional and each had an appropriate level of medical and scientific content with a good balance between this and attendant hospitality and social activities. Several delegates had written subsequently commending the meetings.

The company could find no grounds for the allegations that doctors were asked to put twenty patients on prescription as a qualification for going. The memorandum sent by the professional services manager to sales representatives discussed the method of selection of delegates. It clearly stated that the requirements for potential delegates were to be doctors experienced in the clinical use of Aerocrom, leaders, lobbyists and likeable. No mention was made of patient numbers as a requirement for attendance and the company would never impose any such condition.

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Fisons stated that there were a number of its staff at each of the three meetings. Such meetings, as well as being of benefit to doctors, were important in providing staff with the opportunity to meet with the doctors. A higher proportion of Fisons personnel attended the meeting in Portugal as the sales force conference was held immediately after the meeting. Personnel from the advertising agency, a public relations agency and an organisation which specialised in meetings production attended the meetings in Portugal and in Chester.

The memorandum which stated that "doctors had been invited to Barcelona on the strength of Syncroner sales being forthcoming" had been sent after the meeting in Barcelona by the West Midlands area sales manager to one of the representatives in his area and was intended as a strong reminder from an area manager to a member of staff, requesting explanations for his poor performance. The statement reflected the expectation that sales would occur after a meeting involving a new product. The memorandum also included a reference to "considerable promotional expenditure". The company submitted that this reference was an attempt at putting over the message about the representative's poor performance and this was confirmed by the company's analysis of promotional expenditure.

The programmes for the three meetings were submitted and at each meeting there were a series of syndicate sessions, which were intended to be as informative for the doctors as they were for the company. Details of the syndicate sessions were provided. Copies of letters sent to the delegates prior to each meeting were provided. The company acknowledged that various social activities were on offer including golf, archery, clay pigeon shooting, a four-wheel drive route, blind-fold driving, fly-casting and a walking tour at the Chester meeting. Golf, tennis, squash, sight-seeing and a jeep safari were on offer in Portugal and golf, tennis, visits to museums and the Olympic stadium and a sight-seeing tour of the city were available at the Barcelona meeting. The costs of each meeting were provided together with the numbers attending.

*Panel Ruling* The Panel examined the documentation relating to the meetings and noted from the programmes that the meetings were held over two or three days. Each of the meetings had a presentation from a general practitioner and a presentation from a hospital doctor or equivalent. The remainder of the time was made up with presentations from Fisons staff and syndicate sessions. The Panel noted that the syndicate sessions were generally to appraise various aspects of the campaigns for Tilade and Aerocrom and discuss how they could be improved. The Panel considered that these sessions could not be considered as educational. Each meeting had a number of social activities on offer. With regard to costs, the Panel noted that the cost per head for the meeting held in Barcelona was approximately £1,500, the cost per head for the meeting held in Portugal was approximately £1,100 and the cost per head for the meeting held in Chester was approximately £900. The Panel noted that none of the documentation relating to the invitation to the meetings specified that attendees would only qualify if they put patients on Fisons' medicines. It noted, however, that attendees at at least one of the meetings had to be doctors who would or could be persuaded to support the product and act as speakers for the company in order to promote the product.

The Panel accepted that there was some educational content to the meetings but this was limited. The hospitality and entertainment provided was, however, inappropriate and out of proportion when considered in relation to the nature of the meetings themselves. The Panel therefore ruled that all of the meetings were in breach of Clause 19 of the Code. The Panel also decided that the meetings brought discredit upon the pharmaceutical industry in breach of Clause 2 of the Code. Fisons appealed the ruling of a breach of Clause 2 but accepted the other ruling.

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*Appeal* Fisons submitted that it was not the company's policy to require scripts in exchange for attendance at meetings. The meetings were within the requirements of the Code. The scientific and educational content of the meetings and the costs were appropriate. The hospitality was not lavish. Overseas venues had been chosen as doctors were more likely to attend. The cost of the meeting held in Chester were higher than they might have been as a number of doctors had not turned up but the company was still required to pay some of the costs. With regard to the criteria for attendance at the meetings, The term "champion" - used in the heading "Aerocrom Champions III Briefing notes" to the memorandum from the professional services manager did not mean a champion prescriber but meant that the doctor was favourably disposed to the product, prepared to talk about it and not reject the concept. It was of more value to take doctors who had agreed with the concept of the product and saw opportunities for using it more widely. The purpose of the meetings was to share experience, and to hear from opinion leaders.

The company believed that the finding of a breach of Clause 19 represented the Panel's interpretation of that Clause. The company may have unintentionally gone beyond the Panel's interpretation of the grey area in the Code but it did not warrant a breach of Clause 2 of the Code.

*Appeal Board Ruling* The Appeal Board considered that there was some educational content to the meetings but this was limited. The Appeal Board considered that for any meeting the programme itself should attract attendees and not the location or other activities on offer. The Appeal Board queried the criteria for attendance of the meeting but noted that none of the documentation relating to the invitation to the meeting specified that attendees would only qualify if they put patients on Fisons' medicines. On balance, the Appeal Board considered that the company's activities had brought discredit upon the pharmaceutical industry and therefore ruled a breach of Clause 2 of the Code. The appeal therefore failed.

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The Panel had also decided that the circumstances were such that it would report the company to the Code of Practice Appeal Board under the provisions of Paragraph 8.2 of the Constitution and Procedure for the Prescription Medicines Code of Practice Authority.

*Report to the Appeal Board* Having heard a representative of Fisons, the Appeal Board was concerned at the company's ethos and its procedures relating to the Code. It noted that senior managers in the company had received or sent some of the memoranda criticised. It decided that the circumstances were such that it would report the company to the Board of Management of The Association of the British Pharmaceutical Industry (ABPI) under the provisions of Paragraph 11.1 of the Constitution and Procedure for the Prescription Medicines Code of Practice Authority for it to consider whether further sanctions should be applied.

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*Report to the ABPI Board of Management* When the report came before the ABPI Board of Management, a representative of the company explained what had happened and outlined the steps which were being taken to prevent a recurrence.

The ABPI Board reprimanded Fisons Pharmaceuticals for what had occurred. It required that an audit of the company's procedures in relation to the Code of Practice be carried out by the Prescription Medicines Code of Practice Authority. The costs of the audit would fall upon the company. In the meantime, Fisons Pharmaceuticals would be suspended from membership of the ABPI.

Having subsequently reviewed the audit report, and noted the steps which Fisons Pharmaceuticals had taken over the last few months to improve its procedures in relation to the Code of Practice, the ABPI Board lifted the company's suspension from membership of the ABPI. The Board considered, however, that there would be merit in the company submitting voluntarily to a further audit in a few months' time and recommended that course of action to Fisons Pharmaceuticals.

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| **Proceedings commenced** | **8 November 1993** |
| **PMCPA proceedings completed** | **7 February 1994** |
| **ABPI Board proceedings completed** | **8 March 1994** |

## CASE AUTH/91/11/93

## DIRECTOR V GLAXO LABORATORIES LIMITED

### Allegations of Improper hospitality and gifts

*Complaint* An article in The Sunday Times, 14 November 1993, criticised the activities of Glaxo Laboratories Limited and made three principal allegations. Firstly, that Glaxo sales representatives paid for gifts and entertainment worth thousands of pounds on the understanding that general practitioners would prescribe Glaxo products to patients. Secondly, that Glaxo representatives were each given up to £14,000 a year to entertain doctors and were admonished if they failed to spend it all. Thirdly, that a regional sales manager and at least three sales representatives had been dismissed in the past few weeks after paying for doctors and their wives to eat at expensive restaurants and to take day trips for golf, go-karting, hot-air ballooning and Test Matches at Old Trafford and Headingley.

In accordance with the usual practice, these matters were taken up under the Code of Practice for the Pharmaceutical Industry.

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*Response* Glaxo Laboratories Limited said that the allegations in The Sunday Times did not accurately report the circumstances which had led the company to take responsible and prompt action in dismissing staff who had undertaken clandestine unauthorised activities. The unauthorised activities of the representatives concerned were mainly or entirely social in nature. The company could not be held responsible for these acts by representatives who had been acting contrary to clear instructions, guidance and training from the company and who had been dismissed when the offences were discovered.

Glaxo outlined in detail the steps which it took to ensure that all members of staff, and especially the sales force, were fully briefed on all aspects of the Code and kept up to date with changes to it. The company submitted that it had done everything possible to ensure that all of its representatives were fully aware of the consequences of breaching the Code.

In relation to the first allegation, Glaxo said that irregularities in organising meetings and hospitality were confined to one regional manager and three representatives in the North East area. These members of staff had been dismissed following a thorough investigation for misdirecting company funds and falsifying records to hide activities which were in breach of the Code and consisted of go-karting and golf. The activities were clearly in breach of Clause 19 in having no educational content and with hospitality as the primary factor. It seemed that the intention was to boost call records and mislead the company as to their level of contact with doctors. An internal enquiry had confirmed that no senior managers of Glaxo Laboratories, including the regional manager's immediate superior, were aware of these activities and as soon as senior management became aware of the problem very prompt action had been taken to stop these possible breaches of the Code and to ensure that there would be no repetition of them.

The company had no evidence that gifts, benefits in kind or money, were offered or accepted by doctors in return for an "understanding" to prescribe Glaxo medicine to patients.

While it was the company's opinion that the activities of the dismissed staff were in breach of Clause 19, the company submitted that those activities were entirely initiated by them and were strictly against the company's instructions and procedures and without its knowledge. Glaxo therefore considered that the company was not in breach of the Code.

In relation to the second allegation, Glaxo said that it was simply not true that representatives were given £14,000 each to entertain doctors and were admonished if they failed to spend it. Representatives had access to a regional budget to run medical meetings. Such meetings had to be educational and conform to the Code and the sums involved were considerably less than the alleged £14,000.

In relation to the final allegation, as Glaxo had previously acknowledged, a regional sales manager and three sales representatives had been dismissed for activities which were in breach of the Code. The staff concerned had been dismissed for misdirecting company funds and falsifying records and there was no documentation relating to the irregular meetings. Instead, falsified claims were made for amounts for apparently quite acceptable meetings.

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In summary, Glaxo stated that it believed that the adverse publicity had arisen as a result of totally unauthorised activities by a small number of sales staff. The assertions in the newspaper article appeared to have been made by a member of staff who had been dismissed and the adverse publicity had arisen as a direct result of the company enforcing its own rules and striving to uphold the Code. Its response to the discovery of these activities was that of a wholly responsible and reputable company. The company submitted that its action was more likely to save the reputation of the pharmaceutical industry than to damage it. It was critically important that the implementation of the Code recognised that prompt and forceful action by companies which discovered breaches might lead to adverse publicity. To penalise companies in such circumstances would discourage openness and rigour in the application of the very actions and principles that the Code sought to uphold. Glaxo believed that the action it had taken in reinforcing the message that it would not tolerate activities that might be considered to bring the industry into disrepute made a breach of Clause 2 untenable.

***Panel Ruling*** The Code of Practice Panel had considered that the various allegations which had been made all related to the same general area of activity and had decided to take all of them together.

The Panel noted with approval the steps which Glaxo took to inform its staff, in particular its sales staff, of the requirements of the Code.

The Panel had noted that the allegations in The Sunday Times had apparently arisen from statements made by one of the members of staff dismissed. It was the prompt and effective action by the company which had led to the matter becoming public with attendant adverse press comment. It did indeed seem inequitable that a company which took the correct steps might be placed in a worse position than a company which attempted to hide any wrongdoing which it found. Nonetheless, it was a clearly established principle that companies had to take responsibility for the actions of their employees when these were within the scope of their employment, even if they were acting contrary to the instructions which they had been given.

The Panel had decided that the representatives involved had not maintained a high standard of ethical conduct and ruled that there had been a breach of Clause 15.2 of the Code. The Panel had also ruled a breach of Clause 18.1 of the Code because of the representatives' provision of unacceptable benefits to doctors and a breach of Clause 19 because of their provision of inappropriate hospitality. In addition, the Panel ruled that there had been a breach of Clause 2 as the activities in question were quite unacceptable.

The Panel had also decided that the circumstances were such that it would report the company to the Code of Practice Appeal Board under the provisions of Paragraph 8.2 of the Constitution and Procedure for the Prescription Medicines Code of Practice Authority.

*Appeal* Glaxo accepted the Panel's rulings of breaches of Clauses 15.2, 18.1 and 19 of the Code on the basis of the clearly established principle that companies had to take responsibility for the actions of their employees. It appealed the ruling that there had been a breach of Clause 2.

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The Code of Practice was important to Glaxo, which supported it fully. It believed that the decision in the present case was important for both itself and for industry in general and that it would lay down important principles. There were a number of reasons why it should not be found to be in breach of Clause 2.

Firstly, there were differences between the responsibilities of a company and the responsibilities of individual people employed by it. There was only so much that a company could do to impose standards on its staff. In recent instances where breaches of Clause 2 had been ruled in similar circumstances, the matters had not been appealed. Secondly, criticism in the media should not automatically be regarded as a breach of Clause 2. Thirdly, Clause 2 was now reserved as a sign of particular censure and this concerned Glaxo as it did not consider that such a censure was appropriate. Finally, it should be recognised that if a company took forceful action when it discovered wrongdoing, this might lead to adverse publicity and companies should not be discouraged from taking such forceful action by fear of being prejudiced.

The company provided further information as to the reporting structure within the company. No evidence had been found that anyone above the level of the regional manager was aware of the circumstances. The discovery of what had happened had arisen as a result of the auditing of expenses. False documentation had been submitted including receipts from restaurants where no entertaining had been done. The initial findings had related to the first few months of 1993 and, following the investigation and disciplinary procedures, there had been dismissals in July and August. It had subsequently been found that there had been meetings arranged in 1992 which included visits to Test Matches but the circumstances were not entirely clear. The regional manager involved had been in that position for two years but had been with the company longer. The conduct of those involved had been otherwise acceptable, but clearly the events which were the subject of the case were not.

***Appeal Board Ruling*** There was sympathy for the view that companies which discovered unacceptable conduct and took prompt and appropriate action to root it out might be placed in a worse position than companies which smoothed things over, perhaps by disciplining employees but allowing them to remain in post, which would discourage them from revealing publicly what had happened. It was nonetheless a clearly established principle that companies had to take responsibility for the actions of their employees when these were within the scope of their employment, even if they were acting contrary to the instructions which they had been given. The Code of Practice Appeal Board noted that by accepting the Panel's rulings other than that of a breach of Clause 2, the company had accepted responsibility for the conduct of the representatives.

In a case such as the present one it was difficult to draw the line between the situation where a company deserved the particular censure that a breach of Clause 2 represented and the situation where such a censure was not justified. Each case had to be taken individually on its merits because it was difficult to lay down any principles. In the present case, the company clearly had established procedures in place and when it had discovered that totally unacceptable conduct was occurring it had taken prompt action to deal with it and this action had led to the adverse publicity.

On the facts of this particular case, the Appeal Board decided on balance that the particular censure represented by the ruling of a breach of Clause 2 was not justified. Accordingly, the appeal by Glaxo against that ruling was successful.

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*Report from the Panel to the Appeal Board* The Appeal Board then considered the fact that the company had been reported by the Code of Practice Panel to the Appeal Board under the provisions of Paragraph 8.2 of the Constitution and Procedure for the Prescription Medicines Code of Practice Authority. In the circumstances of this particular case, that meant that, if the Appeal Board considered such action to be warranted, it could report the company to the Board of Management of the Association of the British Pharmaceutical Industry (ABPI) for it to consider whether further sanctions should be applied against the company.

The Appeal Board decided on the facts of this case that it would not report the company to the ABPI Board of Management.

**Proceedings commenced** **15 November 1993**

**Case completed** **19 January 1994**

AUTH/92/11/93

DIRECTOR V ALLEN & HANBURYS

Promotion of Flixonase

*Complaint* An article in The Sunday Times, 14 November 1993, criticised the promotion of Flixonase by Allen & Hanburys Limited. A document on Flixonase issued to sales staff was reported to state: "To persuade pharmacists to identify those patients who either purchase... decongestants or who obtain scripts for other nasal sprays and to refer them back to their GP for consideration of an alternative therapy". There were two campaign objectives set out on the card. These were "To promote Flixonase as a successor to Beconase" and "To persuade pharmacists to identify those patients who either purchase OTC decongestants or who obtain scripts for other nasal sprays, and to refer them back to their GP for consideration of an alternative therapy".

In accordance with the usual practice, the matter was taken up under the Code of Practice for the Pharmaceutical Industry .

*Response* Allen & Hanburys said that the card was an internal document which set out business objectives for sales representatives for the sales cycle September to December 1992 and would not have been seen by doctors. The company had not had any complaints from doctors about the card and submitted that the activities set out on it were legitimate activities for sales representatives to undertake. Flixonase was indicated for the treatment of seasonal and perennial rhinitis, which was an area of high repeat prescribing, and self medication. Chronic self management might lead to clinical problems, and the recognition of patients who were apparently excessively or inappropriately self medicating or who appeared to be inadequately treated and the referral of such patients for review by their doctor were part of the role of the community pharmacist. A recent report of the Joint Working Party on the Future Role of Community Pharmaceutical Services encouraged this dialogue and aimed to ensure improved co-operation between community pharmacists and general practitioners by encouraging debate about individual cases and the appropriate response to them.

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The company submitted that one of the business objectives for sales representatives was to persuade pharmacists to identify appropriate patients and to refer them back to their general practitioners for consideration of alternative therapy. The company submitted that there was no inducement for the pharmacist to make such a referral. There was no breach of patient confidentiality, since all the discussion would take place between the patient and his pharmacist or doctor. There was no inducement for the pharmacist to recommend treatment with Flixonase.

*Panel Ruling* The Code of Practice Panel noted that the campaign objective stated "To persuade pharmacists to identify those patients who either purchase OTC decongestants or who obtain scripts for other nasal sprays and to refer them back to their GP for consideration of an alternative therapy". The Panel noted that the objective was not expressed as being limited to patients who were inadequately controlled with their present treatment. Nor was it stated to be limited to appropriate patients, as submitted by the company. As the objective referred only to "patients", this would include those who were adequately controlled. The Panel considered that the objective in question could lead to patients not already on Flixonase being referred to their GP for consideration of alternative therapy regardless of whether they were controlled by, or satisfied with, their current treatments and this was unacceptable.

The Panel considered that following the objective would lead representatives into unethical conduct contrary to the requirements of the Code. The Panel decided that it was the written material produced by the company which was in breach of the Code, as this was instructing the representatives how to promote Flixonase to retail pharmacists. The Panel therefore ruled a breach of Clause 15.8 of the Code. The Panel also considered that the objective failed to recognise the professional standing of the pharmacist and therefore ruled a breach of Clause 9.1 of the Code.

The Panel considered that there had not been a breach of Clause 2 of the Code. It noted that just because a method of promotion was criticised in the press it was not necessarily in breach of Clause 2 of the Code.

*Appeal* Allen & Hanburys did not accept that the document was a promotional item, as a representatives' training document setting out what they should say to customers or how they should deal with health professionals would be. The company did not accept that the item was subject to the Code. It was, however, approved within the company. It did not instruct representatives to say specific things to pharmacists nor did it represent training. It was merely a statement of commercial objectives.

The company submitted that its representatives received a very extensive training package and were well aware of the type of patients who might reasonably be referred by a pharmacist to a doctor. The company acknowledged that the wording of the document might not be comprehensive but it should have been seen as part of an overall briefing and not in isolation. The company submitted that not all confidential internal documents could be expected to stand in isolation and there was no reason why this document should be an exception in this regard.

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The company acknowledged that the document did not explicitly state that referral should be restricted to those patients who were inadequately controlled or inappropriately treated. This knowledge had been imparted to representatives on many occasions. A number of the specific briefing documents relating to the disease area and to pharmacy relations were included to support the appeal. The company agreed that it would not recognise the professional standing of pharmacists if it were to suggest to them that every patient who was given a script for any nasal spray should be referred back to their doctor. Pharmacists were well aware of which patients it was appropriate to refer. There was no need for the company to spell it out every time a summary of commercial objectives was produced as an aide memoire for the sales cycle.

Allen & Hanburys referred to the role of the community pharmacist and submitted that there was absolutely nothing in its representatives' briefing material which was in contravention of the objectives set out by pharmacists themselves. Its briefing document was totally complementary to the best practice of pharmacy and demonstrated a genuine attempt on its part to work in partnership with key health care professionals in a way in which they themselves had specified.

Allen & Hanburys submitted that the objectives that it was pursuing and the methods it was adopting in the campaign were wholly in line with best medical practice. It was wholly inappropriate to make judgements on the company's objectives and methods on one internal confidential aide memoire. The company confirmed that the statement at issue was not expanded as such in the briefing material though it was covered in depth in several training documents. It stated that the document was the only specific item for the product for that sales cycle.

*Appeal Board Ruling* The Code of Practice Appeal Board noted that the company had extensive briefing material. It further noted that the document in question was the only material issued for the sales cycle and that the objective was not expanded in the briefing material as such.

The Appeal Board noted that the campaign objectives "To promote Flixonase as the successor to Beconase" and "To persuade pharmacists to identify those patients who either purchase OTC decongestants or who obtain scripts for other nasal sprays, and to refer them back to their GP for consideration of an alternative therapy" were printed in bold type. The Appeal Board considered that if representatives had followed the second objective, this could have led to patients not already on Flixonase being referred to their general practitioners for consideration of an alternative therapy, regardless of whether they were controlled by or satisfied with their current treatments and this was unacceptable. Further, it did not recognise the professional standing of the pharmacist. The Appeal Board did not object in principle to pharmaceutical companies recommending that pharmacists referred patients to their general practitioners in appropriate circumstances, but this was not what the objective said.

The Appeal Board decided that the objective "To persuade pharmacists to identify those patients who either purchase OTC decongestants or who obtain scripts for other nasal sprays, and to refer them back to their GP for consideration of an alternative therapy" did not recognise the professional standing of the pharmacist, in breach of Clause 9.1. Having regard to that ruling, the Appeal Board also ruled a breach of Clause 15.8 as the objective did not comply with all the relevant clauses of the Code. The appeal therefore failed.

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**Proceedings commenced** 15 November 1993

**Case completed** 4 February 1994

CASE AUTH/93/11/93

DIRECTOR V DUPHAR

Promotion of Faverin

*Complaint* An article in The Sunday Times, 21 November 1993, criticised the activities of Duphar Laboratories Limited regarding the promotion of Faverin.

The article alleged that Duphar had offered gifts worth more than £1000 to dozens of consultant psychiatrists and in return some psychiatrists were asked to put 40 patients on Faverin. The article alleged that internal company documents revealed that Duphar sales staff targeted more than 70 of Britain's most senior psychiatrists who they believed could arrange for millions of pounds' worth of Faverin to be bought by hospitals and general practitioners. Papers signed by Duphar's hospital sales manager were alleged to instruct representatives to offer a £1500 computer programme called Amigos to consultants. The documents were alleged to refer repeatedly to a transaction between the company and the consultants. One document was alleged to state that representatives should "deliver Amigos in exchange for prescriptions" and another that in return for the software package, psychiatrists would be expected to influence general practitioners and give Faverin formulary status. A memorandum issued in September was alleged to state "Amigos has now been "out and about" for eight months and we have some excellent feedback on how it has helped get Faverin on hospital formularies, turned Prozac users into ardent Faverin fans and caused a lot of psychiatrists to give Faverin the chance it deserves". A consultant psychiatrist, named in the article stated that he had been offered the computer program on the condition that he prescribed Faverin to 20 new patients. The doctor had refused.

The article also reported that the company's managing director admitted that some of the sales force had broken its ethical rules. It was not official policy and it was never the company's intention to offer bribes.

In accordance with the usual practice, the matter was taken up under the Code of Practice for the Pharmaceutical Industry.

*Response* Duphar Laboratories Limited stated that Amigos was a specialist computer system for the management of clinical data in psychiatric practice, including a training module for the recognition and management of depression. The company was closely associated with the development of Amigos, acting as both industrial partner and financial sponsor. The company submitted that Amigos was not a promotional item nor was it regarded as a gift but rather as a service to medicine providing a facility that would improve the running and management of psychiatric clinics. This was how it was explained to and perceived by the recipients.

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The company submitted that it had fully reviewed its papers and could not find any document that stated that representatives should deliver Amigos in exchange for prescriptions. It accepted, however, that in view of the other evidence and briefings given to sales staff, a statement to that effect was quite possibly made.

The company submitted that the references in The Sunday Times article to gifts referred to the Amigos software and not to some other gift. Amigos was purchased from AVC for £250 although it was currently marketed by AVC at £795. Duphar was not aware of AVC having made any sales at this price and submitted that a lower price was appropriate.

The company submitted that the figures of £1000 and £1500 stated in the article were incorrect. The £1000 figure was believed to come from a "ball park" figure given to sales representatives at the time Amigos was first made available. The use of the "ball park" figure of £1000 might have resulted in some sales representatives unconsciously linking Amigos with Faverin prescriptions as the cost of each Faverin prescription was £25. Multiplying this by forty gave a figure of £1000.

The company provided a list of 72 psychiatrists which it believed was the source of the figure given in the article. The company submitted that the term "targeted" misinterpreted the company's intention. Psychiatrists with a heavy clinical load or research interest would derive the most benefit from Amigos and it was therefore offered to such psychiatrists in the first instance. Amigos could not be made available to all psychiatrists at one time because of the time to explain and train them in its use.

The company provided a document headed "Region 600 Amigos Update Day" which it believed was the document referred to in the allegation in the article concerning a "transaction" between Duphar and consultants.

The company provided a copy of the memorandum dated September 1993 which was quoted in the article. The memorandum had been sent to all representatives, regional business managers and other company personnel. The company submitted that the quotation "Amigos has now been "out and about" for some eight months and we have some excellent feedback on how it has helped Faverin on hospital formularies, turned Prozac users into ardent Faverin fans and caused a lot of psychiatrists to give Faverin the chance it deserves", was an attempt to generate enthusiasm for Amigos in the sales force. There was no evidence that formularies had changed their recommendations as a result of anyone having received Amigos. The company pointed out that the memorandum also referred to an Amigos training and support package. It submitted that it did not seek to deny or hide the issues raised by this proposal.

The company was unable to comment on the quote attributed to the doctor named in the article because the sales representative concerned had been dismissed for gross misconduct in October 1993.

The company apologised for its action and assured the Authority that there would be no recurrence. All members of staff had been reminded of the company's responsibilities under the Code.

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*Panel Ruling* The Code of Practice Panel examined the documentation and noted that there was no specific statement that Amigos was to be offered in exchange for prescriptions for Faverin.

The Panel noted that the document headed "Region 600 Amigos Update Day" referred to a "What do we give each other? workshop". The document stated that Amigos was for "high priority consultants and senior registrars", "psychiatrists who can influence GPs and formulary decisions" and that the Faverin logo was associated with Amigos. The document also referred to a "transaction" and to "emphasise quality of offer", although no details were given. The document listed the benefits to the company as "scripts, influence on GPs, formulary status, GP meetings". The Panel noted a heading "Amigos" which then read "Target, explanation, demo, transaction, training, installation, Faverin scripts".

The Panel noted that the memorandum dated September 1993 stated "Amigos has now been "out and about" for eight months and we have some excellent feedback on how it has helped get Faverin on hospital formularies, turned Prozac users into ardent Faverin fans and caused a lot of psychiatrists to give Faverin the chance it deserves" as quoted in The Sunday Times article. The Panel noted that the memorandum referred to training arrangements which would be carried out by AVC and cost £250. The memorandum then stated "However, if after you have delivered the package, they are doing the business for you, then you can offer to pay the £250 for them, in return for.....!!". The Panel queried what was meant by ".....!!". The memorandum also referred to offering to pay £180 for an upgrade to Amigos 2 for key doctors. A flow chart which accompanied the memorandum stated that "... if they have done the business we will pay for the training" and ".... if they have done the business we will buy the Update".

The Panel noted that the program cost £795 from AVC but cost the company £250. The Panel noted the supplementary information to Clause 18.1 of the Code which stated that it was the value to the recipients, in other words what they would have to pay if they were to purchase the item themselves, which was relevant and not the actual cost to the company. Neither £795 nor £250 was inexpensive as required by the Code. The cost would be enhanced by training and the update package where these were provided. The Panel accepted that Amigos was relevant to the practice of medicine.

The Panel decided that there was sufficient material to show that the company had been using the Amigos program, the training and the update package as inducements for the purposes for sales promotion. The Panel ruled a breach of Clause 18.1 of the Code. The Panel also ruled a breach of Clause 15.2 of the Code as representatives had not maintained a high standard of ethical conduct. These breaches had been acknowledged by the company.

In addition the Panel ruled a breach of Clause 2 as the activities were quite unacceptable.

The Panel's rulings had been accepted by Duphar which had provided the requisite form of undertaking and assurance to avoid a similar breach of the Code in the future.

The Panel decided that the circumstances were such that it would report the company to the Code of Practice Appeal Board under the provisions of Paragraph 8.2 of the Constitution and Procedure for the Prescription Medicines Code of Practice Authority.

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*Report to the Appeal Board* Having heard a representative of Duphar, the Appeal Board decided that the circumstances were such it would report the company to the Board of Management of The Association of the British Pharmaceutical Industry (ABPI) under the provisions of Paragraph 11.1 of the Constitution and Procedure for the Prescription Medicines Code of Practice Authority for it to consider whether further sanctions should be applied.

*Report to the ABPI Board of Management* When the report came before the ABPI Board of Management, a representative of the company explained what had happened and outlined the steps which were being taken to prevent a recurrence.

The ABPI Board reprimanded Duphar Laboratories for what had occurred. It required that an audit of the company's procedures in relation to the Code of Practice be carried out by the Prescription Medicines Code of Practice Authority. The costs of the audit would fall upon the company. In the meantime, Duphar Laboratories would be suspended from membership of the ABPI.

Having subsequently reviewed the audit report, the ABPI Board imposed certain requirements upon Duphar Laboratories to improve its procedures in relation to the Code of Practice. There should be a further audit at such time as the company requested but in not less than three months' time. The matter would then come before the ABPI Board again. The company remained suspended from membership of the ABPI.

**Proceedings commenced** **22 November 1993**

**PMCPA proceedings completed** **19 January 1994**

**ABPI Board proceedings ongoing**

CASE AUTH/94/11/93

DERMAL LABORATORIES LTD V SETON HEALTHCARE

Supply of unsolicited samples

*Complaint* Dermal Laboratories Ltd, a company not in membership of the ABPI, complained about a "Dear Doctor" letter sent by Seton Healthcare accompanied by five 3g samples of Transvasin. The complainant alleged a breach of Clause 17.3 of the Code, as the samples were unsolicited.

*Response* Seton Healthcare, a company not in membership of the ABPI, stated that it had reviewed its activity regarding sending samples to practitioners and agreed that its actions had been contrary to the Code. It would not repeat the exercise. The company had not previously agreed to abide by the Code but has now done so.

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*Ruling* The Code of Practice Panel noted that the "Dear Doctor" letter ended with the statement "Please find enclosed 5 x 3g samples of Transvasin which we hope you will find useful". The samples had not been supplied in response to a written request which had been signed and dated as was required. The Panel therefore ruled a breach of Clause 17.3 of the Code.

**Complaint received** **26 November 1993**

**Case completed** **15 December 1993**

CASE AUTH/95/12/93

HOSPITAL DOCTORS V NON-MEMBER COMPANY

Arrangements for a clinical trial

*Complaint* Two hospital doctors complained about arrangements for clinical trials to be carried out on behalf of a company. The company in question was not a member of the ABPI but had nevertheless agreed to comply with the Code. The complainants stated that a clinical research executive had visited the hospital to discuss the trials and had claimed that more studies were needed to produce more safety data to support a product licence application. There seemed to be no clear guidelines as to what was required and the representative said that almost any studies would be acceptable as long as they used the company's product. Some months later, the complainants received a letter saying that the studies they had submitted could not be funded. The complainants alleged that it would appear that there was no need to obtain any more safety data before the product could be marketed and that might explain why the protocol requirements were very vague. They wanted to know if they had been misinformed with respect to the objectives.

*Response* The company submitted that the clinical research executive had visited the doctors to negotiate a phase IV multi-centre clinical trial. The initial contact letter stated that the product was about to be launched. The protocol for the study was above board scientifically and complied with the requirements for good clinical practice. A copy of the draft study protocol was provided. The licence was granted while the company was still negotiating with the complainants. Negotiations had been terminated when the time at the disposal of the clinical research executive ran out. Ten other centres where negotiations had been completed were ready to go. The circumstances had been unfortunate but there had been no subterfuge.

*Ruling* The Code of Practice Panel considered that there had evidently been a failure of communication between the representative and the complainants regarding the nature of the study and the timing of the licence applications. The Panel noted that the Code covered promotional practices only and if a Phase IV study was not in effect a disguised form of promotion it did not come within the scope of the Code. The Panel did not consider that the study was promotional and therefore ruled that there was no breach of the Code.

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**Case received** 1 December 1993

**Case completed** 19 January 1994

CASE AUTH/96/12/93

MEDICAL PRESCRIBING ADVISER V ASTRA PHARMACEUTICALS LIMITED

Dosage leaflet

*Complaint* A medical prescribing adviser in primary care services submitted a complaint regarding a dosage leaflet on Losec (ref LOS LVP O98) issued by Astra Pharmaceuticals Limited.

The complainant drew attention to a claim on the front page of the leaflet "From the start in oesophageal reflux disease, * duodenal and gastric ulcers". The asterisk referred readers to the definition and prescribing information available on the back cover of the leaflet.

The complainant was unhappy because of the front page which implied that Losec should be used from the start in oesophageal reflux disease. The complainant was not aware of any independently reproduced guidelines on gastrointestinal prescribing which implied that this was a reasonable course of action. The complainant alleged that the use of the asterisk drawing attention to the definition and prescribing information on the back cover was insufficient to explain that Losec was not licensed for maintenance prescribing in either duodenal or gastric ulcer except in Zollinger-Ellison syndrome. The complainant alleged that the leaflet was misleading. Further, it was difficult to read the prescribing information.

*Response* Astra Pharmaceuticals Ltd submitted that the promotion of Losec "From the start in oesophageal reflux disease, duodenal and gastric ulcers" was entirely in line with the product data sheet. The company gave the background to the approval of the current indications.

The company submitted that the leaflet dealt with the acid related disorders, oesophageal reflux disease and peptic ulcer and set out the dosage schedules for the use of Losec by a doctor who having made these diagnoses wished the patient to receive acid suppression therapy. The current indications clearly included first line therapy for Losec in these acid related conditions.

The company submitted that the prescribing information on the leaflet was legible in its present format.

*Ruling* The Code of Practice Panel accepted the company's submission that Losec was licensed for initiating treatment in oesophageal reflux disease, duodenal and gastric ulcers. The claim "From the start in oesophageal reflux disease, duodenal and gastric ulcers" was acceptable and the Panel therefore ruled no breach of the Code.

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The Panel noted that the prescribing information on the back cover stated that "Long term therapy with Losec in the treatment of gastric and duodenal ulcers is not currently recommended". The Panel noted that the front of the leaflet did not make any claim for maintenance therapy with Losec, it only referred to initiating treatment with Losec in oesophageal reflux disease, duodenal and gastric ulcers. The Panel therefore ruled no breach of the Code in relation to the allegation concerning maintenance therapy.

The Panel did, however, accept that it was difficult to establish the position of Losec with regard to maintenance therapy from the prescribing information as it considered that the prescribing information had not been set out in a clear and legible manner as required by Clause 4.1 of the Code. In this regard the Panel considered that the line length was too long and the typeface was too small. The Panel therefore ruled a breach of Clause 4.1.

**Complaint received** 18 December 1993

**Case completed** 28 January 1994

CASE AUTH/101/1/94

MEDICINES CONTROL AGENCY V ASTRA PHARMACEUTICALS LTD

Journal advertisement for Losec

*Complaint* The Medicines Control Agency (MCA) submitted a complaint about a journal advertisement for Losec published in The Lancet, 1 January 1994. The advertisement had appeared in the name of Astra Hassle AB of Sweden.

The MCA alleged that the advertisement did not comply with the requirements of The Medicines (Advertising to Medical and Dental Practitioners) Regulations 1978. In addition, the MCA asked if the company could supply the principal references to support certain claims made in the advertisement.

Astra Pharmaceuticals Ltd was advised that the failure to comply with the requirements of the Medicines (Advertising to Medical and Dental Practitioners) Regulations 1978 referred to the omission of some of the obligatory information. Quantitative particulars of the active ingredient, the legal classification, the product licence number and the name and address of the product licence holder were missing. These were required by Clause 4.1 of the Code.

*Response* Astra submitted that the advertisement was an international advertisement for Losec which should have not appeared in the UK edition of The Lancet. The advertising department of The Lancet had been sent the UK advertisement which had been approved by the company's legal signatories. The international marketing department also sent its advertisement to the journal for inclusion in the international edition. The international advertisement arrived a few days before the UK advertisement and The Lancet production team unfortunately inserted the international advertisement in all editions. The company

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submitted that this error was not a breach of the Code as it was entirely beyond the control of the company unlike other situations where, for example, printing errors had occurred and where the company concerned would have had the opportunity to check the final form before it was issued. The company enclosed a letter of apology from The Lancet for the error which had been corrected in all subsequent editions.

*Ruling* The Code of Practice Panel noted that it was a clearly established principle under the Code that pharmaceutical companies had to take responsibility for the actions of their agents. The Panel considered that in this case, although the international advertisement had been included in the UK edition of The Lancet in error by The Lancet, Astra was nonetheless responsible under the Code and would have to seek such redress from The Lancet as it thought appropriate.

The Panel noted that the quantitative particulars, the legal classification, the product licence number and the name and address of the product licence holder were missing from the prescribing information in the advertisement. The Panel therefore ruled a breach of Clause 4.1 of the Code.

The Panel noted that the MCA had requested the principal references to support certain claims. These were provided by Astra and sent on to the MCA.

**Complaint received** **14 January 1994**

**Case completed** **17 February 1994**

# CODE OF PRACTICE FOR THE PHARMACEUTICAL INDUSTRY

| NUMBER | | SUBJECT | BREACH |
|---|---|---|---|
| 71 | Doctor v Member Company | Information to the public | NoB |
| 72&77 | Consultant Microbiologist v Roussel & Panpharma | Mailing | 7.2 (A) |
| 83 | Community Pharmacist v Glaxo | "Dear Pharmacist" letter | 7.2 (A) |
| 87 | Director v Member Company | Letter in the British Medical Journal | NoB (A) |
| 88 | Pharmaceutical adviser v Member Company | "Dear Hospital Pharmacist" letter | NoB |
| 90 | Director v Fisons | Article in The Sunday Times | 2, 15.2, 18.1, 19 (A) |
| 91 | Director v Glaxo | Article in The Sunday Times | 15.2, 18.1, 19 (A) |
| 92 | Director v Allen & Hanburys | Article in The Sunday Times | 9.1, 15.8 (A) |
| 93 | Director v Duphar | Article in The Sunday Times | 2, 15.2, 18.1 |
| 94 | Dermal v Seton | Provision of a sample | 17.3 |
| 95 | Hospital Doctors v Non-Member Company | Clinical trial arrangements | NoB |

**KEY**

(A) Appeal

# CODE OF PRACTICE FOR THE PHARMACEUTICAL INDUSTRY

| NUMBER | | SUBJECT | BREACH |
|---|---|---|---|
| 96 | Medical Prescribing Adviser v Astra | Dosage Leaflet | 4.1 |
| 101 | Medicines Control Agency v Astra | Journal advertisement for Losec | 4.1 |

**KEY**

(A) Appeal