PRESCRIPTION MEDICINES
CODE OF PRACTICE AUTHORITY

CODE OF PRACTICE REVIEW

NUMBER 8

MAY 1995

The Prescription Medicines Code of Practice Authority was established by The Association of the British Pharmaceutical Industry (ABPI) in 1993 to operate the ABPI Code of Practice for the Pharmaceutical Industry separately from the Association.

Review of the Code of Practice and the procedures for its operation

As reported in the February Code of Practice Review, a review is being carried out of both the working of the Authority in its first two years of operation and of the Code itself. A Working Party established by the ABPI Board of Management has been carrying out this review aided by responses to the questionnaire on the matter which have been received from both ABPI member companies and those non member companies which have agreed to comply with the Code and accept the jurisdiction of the Authority. A progress report was given at the ABPI Annual General Meeting in May.

Examinations for Representatives

Companies are reminded that medical representatives must pass the medical representatives' examination within two years of starting employment as such. That is to say within two years of starting to be employed as a medical representative, not within two years of starting to be employed as a medical representative by a particular company.

Representatives cannot do eighteen months with one company and then go on to do eighteen months with another company and so on, thus avoiding taking the examination completely.

European Journals

The attention of companies is drawn to the fact that advertisements in "European" journals intended for a Europe wide audience are subject to the ABPI Code of Practice if the journal is produced in English in the United Kingdom and some of the circulation is to UK recipients. This applies whether the advertisement is placed by a UK company or by a head office or affiliate overseas. Cases AUTH/215/9/94 and AUTH/271/2/95 in this issue of the Review refer.

Public reprimand for Cyanamid

Cyanamid has been publicly reprimanded by the ABPI Board of Management as a result of the conduct of one of its representatives. The representative offered a doctor the loan of an ambulatory blood pressure machine if the practice changed its prescribing of bisoprolol to the Cyanamid brand, Monocor. Case AUTH/210/9/94 in this issue of the Review refers.

Don't take it - Leave it!

A medical representative who calls upon a doctor to deliver an item, such as a requested monograph, must not make getting to see the doctor a precondition of leaving the item. Having indicated that he has called upon the doctor with a view to leaving the item with him, the representative must leave it even though he does not get to see the doctor. Taking the item away in such circumstances would amount to a breach of Clause 15.3 of the Code.

New format

The new format which was adopted for the first time in the February issue of the Code of Practice Review (formerly the Quarterly Review) has been well received and, subject to some minor changes, will be used from now on.

We apologise for the fact that there was a four month gap between the last Quarterly Review in October 1994 and the first Code of Practice Review in February 1995.

Six issues of the Quarterly Review were published, these being in July and October 1993 and in January, April, July and October 1994, with the first Code of Practice Review in February 1995. It may be helpful to recipients if issues are numbered from the beginning and this is starting with this issue which is number 8.

Companies not complying

As will be seen from the report in Case AUTH/169/6/94 in this issue of the Review, Vestar Ltd, which had originally agreed to comply with the Code of Practice and to accept the jurisdiction of the Prescription Medicines Code of Practice Authority, failed to comply with the procedures in that it refused to either accept a ruling of the Code of Practice Panel or to appeal it to the Code of Practice Appeal Board. It subsequently rescinded its agreement to accept the jurisdiction of the Authority. The papers in the case were sent to the Medicines Control Agency.

Compliance with the Code and acceptance of the jurisdiction of the Authority is obligatory for ABPI member companies and more than fifty non members of the ABPI have also agreed to comply with the Code and accept the Authority's jurisdiction. Apart from Vestar, only two other companies that have been the subject of complaints have failed to follow the procedures, these being Harley Street Medical Supplies Limited and Unigreg Limited. Neither of these companies was a member of the ABPI and nor had they previously agreed to comply with the Code and accept the jurisdiction of the Authority. Papers in both cases were sent to the Medicines Control Agency.

How to contact the Authority

Our address is:
Prescription Medicines Code of Practice Authority
12 Whitehall, London SW1A 2DY

Telephone	0171-930 9677
Facsimile:	0171-930 4554

Copies of the Code of Practice for the Pharmaceutical Industry and of this Review can be obtained from Emer O'Reilly on 0171-930 9677 Extn. 1443.
Direct lines can be used for the three members of the Authority.

David Massam	0171-747 1405
Karen Falkner	0171-747 1415
Heather Simmonds	0171-839 1058

The above are available to give informal advice on the application of the Code of Practice.
The Authority rather than the ABPI is the contact point for information on the application of the Code.

CODE OF PRACTICE TRAINING

Training seminars on the Code of Practice, open to all comers, are run by the Code of Practice Authority on a regular basis at the Royal Society of Medicine in London.

These seminars comprise a full day course offering lectures on the Code and the procedure under which complaints are considered, discussion in syndicate groups on case studies and the opportunity to put questions to the Code of Practice Authority.

Forthcoming Code of Practice seminar dates are:

Thursday, 6 July
Monday, 11 September

Further dates for 1995 will be notified in due course.

Short training sessions on the Code or full all day seminars can be arranged for individual companies, including advertising and public relations agencies and member and non member companies of the ABPI. Training sessions can be tailored to the requirements of the individual company.

For further information regarding any of the above, please contact Emer O'Reilly at the PMCPA for details (0171-930 9677 extn 1443)

CASE AUTH/169/6/94

ZENECA PHARMA v VESTAR

Medical representative's letter on AmBisome - rescission by Vestar of its agreement to accept the jurisdiction of the Authority

Zeneca Pharma complained about a letter written by a Vestar representative to a hospital pharmacist. The Panel ruled that there had been breaches of the Code in relation to the lack of prescribing information and the use of Zeneca's brand name without permission. Vestar contended that the letter was not subject to the Code and declined to either accept or appeal the Panel's decisions and subsequently rescinded its agreement to accept the jurisdiction of the Authority.

COMPLAINT

Zeneca Pharma complained about a letter which had been written by a representative of Vestar Ltd to a hospital pharmacist. Zeneca alleged that its brand name Amphocil had been used without its permission and that the letter failed to provide prescribing information for Vestar's product, AmBisome. Zeneca also had concerns about the technical content of the letter but this had already been raised in an earlier complaint.

RESPONSE

Vestar, although not a member of the ABPI, had nevertheless agreed to comply with the Code. Vestar said that the letter was a response to an individual enquiry from a health professional and, in accordance with Clause 1.2 of the Code, it did not fall within the definition of promotion and was therefore not subject to the Code. It considered that the letter was entirely in order.

RULING

The Panel noted that the letter had been written in a promotional tone with approving comments on various aspects of Vestar's product, AmBisome. The Panel considered that the exception given by Clause 1.2 applied only to straightforward answers to particular questions and could not be extended to letters which were promotional in tone and which lauded properties of the correspondent's products over those of competitors. The letter in question went beyond what was permissible. It was ruled that there had been a breach of Clause 4.1 because of the absence of prescribing information and of Clause 7.10 because of the use of Zeneca's brand name without its permission.

RESPONSE FROM VESTAR

In response to the ruling, Vestar reiterated that such a letter was not subject to the Code and said that the pharmacist had assured it that the representative was responding to his specific request for information and was concerned that a confidential letter had been made the subject of complaint.

SUBSEQUENT DEVELOPMENTS

Vestar declined to either accept the Panel's rulings or to appeal them. Vestar Inc, the parent company in the United States, subsequently rescinded its agreement to accept the jurisdiction of the Prescription Medicines Code of Practice Authority.

The matter was reported to the Code of Practice Appeal Board which in turn reported it to the ABPI Board of Management. The ABPI Board decided that the Authority should be asked, firstly, to refer in the published report on the case to the fact that Vestar had rescinded its agreement to accept the Authority's jurisdiction and, secondly, to send the papers in the case to the Medicines Control Agency. The latter should apply also to any complaints received about Vestar Ltd in the future.

Complaint received	**20 June 1994**
Agreement to accept jurisdiction terminated	**1 September 1994**
ABPI Board proceedings completed	**13 December 1994**

CASE AUTH/177/7/94

SERONO LABORATORIES v ORGANON LABORATORIES

Normegon booklet for patients and price comparison data

Serono complained about a patient booklet on Normegon made available to doctors at a scientific meeting and about price comparison data issued by Organon. It was determined that the booklet was subject to the Code. The Panel ruled no breach with regard to an allegation that the booklet did not include prescribing information. It was inappropriate for items to be given to patients to include prescribing information but when distributed to health professionals they should be accompanied by the prescribing information for the product. Two statements in the booklet referring to a safe preparation and that Normegon should only be given by a doctor or nurse were ruled not to be in breach of the Code by the Panel.

A statement in the booklet comparing the hormone content of Normegon with other gonadotrophins was ruled to be misleading as it implied that other products were less good than Normegon. This was upheld by the Appeal Board on appeal by Organon. The allegation relating to the price comparison data that it was not comparing like with like was rejected by both the Panel and the Appeal Board on appeal by Serono.

Serono Laboratories (UK) Ltd submitted a complaint about a booklet entitled "Normegon Hormones in the Treatment of Infertility" and price comparison data issued by Organon Laboratories Ltd. There were several allegations which were considered as follows:

1 Allegation Concerning Prescribing Information

COMPLAINT

Serono alleged that the booklet looked like a promotional item but was in fact a patient booklet which was made available on the Organon stand at scientific meetings. The company alleged breaches of Clauses 4.1 and 4.2 of the Code as prescribing information was not provided. The statutory information at the back of the booklet was patient information leaflet text.

RESPONSE

Organon submitted that such booklets were widely used in the industry to enhance user familiarity with products which patients had already been prescribed. Organon had been advised by the MCA (Medicines Control Agency) to treat them as patient information leaflets and the booklet in question had been approved by the MCA under The Medicines (Leaflets) Regulations 1977. The company submitted that the booklet was not within the remit of the Authority as it was prepared as information for patients.

Organon advised that the booklet was provided at the company's stand at a scientific meeting at which data sheets for Normegon were also available. The booklet was provided not to promote the medicine but to make doctors aware of the availability of the booklet for patients. Organon submitted that it was accepted practice that education services were brought to the attention of physicians. The company considered that the dissemination of the booklet seemed to be analogous to the provision of the ABPI Compendium of Patient Information Leaflets.

RULING

The Panel considered that the provision of patient booklets such as the one in question were acceptable and such booklets should not include prescribing information. Prescribing information was required when promoting medicines to members of the health professions and appropriate administrative staff. Booklets for patients on medicines should not be promotional in nature and thus it would be inappropriate for them to include prescribing information. When, however, such booklets were given to doctors to give to patients or when they were made available to doctors such as at a company stand at a meeting, those actions constituted the promotion of the medicine which was the subject of the booklet and therefore prescribing information for the medicine should be provided separately from the booklet.

The Panel did not accept that the booklet was outside the scope of the Code. Clause 1.1 stated that the Code applied to information made available to the general public. Although, Clause 1.2 of the Code stated that promotion did not include the "labelling on medicines and accompanying package leaflets insofar as they are not promotional for the medicines concerned; the contents of labels and package leaflets are covered by regulations under the Medicines Act 1968", it had previously been decided that leaflets which were not included in packs were subject to the Code. Leaflets included in packs would be subject to the Code if they promoted the product concerned. The Panel queried whether the booklet in question had needed to be approved by the MCA as it understood that current legislation only required that leaflets included in packs needed to be so approved.

The Panel did not accept that the provision of the booklet was analogous to the provision of the ABPI Compendium of Patient Information Leaflets as submitted by the company. There was a distinction between companies providing bulk copies of booklets such as the one at issue, or their patient information leaflets, to doctors, which constituted the direct promotion of those products. The provision of the ABPI Compendium of Patient Information Leaflets to doctors was by a third party for reference purposes.

The Panel decided that the allegation was that prescribing information had not been included in the booklet. The Panel considered that prescribing information should not be included in the booklet or attached to the booklet as it was intended for patients. The Panel therefore ruled no breach of the Code.

2 Claim "Normegon contains the natural ratio of FSH and LH and, unlike other gonadotrophin products available, has no LH activity added or removed"

COMPLAINT

Serono alleged that the claim was untrue in breach of Clauses 7.2, 7.3, 7.8 and 8.1 as its product Pergonal contained the natural ratio of FSH and LH and did not have LH activity added or removed.

RESPONSE

Organon submitted that there was published scientific information showing that Pergonal did contain added LH activity while there was no available documentation to support Serono's denial. The company submitted there were two relevant points. Firstly, there was no clinical difference in the efficacy of such products as evidenced by the existence of identical licensed indications and secondly, the claim did not say unlike *all* other gonadotrophin preparations. The company's own preparation Humegon contained added LH and therefore the claim was not untrue.

PANEL RULING

The Panel noted the submission that there was no clinical difference in the efficacy of such products and considered that it was misleading to draw attention to the addition or removal of LH activity if it had no clinical significance. The Panel did not accept the company's submission that because the claim did not state unlike all other gonadotrophin products, the claim was acceptable. In the Panel's view the claim did in effect state that *all* other gonadotrophin products had LH activity added or removed. The claim was not true as submitted by Serono in relation to its own product and the Panel therefore ruled a breach of Clause 7.2 of the Code.

APPEAL BY ORGANON

Organon reiterated its submission to the Panel. With regard to the claim for LH activity, the company submitted that the statement was not promotional. It distinguished for the patient the available Organon gonadotrophin products by way of describing their LH activity. Normegon had no LH activity added or removed, Humegon had LH activity added and Orgafol had LH activity removed. The patient might have been prescribed Humegon or Orgafol in earlier treatment cycles.

APPEAL BOARD RULING

The Appeal Board noted that there had been some confusion about the supply of information to patients. The position in the UK had been clarified with the introduction of new regulations The Medicines (Leaflets) Amendment Regulations 1992 and the Appeal Board queried whether the booklet in question had to be approved by the MCA as the legislation only required that leaflets to be included in packs be so approved.

The Appeal Board considered that the booklet was subject to the Code as the Code applied to the promotion of medicines to members of the UK health professions and to appropriate administrative staff and to information made available to the general public about medicines so promoted (Clause 1.1). The booklet did not fall within the exemption of Clause 1.2 of the Code which excluded "the labelling on medicines and accompanying package leaflets insofar as they are not promotional for the medicines concerned..."

The Appeal Board did not accept the company's submission that the provision of the booklets to doctors was similar to the provision of the ABPI Compendium of Patient Information Leaflets. The provision of the Compendium was not viewed as promotion as it was published and distributed by a third party and incorporated leaflets for all participating companies. The Appeal Board's view was that companies could provide health professionals with individual copies of information for patients but this was promotion of the medicine to the health professional. The material therefore had to be accompanied by prescribing information for the product when it was provided to the health professional in order to meet the requirements of the Code.

The Appeal Board considered that the impression of the claim was that the other products which had LH activity added or removed were not as good as Normegon and this was misleading. The Appeal Board noted the submission that there were no clinical differences in the efficacy of products. The Appeal Board considered that given that the purpose of the booklet was for patients it was irrelevant to mention any other product. The Appeal Board upheld the Panel's ruling that the claim was in breach of Clause 7.2 of the Code.

The appeal therefore failed.

3 Statement "Normegon is mixed with a sodium chloride solution to make a safe preparation for the syringe"

COMPLAINT

Serono alleged that the use of the word "safe" was inappropriate and in breach of Clause 7.7 and that if the booklet were to be given to patients the use of the word "safe" was promotional in breach of Clause 20.2.

RESPONSE

Organon accepted that the word "safe" was emotive but its usage for patients was meant to imply that the solution was now ready for use. The company might replace "safe" with "suitable".

RULING

The Panel considered that in the context of the booklet and the fact that the use of the word "safe" referred to the preparation for the syringe, the absolute prohibition on the use of the word "safe" did not apply in these circumstances. The Panel therefore ruled no breach of Clause 7.7 of the Code. The Panel nevertheless considered that the word was best avoided. The Panel did not accept that the use of the word "safe" was in breach of Clause 20.2 of the Code and ruled no breach of that Clause.

4 Statement "Normegon should only be given by a doctor or nurse"

COMPLAINT

Serono alleged that there was an inconsistency as the inside front cover stated that Normegon could be self administered while the patient information leaflet text stated that the product should only be given by a doctor or a nurse.

RESPONSE

Organon submitted that the inclusion of text for self administration was discussed with and approved by the MCA. This was a commonsense recognition that for this category of product which must be administered at very precise time points, it was current clinical practice for some clinicians to train patients or their partners how to administer the product. The inconsistency arose because the product licence did not explicitly allow the company to claim self administration.

RULING

The Panel noted the explanation from Organon as to why there was an apparent inconsistency and did not accept that there had been a breach of the Code.

5 Price comparisons

COMPLAINT

Serono provided two price comparisons, one a page headed "Price comparison of available gonadotrophin preparations" the other, a graph headed "Price differential of available preparations". A breach of Clause 7.2 was alleged.

Serono alleged that the reference to Organon's product Humegon in the chart as "Humegon (Human Menopausal Gonadotrophins, FSH:LH, 1:1)" compared with the reference to its product Pergonal as "HMG (Human Menopausal Gonadotrophins)" in the chart appeared to make the Serono product inferior and more expensive. Only Pergonal conformed to the BP and EP standards for menotrophin.

Serono pointed out that the product Humegon, although claimed to be FSH:LH ratio of 1, was manufactured according to a different method which allowed the addition of human chorionic gonadotrophin. While hCG might have similar actions to LH it was not the same entity. The product licence for Humegon described the product as Human Menopausal Gonadotrophin plus hCG not menotrophin BP.

Serono also drew attention to a comparison of Orgafol to urofollitrophin FSH (its product Metrodin High Purity). Serono pointed out that Orgafol was a national procedure product licence whereas Metrodin High Purity used monoclonal antibody technology and was registered under List A of the concertation procedure. There was an intrinsic difference in the products as Orgafol contained approximately 5% FSH whereas Metrodin High Purity contained more than 95% FSH which accounted for the difference in price. Serono alleged that like products were not being compared.

RESPONSE

Organon submitted that the two price comparisons contained identical information in different formats and were provided together. They were provided by its representatives and made available at the same time as its price list.

The company submitted that Humegon and Pergonal were licensed in the same dosages for the same clinical indications and contained LH and FSH activities in a ratio of 1:1, and the company was therefore justified in comparing prices. The company did not accept that the reference to the Serono product inferred that Serono's product was inferior to Humegon. Serono referred to HMG in the Pergonal data sheet and therefore the use of the abbreviation HMG was not derogatory. The price comparisons simply demonstrated that Humegon was less expensive.

Organon submitted that Orgafol and Metrodin High Purity both contained urofollitrophin as the active ingredient. It seemed reasonable to compare prices of like products used in the same dosages in identical indications.

PANEL RULING

The Panel noted there had been no complaint about the actual prices quoted in the comparisons.

The Panel accepted that the products had similar indications and did not accept that it was unfair to compare the products as in the price comparisons. The Panel had therefore ruled no breach of the Code.

APPEAL BY SERONO

Serono submitted that Metrodin High Purity was not essentially similar to either Metrodin (which was now discontinued in the UK) or Orgafol as it contained highly purified urofollitrophin and could not be compared directly to either of the products for a number of reasons. Firstly, the product was extracted from urine using state of the art monoclonal purification techniques and the finished product could be regarded as "first pharmaceutical grade gonadotrophin". Secondly, the traditional technology products Orgafol and Metrodin consisted of 2-5% FSH of the total protein content with the balance being impurities whereas Metrodin High Purity was 95-98% pure FSH protein. Thirdly, the total protein loading was reduced. Fourthly, the non-highly purified product contained biologically active proteins. Fifthly, Metrodin and Orgafol contained FSH and some LH whereas Metrodin High Purity contained FSH only. Finally there was a difference in method of administration, Metrodin High Purity was so pure that it could be given subcutaneously whereas Orgafol and Metrodin must be given intramuscularly due to high levels of extraneous uncharacterised proteins.

APPEAL RESPONSE

Organon submitted that Orgafol and Metrodin High

Purity contained the same active ingredient and were available in a strength of 75 IU. Orgafol, Metrodin and Metrodin High Purity were used in the same clinical indications and in the same recommended dosage ranges. There was no difference in the clinical efficacy of the products. There was no evidence that use of Metrodin High Purity conferred any additional benefit in efficacy.

With regard to Serono's claim for additional safety benefits, Organon submitted that the data sheets for all the products contained broadly the same list of adverse events, there being no documented reduction in incidence or range of events for Metrodin High Purity. Organon referred to a published report which suggested that one patient developed an immune response to antigens in Pergonal. Subsequent exposure of the patient to Metrodin elicited a similar response. Later injection of Metrodin High Purity subcutaneously did not cause an adverse reaction. The company submitted that attribution of an adverse reaction profile to a range of gonadotrophins presented as different pharmaceutical presentations was not warranted on the basis of one case report.

With regard to method of administration, Organon submitted there was abundant clinical evidence that all of the urinary gonadotrophins were being used by the subcutaneous route without being promoted for use in this way by either company. The company submitted there was no suggestion that the urinary products needed to be further purified to make them suitable for subcutaneous administration. It was correct to say that only Metrodin High Purity was licensed for subcutaneous administration. This was quite different from claiming that Orgafol and Metrodin must be given intramuscularly because they were impure.

APPEAL BOARD RULING

The Appeal Board considered that the crux of this allegation was whether or not like was being compared with like. The Appeal Board noted that the products had similar dosages and similar indications. It did not accept that because one product was administered subcutaneously and the other intramuscularly, the products could not be compared. The Appeal Board upheld the Panel's ruling that there was no breach of the Code.

The appeal therefore failed.

Complaint received **12 July 1994**

Case completed **9 December 1994**

GLAXO/CLINICAL DIRECTOR OF NHS TRUST v LEDERLE LABORATORIES/SMITHKLINE BEECHAM PHARMACEUTICALS

Use of economic evaluation in promotional material for Zoton, unfair comparison and substantiation of claim in newspaper

Glaxo Pharmaceuticals and a clinical director with an NHS Trust complained separately about the use in promotional material of data derived from an economic evaluation of Zoton in comparison with omeprazole and ranitidine in the treatment of acid-peptic disorders. The Panel ruled that a Zoton disk-dialler showing comparative treatment costs with omeprazole and ranitidine was misleading, as on initial impression it appeared to be concerned about the cost of medicines without there being any indication that other costs, such as consultation costs and costs for procedures, were being taken into account. Aspects of the Panel's ruling as it related to the presentation of data from the study in other promotional material for Zoton was appealed.

The Appeal Board observed that it had to be recognised that a study could be mathematically supportable but might not be clinically acceptable, in which case it would not be appropriate as a basis for promotional claims. Furthermore, as of necessity, studies were based on estimates and on assumptions which meant there was a danger of presenting data from such studies as hard facts. This was of particular relevance to the presentation of precise cost savings. If they were not adequately qualified, they were in themselves misleading as was the case with the Zoton disk-dialler. The Appeal Board accepted however that the other promotional material before it incorporating data from the study were acceptable and ruled there was no breach.

The Panel also ruled that comparative claims for duodenal ulcer healing rates were in breach as the comparisons were unfair as they selectively presented only the best results of three comparative studies. This was not appealed.

A further allegation by Glaxo concerned the failure to substantiate a claim for cost savings to the NHS reported in a newspaper article. This allegation concerned Lederle only. Lederle submitted that it was not responsible for the claim appearing in the newspaper article as the statement was made at a press conference at which this particular newspaper was not represented. This was not accepted by either the Panel or the Appeal Board on appeal from Lederle. A breach was ruled due to the failure to substantiate the claim when requested to do so by a member of the medical profession.

These cases were concerned with two complaints, one submitted by Glaxo Pharmaceuticals (AUTH/187/7/94 & AUTH/189/7/94) and one by a clinical director of an NHS Trust (AUTH/197/8/94 & AUTH/198/8/94) regarding the promotion of Zoton. As Zoton was jointly promoted by Lederle Laboratories and SmithKline Beecham Pharmaceuticals, the complaints were taken up with both companies.

Cases AUTH/187/7/94 & AUTH/189/7/94

1 Economic evaluation data - disk-dialler

COMPLAINT

Glaxo complained about a disk-dialler entitled "Zoton - comparative treatment costs with omeprazole and ranitidine" based on data derived from a study "Cost-effective management strategies for acid-peptic disorders" by R H Jones *et al* published in the British Journal of Medical Economics. Certain sums of money were shown on the disk-dialler as representing the "Budget available for the treatment of GI disorders" and against this the number of "ranitidine patients treated" for that sum of money. Glaxo pointed out that the promotional item did not state in which licensed indications the comparisons were made.

Glaxo also pointed out that in the study on which the data was based, the authors had attempted to estimate, based on many assumptions, the relative cost and cost effectiveness of lansoprazole (Zoton), ranitidine and omeprazole in the empirical treatment of "undiagnosed dyspepsia" in general practice, assuming that 16% of patients with this condition would have duodenal ulcer and 26% would have gastro-oesophageal reflux disease (GORD). Glaxo pointed out that although the authors stated that in peptic ulceration ".....ranitidine represents the treatment option, which is slightly less costly and more cost effective...[than lansoprazole]", this was concealed and the calculations skewed in favour of lansoprazole in the promotional material by combining the comparative cost effectiveness estimates in duodenal ulcer, favourable to ranitidine, with those in oesophagitis, more favourable to potent acid suppressants. Glaxo alleged that this was unbalanced and misleading in breach of Clause 7.2.

Furthermore, assumptions about relative efficacy in GORD were based upon trials in oesophagitis which was an endoscopically diagnosed condition at the severe end of the spectrum of GORD. Indeed, the company pointed out that one trial cited in the cost effectiveness paper was in erosive oesophagitis, where potent acid suppressants like lansoprazole could be expected to be more effective than H2 antagonists. Zantac (ranitidine) had been shown to be highly effective at providing symptomatic relief in patients at the milder end of the spectrum of gastro-oesophageal disease. Zoton, unlike Zantac was only licensed for the treatment of oesophagitis and not for the wider indication of GORD. Glaxo therefore alleged that in presenting cost effectiveness data in GORD for lansoprazole, Zoton was being promoted beyond its licensed indications in breach of Clause 3.2 of the Code.

Finally, with regard to the disk-dialler and related materials, Glaxo alleged that to the casual reader not familiar with the details of the study, the disk-dialler and related materials misleadingly implied, for example, that 150 patients could be treated with ranitidine for eight

weeks for a sum of £10,000. In fact eight weeks of treatment with ranitidine at 150 mg twice daily would cost £52 and therefore £10,000 could treat 193 patients. Furthermore, even when the reference was studied, the company calculated that the number of ranitidine patients symptom free at eight weeks would be 112 and not 106 as shown on the disk-dialler. A further breach of Clause 7.2 of the Code was alleged.

RESPONSE

Lederle explained that the disk-dialler was attached to the back of the Zoton detail aid and was intended for use by representatives and was not to be left with doctors. Prescribing information was put on the disk-dialler, however, in case it became inadvertently detached. In addition to the information contained on the dialler, the representative had further details of the study techniques contained in a technical piece which was used for detailed discussions. A copy of the technical piece was submitted.

The company pointed out that the study in use had been independently written by experts in the field of health economics. By definition, such studies involved assumptions but these were clearly explained in the published articles. The use of the phrase "undiagnosed dyspepsia" by the authors was intended to indicate that group of patients who were suspected to have duodenal ulcer or reflux oesophagitis but for which the GPs, as was the usual scenario, had no confirmed diagnosis. The authors justified from published data that in a group of such undiagnosed patients it would be likely that duodenal ulcer and reflux oesophagitis would occur at a ratio of 16:26. There would also be a group with the condition of non-ulcer dyspepsia but as this was not a licensed indication this data had not been included in the calculations.

The company denied that the data was skewed in favour of Zoton and submitted that given that a doctor sees groups of patients in whom the presenting symptoms might suggest duodenal ulceration or reflux oesophagitis in the ratio indicated, the figures were calculated to indicate the most cost effective management options. The company accepted that if a doctor knew a patient had duodenal ulcer, ranitidine would be cheaper in terms of drug cost only but the doctor would have already incurred additional costs by getting the confirmed diagnosis (ie outpatient referral or endoscopy) - this would not represent a cost effective option but one that was merely cheaper in drug terms.

With regard to the use of the term GORD, the company submitted that it was a new term currently used interchangeably with reflux oesophagitis. The company denied that it was promoting outside the terms of its licence. It did not use the phrase GORD although the authors of the publication had done so in order to use the most recently accepted phraseology for what was the same condition.

Details were provided of the calculations used in the disk-dialler with which Glaxo had disagreed. The company pointed out that although Glaxo stated that eight weeks treatment with ranitidine would cost £52 it was describing drug costs only not total treatment costs which were the subject of the study.

SmithKline Beecham Pharmaceuticals pointed out that the disk-dialler on which the paper was based compared the treatment of dyspepsia, which included duodenal ulcer, gastric ulcer, gastro-oesophageal reflux and undiagnosed dyspepsia. As undiagnosed dyspepsia was not an approved indication for Zoton, data on this indication had been omitted from the disk-dialler. Data on the disk-dialler related to the treatment of duodenal ulcer and gastro-oesophageal reflux in primary care. It was assumed that cases would present an approximate ratio of 16:26 as reported and used in the model in the study. The paper and the disk-dialler considered treatment and associated costs of patients presenting in general practice in whom endoscopic confirmation of diagnosis was not routine before treatment was initiated.

With regard to the comments by Glaxo that the fact that ranitidine represented a treatment option which was slightly less costly and more cost effective had been concealed, the company submitted that it was not relevant to primary care as this referred to endoscopically confirmed duodenal ulcer. Confirmation of diagnosis was not practical and even if performed would greatly alter costs as the cost of the endoscopy would need to be included. The company confirmed the Lederle submission regarding the use of the term GORD and the calculations on the disk-dialler relating to the number of symptom free patients on ranitidine at eight weeks.

PANEL RULING

The Panel considered the information before it and made a number of observations in respect of the economic evaluation of medicines. As noted in the supplementary information to Clause 7.2 of the Code, the economic evaluation of medicines was a relatively new science and care had to be taken that any claim involving economic evaluation of a medicine was borne out by the data available and did not exaggerate its significance.

The economic evaluation of medicines was not an exact science and all such studies would by necessity be based on certain assumptions regarding treatment and usage of the product etc. Those assumptions must, however, accord with clinical practice and, if claims were to be made in promotional material based on the evaluation, those assumptions must also accord with the licence. Any claims made in promotional material based upon such studies should indicate the major assumptions which had been made in the study from which the data or claim was derived.

The Panel noted that the disk-dialler was intended to be used by representatives with the expectation of an accompanying explanation as to the basis of the study, but considered that it was well established that all promotional items were required to stand alone.

With regard to the actual study involved the Panel accepted the concerns expressed by Glaxo with regard to the assumptions made in the study about relative efficacy in GORD given that these were based on trials in oesophagitis which was at the severe end of the GORD spectrum. It did not accept that GORD and reflux oesophagitis were interchangeable terms as submitted by Lederle and SmithKline Beecham. A number of other criticisms could be made of certain assumptions on which aspects of the study were based including those regarding

comparative outcomes of treatment given that there was no one study which appeared to compare all three treatments, the actual costs assigned to procedures such as endoscopies and the assumptions made regarding the numbers of endoscopies and when they would be performed.

With regard to the assumptions in the study concerning treatment outcome, the Panel noted that it had ruled a claim that Zoton provided "faster symptom relief than ..... omeprazole ...." was misleading in breach of Clause 7.2 in Cases AUTH/165/6/94 & AUTH/166/6/94. This ruling was upheld on appeal although this had not been decided at the time of the Panel's consideration.

In respect of the different calculations as to the number of symptom free patients achievable with £10,000, the Panel noted it appeared that both Glaxo and Lederle were correct in their calculations. The paper itself appeared to be capable of more than one interpretation.

The Panel considered that the disk-dialler was misleading on three counts. First, on initial impressions the disk-dialler appeared to be concerned about the cost of medicines without there being any indication that other costs such as consultation costs and costs for procedures, eg endoscopies, were being taken into account. Second, it was misleading to take data derived from a study such as the one in question based on many variable assumptions and use it as the basis of making crude calculations about cost. This was misleading and would have been whether or not certain assumptions within the study were open to criticism. Third, that the actual data presented was misleading in that certain aspects of the study were open to criticism as referred to above. The Panel therefore ruled there was a breach of Clause 7.2 of the Code in respect of the disk-dialler. This ruling also applied to the presentation of data from the study in other promotional material for Zoton.

The Panel did not accept there was a breach of Clause 3.2 as alleged on the basis that even though it did not accept that GORD and reflux oesophagitis were interchangeable terms as submitted by Lederle and SmithKline Beecham, it did not consider that presentation of data from the study in itself constituted promotion of Zoton for an unlicensed indication of GORD.

Lederle and SmithKline Beecham appealed against certain aspects of this ruling and details are reported at the end of this report.

2 Comparative claims for duodenal ulcer healing rates

COMPLAINT

Glaxo alleged that several promotional items for Zoton including a detail aid (ref ZOT 100) showed duodenal ulcer healing with lansoprazole at four weeks to be 96% in comparison with ranitidine at 74%. Glaxo alleged that of the three published studies in this indication this figure was the poorest healing rate for ranitidine and was taken from the smallest study. Indeed, in one study showing healing rates of 95% versus 89% the differences were not statistically significant. A breach of Clause 7.2 was alleged.

RESPONSE

Lederle provided details of the studies in question and pointed out that at two weeks there was a significant advantage in all studies in favour of Zoton 30mg. This advantage was maintained at four weeks in two of the three studies but in the third study the results were numerically in favour of Zoton although not statistically significant. Overall, the company believe that the body of data was firmly in favour of Zoton and that the choice of one study did not mislead in any way.

This submission was confirmed by SmithKline Beecham.

PANEL RULING

The Panel considered it was not a fair comparison to select and present only the best results of the three comparative studies. The Panel therefore ruled that it was in breach of Clause 7.2.

This was accepted by the companies without appeal.

3 Substantiation of claims in press statements

COMPLAINT

Glaxo stated that there were widely publicised claims made by Lederle in press statements at the time of Zoton's launch, that the use of the product in place of Zantac would save the NHS £55 million per year. Glaxo stated that, as it considered this to be a promotional claim, the company should have been prepared to provide substantiation for the claim at the request of members of the health professions. A doctor employed by Glaxo had requested substantiation of the claim but Lederle had replied stating that it saw no reason to explain how it was calculated. A breach of Clause 7.4 was alleged.

RESPONSE

Lederle provided details of how the figure had been calculated and explained that when Glaxo raised the issue it was two months since the appearance of the article and the figure had not appeared subsequently. Since the company had no materials at the time of the contact by Glaxo containing this claim it saw no reason to substantiate it.

SmithKline Beecham stated that it had not presented data on the total annual savings to the NHS and had never been asked for data to substantiate the claim.

PANEL RULING

The Panel considered that Lederle had failed to substantiate a claim when requested to do so by a member of a health profession as required under Clause 7.4 of the Code and ruled there was a breach of that Clause. The Panel did not consider whether or not the material provided by Lederle substantiated the claim.

This ruling did not apply to SmithKline Beecham as it was not involved in this aspect of the complaint. Lederle appealed against the ruling and details are reported at the end of this report.

Cases AUTH/197/8/94 & AUTH/198/8/94

COMPLAINT

A clinical director with an NHS Trust complained about the use of an economic evaluation study by J H Jones *et al* in the promotion of Zoton.

The complainant pointed out that the study was incorrectly referenced to the British Journal of Health Economics in promotional literature for Zoton. The article itself, the complainant alleged, was seriously flawed. The complainant alleged that it was an economic model purporting to show that lansoprazole was more cost effective than omeprazole and ranitidine. However, the clinical efficacy data used in the model was so highly selected that the interpretation and the use of the paper for promotional purposes was unjustified. For example, the benefit of lansoprazole over omeprazole relied wholly on one symptom assessment (heartburn measure at clinical visits) at one time point in one trial; other symptom assessments reported in the trial did not corroborate this claim. Moreover, as healing or more importantly healing plus symptom relief, were used as the criterion for clinical success, the only possible conclusion was that lansoprazole and omeprazole were equally cost effective.

The complainant stated that it was doubtful whether commercial claims should be based wholly on economic models especially if the assumptions on which the model were based were open to debate. For example, it was contentious to assume that dyspepsia treated in general practice responded in the same way as endoscopically verified reflux oesophagitis treated in hospital clinical trials. Further, as far as the complainant was aware, lansoprazole was licensed only for the short term treatment of reflux oesophagitis and not for the management of undiagnosed dyspepsia. The complainant pointed out that health economics was a developing science and the publication of economic models was a proper part of the process of development. Models based on unrepresentative clinical data were not, however, acceptable and gave the science a bad name. When this was taken one stage further to form the platform for major promotional claims it further debased the use of health economics in making prescribing decisions.

The complainant asserted that the article and materials derived from it were being used very widely in promoting lansoprazole and that the cost savings which were claimed to be possible from lansoprazole were exaggerated, based as they were on a flawed analysis.

RESPONSE

Lederle accepted that there had been a misprint in the referencing to the study in the promotional material for Zoton which it undertook to correct.

The company stated that, as the article was the only published data on lansoprazole cost effectiveness it was therefore reasonable to use it and that when, and if, additional conflicting data were published on the subject, it would accept that it would have to relook at its use as its sole referenced source. Further, the article was written by two authors respected and experienced in the field of health economics. The complainant might not agree with their views but this did not preclude it from using the article which appeared in a peer reviewed journal specialising in the publication of such studies.

With regard to the complainant's assertion that healing plus symptom relief should be used as the criterion for clinical success, the company submitted that it failed to recognise that most prescribers (ie general practitioners) did not have the luxury of knowing when healing occurred. This point was clearly used as the premise for the paper. The company also pointed out that as lansoprazole was £3 a month cheaper than omeprazole, it asserted the only conclusion was that, even assuming they were equally efficacious, lansoprazole was more cost effective than omeprazole.

Finally, the company reaffirmed that it did not use non-ulcer dyspepsia data from the study but used only the reflux oesophagitis:duodenal ulcer ratio 26:16. The company referred to its earlier submissions in Cases AUTH/187/7/94 & AUTH/189/7/94 above regarding undiagnosed dyspepsia and its management in general practice where no truly confirmed diagnosis was available for these groups of patients.

SmithKline Beecham endorsed the submission from Lederle as representing its own views.

PANEL RULING

The Panel noted its previous consideration of Cases AUTH/187/7/94 & AUTH/189/7/94 above in which it had made a number of observations regarding the use of economic evaluations generally and the actual study at issue in these cases. Those observations equally applied in the cases now before the Panel. The Panel considered that its ruling of breach of Clause 7.2 in those cases applied equally to the cases now under consideration and further ruled there was a breach of Clause 7.2 of the Code.

The Panel did not accept the submissions put forward by Lederle that as the article in question was the only published data on lansoprazole cost effectiveness that it was reasonable to use it. Acceptability of usage of data was dependent on its quality and not whether it was the only data available.

With regard to the incorrect reference to the British Journal of *Health* Economics rather than the British Journal of *Medical* Economics, the Panel did not consider that it constituted a breach. Although there was an error in the citing of the reference it was not misleading and did not breach Clause 7.5 as that clause did not apply. Clause 7.5, which required the provision of clear references, applied only when published studies were specifically referred to by name in the text of the promotional material. This was not the case with the material before the Panel. The Panel therefore ruled no breach on this allegation.

****

Appeals by Lederle & SmithKline Beecham - Economic evaluation & substantiation of claims in press statements

Lederle and SmithKline Beecham accepted the Panel's ruling with respect to the disk-dialler insofar as it related to the Panel's view that, on initial impression, the disk-dialler appeared to be concerned about the cost of the medicines without there being any indication that other

costs were taken into account. Whilst the companies emphasised that the disk-dialler formed part of the detail material used by the representative and was not intended as a stand alone leavepiece, they accepted the Panel's ruling on the item and advised that it was no longer in use. The companies appealed against the second and third points of the Panel's ruling with regard to the use of the economic data. These were that it was misleading to take data derived from a study such as the one in question based on many variable assumptions and use it as a basis of making crude calculations about cost, and that the actual data presented was misleading in that certain aspects of the study were open to criticisms regarding assumptions about comparative clinical efficacy and the use of the term GORD based on trials in oesophagitis. The application of the Panel's ruling to presentation of the data from the study in other promotional material for Zoton, in the companies' view, meant that it could not use data derived from the study in its promotional material. It was against that which the companies appealed.

The companies submitted that although economic evaluations would always involve assumptions, these assumptions were tested in the Jones paper by the use of sensitivity analyses and whilst an individual might challenge certain assumptions, sensitivity analyses allowed an individual to assess the impact of changing them. The paper showed that lansoprazole was more cost effective in undiagnosed dyspepsia than the other two products with which it was compared.

A detailed defence was made in respect of the clinical assumptions used in the paper. It was pointed out that published data comparing all three treatments did not exist but that symptom relief was a relevant end point for general practitioners and it was reasonable to assume that similar rates of symptom relief would be likely in clinical practice as demonstrated in clinical trials. The end point of symptom relief in reflux oesophagitis had been challenged by Glaxo because it was applied to GORD, but a GP initiating treatment would only know that a patient had heartburn and not whether they were suffering from reflux oesophigitis or GORD. Therefore it was reasonable to assume that this was representative in what would happen in GORD. It was also pointed out that there was a wide confidence interval in the study results. Response rates in symptom relief for lansoprazole could be 30% less and it would still be more cost effective than ranitidine.

The companies submitted that the health economic data regarding Zoton was robust and, even taking into account drug costs alone, Zoton was more cost effective than ranitidine because even though it cost a little more it was considerably more effective. Economic justification for medicines were common and without expert publications, physicians would make decisions about cost effectiveness based on "feelings" and "estimates". Health economic publications of the type in question at least provided a structured methodology on which to make such claims.

The study by Jones *et al* had been commissioned by Lederle and although it had been carried out prior to the publication of the ABPI/Department of Health Guidance on Good Practice in the Conduct of Economic Evaluations of Medicines, Lederle submitted that the study did in fact conform with that guidance.

With regard to the Panel's ruling of a breach of Clause 7.4, this was appealed by Lederle. Lederle explained that the statement regarding cost savings of £55 million to the NHS were made in response to a question at a press conference at which certain medical/pharmaceutical journalists had been invited. It had been reported only in the Financial Times' trade publication Pharmaceutical News. This had been picked up and reported in The Times newspaper where Glaxo had seen it and requested substantiation from Lederle. In Lederle's view, as it had not disseminated the figure to The Times, it was not required to provide substantiation for that claim to Glaxo. The company could substantiate the claim although this was not at issue.

APPEAL BOARD RULING

The Appeal Board noted that the promotional material before it incorporating claims made on the basis of the economic evaluation paper were a detail aid (ref ZOT 079) which included a general claim for lower treatment cost per patient symptom free than either omeprazole or ranitidine based on the Jones study and a technical detail aid on health economics. The technical detail aid provided details of the Jones study including the assumptions on which the economic evaluation had been carried out and the results obtained. It was the use of the Jones study in the promotional material before the Appeal Board which was the subject of appeal. A study could not be ruled in breach *per se*, only how data derived from a study or studies were used in promotion.

There were a number of aspects of economic evaluations which need to be considered. Firstly, it had to be recognised that a study could be mathematically supportable but might not be clinically acceptable, in which case it could not appropriately be used as the basis for promotional claims. Furthermore, as of necessity such studies were based on estimates and assumptions which meant there was a danger of presenting data from such studies as hard facts. This was of particular relevance to the presentation of precise cost savings. If they were not adequately qualified they were in themselves misleading, as was the case with the Zoton disk-dialler.

The Appeal Board considered that the general claim "Lower treatment costs per patient symptom free than either omeprazole or ranitidine" made in the document ZOT 079 was acceptable as was the presentation of the study in the technical detail aid on health economics. The Appeal Board therefore considered that the presentation of the data from the study in the material before it was acceptable and ruled there was no breach of the Code.

The appeal therefore succeeded.

The Appeal Board considered, however, that if the information contained on the one page in the technical detail aid showing a chart on costs and cost-effectiveness of therapy for 100 GORD patients was presented on its own that would not be acceptable on the same basis as the disk-dialler was unacceptable. This was that it was presenting precise cost savings derived from an economic evaluation as hard fact without qualification by way of explanation of the basis on which the figures had been calculated.

With regard to the refusal by Lederle to provide substantiation for the claim that the use of Zoton instead

of Zantac would save the NHS £55 million per year, the Appeal Board considered that a company had to take responsibility for all information presented at a press conference. Lederle was therefore responsible for the claim as reported in The Times and was therefore obliged to provide substantiation of that claim when requested to do so by a health professional as required under Clause 7.4. The Appeal Board upheld the Panel's decision and ruled there was a breach of Clause 7.4.

The appeal on this issue therefore failed.

Complaints received **10 August 1994 & 15 August 1994**

Cases completed **9 December 1994**

CASE AUTH/206/8/94

PARKE DAVIS v WELLCOME

Lamictal promotional material & letter to journal

Parke Davis complained about promotional items for Lamictal issued by Wellcome and about a cost comparison made in a letter from Wellcome to Pulse. The Panel considered that it had not been made adequately clear in the items at issue that Lamictal was licensed only for partial seizures and secondary generalised tonic clonic seizures and that it was an add-on therapy, only, even though the information was given somewhere in them, and ruled the items in breach. The Panel considered that the letter came within the scope of the Code and ruled a misleading cost comparison in breach. The Panel's rulings were confirmed by the Appeal Board on appeal.

1 Promotional material

COMPLAINT

Parke Davis complained about the promotion of Lamictal by The Wellcome Foundation Ltd, alleging that the campaign was deliberately misleading as Lamictal was promoted for "epilepsy" without qualification and for "reducing seizure frequency".

Adult detail aid M1201119C: Dosage card M1201123M: Paediatric detail aid M1201110W. Parke Davis alleged that there was no clear mention that Lamictal was for use in partial and secondary generalised seizures only, although it was mentioned in the small print in the adult detail aid and in the prescribing information for all three items. It was a well established principle of the Code that one could not correct a misleading and inadequate statement in this way.

Dosage card M1201123M: Journal advertisement. Parke Davis alleged that Lamictal was being promoted as monotherapy. It was not made clear that it was an add-on treatment or that it was for partial and secondary generalised seizures only. Again this was only mentioned in small print and in the prescribing information.

RESPONSE

Wellcome disagreed with the interpretation that Lamictal was being promoted for "epilepsy" without qualification and considered that the items made the licensed indication clear. Not only was the indication section from the licence stated at the first mention of efficacy but also in the prescribing information. The studies used stated clearly that the patients had refractory partial seizures. The use of "epilepsy" was analogous to the use of "infection" in the advertising of antibiotics. It did not imply that any medicine would treat "all epilepsy" or "all infection", but merely that this was the generic area where the drug had an effect. Precise seizure type, or susceptible bacteria, were usually restricted to prescribing information. Wellcome had further highlighted the licensed indications by stating them at the first claim on efficacy in order to ensure clarity.

With regard to the paediatric detail aid, Wellcome had advised Parke Davis that instructions had already been given for the insertion of an indication statement at the same point as the other pieces to maintain consistency. However, despite this alteration, Wellcome believed that it was already clear for what Lamictal was being promoted, the indications being in the prescribing information.

In relation to the journal advertisement, Wellcome disagreed with the interpretation that Lamictal was being promoted as monotherapy. It was clearly stated that Lamictal was licensed as add-on therapy for partial seizures and secondarily generalised tonic clonic seizures not satisfactorily controlled with other antiepileptic drugs. This was also stated in the prescribing information. Wellcome did not agree that these pieces would leave the prescriber in any doubt as to the indications for Lamictal.

PANEL RULING

The Panel noted that the data sheet for Lamictal stated that it was an antiepileptic drug "indicated as add-on treatment of partial seizures and secondarily generalised tonic clonic seizures, not satisfactorily controlled with other antiepileptic drugs".

The Panel considered that these limitations had not been adequately reflected in the promotional items and that they all breached the Code because of their failure to make the position adequately clear on all relevant pages, notwithstanding the fact that the information was given somewhere in them. Breaches of Clause 7.2 of the Code were ruled separately in relation to, firstly, the failure to make clear that Lamictal was an add-on therapy and, secondly, the failure to make clear that it was intended for use for certain types of seizure only.

APPEAL BY WELLCOME

Wellcome said that it was firmly of the opinion that it had adhered to both the spirit and the letter of the Code. Each item contained not only a statement relating to the fact that the drug was indicated for add-on use, but also a succinct statement of the indications, either in the text or in the prescribing information. As such, the materials were in keeping with the current practice used by manufacturers of hypertensive drugs, anti-infective drugs and asthmatic agents where the use of generic terminology was commonplace. A number of examples of other companies' promotional materials were provided.

The use of the word "epilepsy" in the advertising material could not, and should not, be taken as a claim of indication *per se*. This was generic terminology for the therapeutic area in which the drug had use. Again, this was consistent with areas such as hypertension, asthma and infection where one would not expect the full indication statement from the data sheet to be listed in every page of every item.

Wellcome was concerned at the Panel's decision that it was in breach of the Code because a detailed and complete statement of the indications and limitations of the product was not made on every page of its advertising material. It did not believe that this was common practice throughout the industry, and felt that the inclusion of such information on every page might be seen as condescending to any doctor being detailed.

Wellcome advised that when the materials at issue were written, Lamictal was only licensed for add-on therapy although this was no longer true.

APPEAL BOARD RULING

The Appeal Board noted Wellcome's contention that advertisements regularly omitted full details of the limitations of the products advertised. It considered, however, that that was irrelevant to the case before it. It had to deal with each case separately on its own merits.

In the present case, the Appeal Board considered that inadequate notice had been given as to the limitations of the product, both as to indications and as to it being add-on therapy. This was notwithstanding the fact that the information was given somewhere in the promotional items in question. It was not the case, however, as Wellcome stated, that these limitations should be stated on every page but, as the Panel had stated, on every relevant page.

The Appeal Board therefore upheld the Panel's rulings that there had been breaches of Clause 7.2 in relation to, firstly, the failure to make clear that Lamictal was an add-on therapy and, secondly, the failure to make clear that it was indicated for use in certain types of seizure only.

The appeal therefore failed.

2 Letter to Pulse

COMPLAINT

Parke Davis complained about a letter from Wellcome's medical division which appeared in Pulse on 6 August 1994 alleging that there was an unbalanced and unfair cost comparison between Lamictal and its own product gabapentin (Neurontin). It was stated that the lowest daily maintenance dose of Lamictal at 200mg/day for one year cost £799. This was compared with 1200mg/day of Neurontin which was not the lowest usual dose as this was 900mg/day at a cost of £534 per year.

RESPONSE

Wellcome said that the letter to Pulse had been sent in response to inaccuracies in an article, copies of which were provided. The comparison of Lamictal and gabapentin used in the letter referred to the lowest usual maintenance dose. The gabapentin figure was taken from Parke Davis' promotional items showing the usual maintenance dose to be 1200mg/day. Wellcome believed that this was a fair comparison especially as the doses used to reach the figure were also quoted.

PANEL RULING

The Panel noted that the letter to Pulse from Wellcome had been sent in response to an article headed "10 questions answered" on epilepsy and considered that the content of the letter came within the scope of the Code. The Panel noted that the Neurontin data sheet stated that "the anti-epileptic effect of Neurontin generally occurs at 900-1200 mg/day". Similarly, the data sheet for Lamictal stated that in patients not taking sodium valproate the usual maintenance dose was 200 to 400mg per day and in patients taking sodium valproate the usual maintenance dose was 100 to 200mg per day. The letter sent to Pulse compared a daily dose of gabapentin (Neurontin) of 1200mg and a dose of Lamictal of either 100mg or 200mg.

The Panel noted that the comparison used the lowest maintenance doses of Lamictal and the highest maintenance dose of Neurontin. The Panel acknowledged that Parke Davis' promotional material for Neurontin did state that the usual maintenance dose was 1200mg/day. The Panel nonetheless decided that the comparison was misleading and ruled a breach of Clause 7.2 of the Code.

APPEAL BY WELLCOME

Wellcome questioned whether the letter came within the provisions of Clause 1 of the Code. The letter was a direct response to a published article in Pulse which contained inaccurate data comparing the prices of antiepileptic medicines. The letter was not in any way intended to promote Lamictal, but to defend Wellcome's position and to ensure commercial advantage was not gained by any pharmaceutical company. If the Appeal Board decided that the letter was within the Code, Wellcome submitted that it had made every effort to ensure that the comparison was fair and honest in relation to both products' current usage. Wellcome felt justified in quoting 1200mg as the minimal maintenance dose of Neurontin as this was what was currently being promoted by Parke Davis as the usual maintenance dose. It was worth noting that for Neurontin the maintenance dose was quoted as being between 1200 and 2400mg and the lower limit of this was taken by Wellcome for full dosage comparison.

With respect to Lamictal, patients might be either on 100-200mg per day, if they were concurrently taking valproate therapy, or 200-400mg per day if they were concurrently

taking an enzyme inducer such as carbamazepine. It was stated in the letter that the calculation was made on the principle that 40% of patients would be concurrently taking valproate, and 60% of patients would be concurrently taking carbamazepine or phenytoin. As such, dosage for comparison was calculated using the lower maintenance doses for each, but corrected for this ratio. This gave a dosage for comparison of 160mg per day.

By stating how the comparison had been derived, and by using published data on the maintenance doses of each individual product, Wellcome submitted that it had made every effort to ensure that the comparison was fair and honest.

APPEAL BOARD RULING

The Appeal Board first addressed the question of whether the letter to Pulse came within the scope of the Code or whether it was excluded by Clause 1.2 which excluded "replies made in response to individual enquiries from members of the health professions or in response to specific communications whether of enquiry or comment, including letters published in professional journals". The Appeal Board considered that the inclusion of a cost comparison with a competitor, gabapentin, given in the final paragraph of the letter meant that it came within the scope of the Code and could not take the benefit of Clause 1.2 as it went beyond what was necessary to respond to the original article.

In relation to the allegation now under appeal, the Appeal Board considered that the comparison had used the lowest maintenance doses of Lamictal but had not used the lowest maintenance dose of gabapentin. The Appeal Board considered that this was misleading and in breach of Clause 7.2.

The appeal therefore failed.

Complaint received **30 August 1994**

Case completed **9 January 1995**

CASE AUTH/208/9/94

WELLCOME v PARKE DAVIS

Allegations concerning Neurontin detail aid

Wellcome made a number of allegations about a detail aid for Neurontin issued by Parke Davis. The Panel ruled breaches of the Code in relation to the use of the wrong mathematical symbol in a diagram relating to seizure frequency and in relation to a page bearing a table summarising the most frequent treatment signs which was misleading. Both of these decisions were unsuccessfully appealed to the Appeal Board. The Panel ruled no breach in relation to a statement concerning interactions with other antiepileptic drugs and the alleged failure to provide supporting information.

The Wellcome Foundation Ltd complained about a detail aid for Neurontin issued by Parke Davis (ref M212/April 1994/UK). There were four allegations.

1 Claim for seizure reduction

COMPLAINT

Wellcome alleged that a diagram showing the percentage of patients with greater than 50% reduction in seizure frequency was incorrect and in breach of Clause 7.2 as it should have been the percentage of patients with a greater than or equal to 50% reduction in seizure frequency.

RESPONSE

Parke Davis accepted that there was a typographical error. The "greater than" sign should have been the "greater than or equal to" sign. This point had been conceded prior to Wellcome's complaint to the Authority. A memorandum had been sent out to Parke Davis representatives instructing them to amend this error. It had not been Parke Davis' intention to mislead and, in fact, on the opposite page the main body of the text mentioned ".....had seizures reduced by half or more".

PANEL RULING

The Panel considered that the heading to the diagram "Percentage of patients > 50% reduction in seizure frequency" was inaccurate. Instead of the symbol >, the symbol $\geq$ should have been used, meaning greater than or equal to. Even though this had been a typographical error, the fact was that the claim had been made. The Panel ruled that there had been a breach of Clause 7.2 of the Code.

APPEAL BY PARKE DAVIS

Parke Davis submitted that the use of the wrong symbol was a small typographical error similar to a case previously considered by the Panel (Case AUTH/140/3/94, part Biii), in which an "n" value was incorrectly stated. In that case the Panel had considered that although there was an error, it was minor and conferred no advantage to the advertised product. The Panel had not considered that it was misleading and had ruled no breach.

In the Neurontin detail aid, ">50%" would infer seizure reductions of 50.1% or more rather than 50.0% or more. This difference would not mislead the reader to any significant extent and certainly did not convey any clinical advantage. In addition, the text on the facing page of the detail aid ("....seizures reduced by half or more") fully qualified the claim and also indicated that any deception was entirely unintentional.

APPEAL BOARD RULING

The Appeal Board considered that the present instance was to be distinguished from Case AUTH/140/3/94 where the error had not been part of an actual claim but had been subsidiary in nature.

The Appeal Board decided that the use of the wrong symbol meant that the statement had been inaccurate and upheld the Panel's ruling that there had been a breach of Clause 7.2.

The appeal therefore failed.

2 Interactions with other antiepileptic drugs

COMPLAINT

Wellcome pointed out that there was an absolute statement in the detail aid that gabapentin had no interactions with conventional antiepileptic drugs (AEDs) and it was stated that there was "no need to monitor serum levels when adding Neurontin". Reports had been made of increases in phenytoin in levels following the addition of low doses of gabapentin which made the statement incorrect and in breach of Clause 7.2.

RESPONSE

Parke Davis stated that the reference Wellcome quoted was a letter which described a single report of a possible interaction between gabapentin and phenytoin in a patient on a complex regimen of drugs and was the only reported alleged interaction published worldwide. The author's interpretation of his patient's clinical course as indicating a phenytoin-gabapentin interaction was contradicted by all pharmacokinetic studies of gabapentin and phenytoin, carbamazepine and valproate to date as well as by controlled clinical trial data in 792 patients who received add-on gabapentin at doses ranging from 600 to 1800mg/day. The author had in fact written to Parke Davis stating that the case referred to in his letter was, in his view, an interesting exception to the rule of freedom from drug interaction with gabapentin.

Furthermore, in the five pivotal, placebo controlled trials, 69% of 543 patients who received add-on gabapentin were treated with at least two standard AEDs in addition to gabapentin. 143 patients received phenytoin in combination with gabapentin, alone, or in combination with gabapentin and other standard AEDs. No changes were observed in mean serum levels of phenytoin, carbamazepine or valproate over twelve weeks of blinded add-on therapy. In addition, over 950 partial epilepsy patients had been treated in long term, open label, add-on studies with no evidence of pharmacological interations with phenytoin, carbamazepine, valproate, phenobarbitone or benzodiazepines.

RULING

The Panel noted that the data sheet stated that "Neurontin may be used in combination with other anti-epileptic drugs without concern for alteration of the plasma concentrations of Neurontin or serum concentrations of other anti-epileptic drugs". In the light of this, and the evidence which had been provided by Parke Davis, it was considered that the statements were acceptable and the Panel ruled there had been no breach of the Code.

3 Adverse events

COMPLAINT

Wellcome drew attention to a table which was a summary of the most frequent treatment-emergent signs and symptoms of patients in placebo controlled studies for Neurontin which gave the percentage of patients developing somnolence, dizziness, ataxia and fatigue when compared to placebo. This was referenced 1 and 2 which were data on file and the summary of product characteristics respectively. Further down the same page was a statement that "No new or unusual adverse effects or an increased frequency of adverse effects were observed with Neurontin during treatment periods of up to 24 months at doses of up to 2400mg per day". This was also referenced 1 and 2. Wellcome alleged that the clear implication was that the patients in the table were the same group of patients who were treated for up to 24 months at 2400mg per day. This was incorrect. Indeed, 200 of the 485 patients included in the Neurontin group were receiving either 600mg (n=53) or 900mg (n=147) and none received 2400mg. The maximum dose used was 1800mg per day.

RESPONSE

Parke Davis said that it was not its intention that the page be read as Wellcome had done and nor did it believe that it would be interpreted in that way. The fact that the detail aid went on to discuss doses of up to 2400mg in a distinct separately labelled section, below the table, highlighted the fact that Parke Davis was discussing different data. It was also important to bear in mind that the item was a detail aid and not a leavepiece. The representative would therefore be leading the physician through the information.

Parke Davis submitted that the data in the table represented the results from double blind studies. These data were used to prepare the summary of product characteristics which was approved as part of the licence submission. These studies used doses of gabapentin of up to 1800mg per day. The data were not selectively chosen since higher doses of up to 2400mg per day were only studied in the open label phase and thus including such information within the double blind data would be inappropriate. Wellcome drew the implication that, because both sets of text were referenced 1 and 2, then the information must be derived from the same patient population. References 1 and 2 referred to data on file and the Neurontin summary of product characteristics, both of which contained a multitude of data and did not refer to just one study.

With regard to the allegation that the inclusion of 200 patients at or below the minimum daily dosage recommendations and the failure to include any patients taking the maximum recommended daily dosage would clearly give a misleading representation of the true level of side effects in this treated population, Parke Davis submitted that this did not mislead since doses of up to 2400mg had not yet yielded any new or unusual side

effects or an increased frequency of adverse effects during treatment periods of up to 24 months.

PANEL RULING

The Panel considered that it was a reasonable expectation that the reader would assume that the patients involved in the summary of the most frequent treatment-emergent signs and symptoms in placebo controlled studies which were set out in a table in the first part of the page were the same patients who were referred to lower down the page as having had treatment with doses of up to 2400mg per day.

The patients involved in the table had not had doses of that magnitude and the Panel therefore considered that the page was misleading. A breach of Clause 7.2 of the Code was ruled.

APPEAL BY PARKE DAVIS

Parke Davis submitted that the fact that the detail aid went on to discuss doses of up to 2400mg in a distinct, separately labelled section, below the table, highlighted the fact that it was discussing different data from that included in the table. Wellcome highlighted that 200 patients were at (n=147) or below (n=53) the recommended daily dosage. The Summary of Product Characteristics stated that the antiepileptic effect of Neurontin, "generally occurs at 900-1200mg/day." This meant that some patients would experience a benefit below this dose; ie it was not necessarily a sub-therapeutic dose. It would be expected for the dose distribution to be skewed to the lower end of the range, since few patients would require the maximum recommended daily dose but all would have to be titrated up through the lower dosages. It was therefore not surprising that 147 patients were taking the 900mg dose. Furthermore, this did not mislead since doses of up to 2400mg had not yet yielded any new or unusual adverse effects or an increased frequency of adverse effects during treatment periods of up to 24 months and although Parke Davis chose not to make any claim, many eminent authors had commented on the absence of a dose/side effect response.

APPEAL BOARD RULING

The Appeal Board considered that the page in question was misleading because a reasonable interpretation of it was that the same group of patients was being referred to, firstly, in the table, and, secondly, lower down the page as having had treatment with doses of up to 2400mg per day. Both the layout and the referencing, which was identical, led to that view. The Appeal Board upheld the Panel's ruling of a breach of Clause 7.2.

The appeal therefore failed.

4 Request for substantiating data

COMPLAINT

Wellcome alleged that, despite repeated requests, Parke Davis had refused to supply data in support of its detail aid. Wellcome believed that a request for data relating to the side effect table showing the number of patients receiving the varying dosage of Neurontin, and the side effect frequency in each group was entirely pertinent. Failure to supply such data was a breach of Clause 7.4.

RESPONSE

Parke Davis stated that as copies of correspondence with Wellcome demonstrated, it had been fully cooperative, sending everything that was felt pertinent to the questions raised. Parke Davis did not supply a breakdown of side effects versus dose because it did not make such a claim in the detail aid and, as such, it did not feel obliged to provide such information to a competitor.

RULING

Parke Davis had provided the information it had sent to Wellcome in response to Wellcome's request for data in support of the detail aid. The Panel examined the data and considered that it was adequate to substantiate claims relating to the side effect table in the detail aid. The Panel considered that Parke Davis had not made any claims about the relationship of dose level to side effects and therefore the company was not obliged to provide any information relation to such claims. The Panel ruled no breach of the Code.

Complaint received	**5 September 1994**
Case completed	**10 January 1995**

CASE AUTH/209/9/94

GENERAL PRACTITIONER v MEMBER COMPANY

Post marketing surveillance study

A general practitioner complained that a post marketing surveillance study constituted a financial inducement to prescribe a medicine. The Panel ruled that the study was disguised promotion in breach of Clause 10.1 and therefore the £14 fee was inappropriate in breach of Clause 18.1. The Appeal Board noted that the study was carried out on a different patient population taking a new formulation. The Appeal Board overturned the Panel's ruling on appeal and no breach was ruled.

COMPLAINT

A general practitioner, submitted a complaint about a post marketing surveillance (PMS) study carried out by a member company and alleged that it seemed not too far away from outright bribery.

The complainant enclosed a copy of a letter he had received from the company about the study and pointed out that if he prescribed the product and filled in a card, he would receive £14. This could be done for up to fifteen times which gave a maximum sum of £210. The complainant stated that he had no doubt that the product was perfectly good though he had yet to prescribe it, but he considered that he had quite a powerful financial inducement to do so.

RESPONSE

The company submitted that the design and execution of the PMS study conformed to the UK guidelines agreed by the joint committee of The Association of the British Pharmaceutical Industry (ABPI), British Medical Association (BMA), Committee on Safety of Medicines (CSM) and the Royal College of General Practitioners (RCGP), prevailing at the time of its initiation in September 1993. The guidelines stated in section 8 that in prospective studies patients should be identified for inclusion only after the decision to prescribe a particular medicine had been taken. The company submitted that this requirement was stated clearly both in the "Dear Doctor" letter about the study and in the inclusion criteria section of the study protocol.

The company pointed out that the doctors participating in the study were asked to evaluate patients at two separate visits, before and after treatment. They were required to record data generated at these visits on a seven page case report form. The fee of £14 for completion of each case report form was in line with the BMA suggested fees which prevailed at the time of the initiation of the study. The company submitted that this was a reasonable payment to a doctor for the work involved in the study. The number of patients that could be recruited by one doctor was not open ended. The "Dear Doctor" letter clearly stated that each doctor could enrol up to a maximum of fifteen patients. Since the target enrolment for the study was ten thousand patients, the maximum of fifteen patients per doctor did not seem unreasonable if the company was to complete the study within an acceptable time period.

The company stated that both the ABPI and the Drug Evaluation Unit at the Medicines Control Agency had been provided with a copy of the study protocol prior to its initiation.

The company submitted that the objective of the study was to capture safety data from a large cohort of patients treated with the product. Previous exposure to the product in this group was small and following approval of the product licence, the company had received some anecdotal reports of compliance problems due to product taste and/or consistency which were not previously detected in the randomised controlled studies. Lack of compliance could present a potential safety issue. For this reason plus the relatively low number of patients previously exposed to the medicine, a PMS study was started in September 1993.

PANEL RULING

The Panel made a number of observations about the study. Firstly, the Panel had noted that if the pre-licensing studies of the new formulation showed a similar side effect profile to the existing formulation, a PMS study on more than 10,000 patients would be needed to show differences or to prove there was no difference between the two formulations. Secondly, that although the company had submitted that compliance was a potential problem and had put this forward as one of the factors in setting up the PMS, this was not mentioned in the protocol and, furthermore, the follow up case report form did not include any questions on compliance. No analysis of any sort was mentioned although a report was promised. The follow up assessment could be done by telephone which the Panel considered might weaken the value of the database.

The Panel considered that although the study documentation stated that participating doctors should identify patients for whom they intended to prescribe the product as part of their normal clinical practice, it was inescapable that PMS studies would have some influence on doctors' prescribing decisions. To some extent this was largely unavoidable even if a study was a properly set up scientific study with appropriate objectives. The Panel considered, however, that in this particular instance, although it was possible that some useful information on the product might be obtained from the study, there did not appear to be sufficient scientific justification for the study.

The Panel decided the study was a promotional exercise and ruled a breach of Clause 10.2 of the Code which prohibits the use of such studies as disguised promotion. It thus followed that the offer of the £14 fee in connection with the study was inappropriate. The Panel therefore ruled a breach of Clause 18.1 of the Code.

APPEAL

The company responded to the Panel's concerns. It submitted that it was not an objective of the study to compare the safety profile of the two formulations. One of the specific areas of interest in setting up the study was to investigate whether the taste or consistency of the product led to premature discontinuation of the course of treatment. These data were a component of the adverse event data. The boxes provided on the adverse event form were to record whether an adverse event led to premature discontinuation of the product. The company agreed that data obtained from a follow up assessment done by telephone were weaker than data obtained at a home or surgery visit but submitted that this was better than no data at all.

With regard to the Panel's view that it was inescapable that PMS studies would have some influence on a doctor's prescribing habits, the company concurred with some aspects of this view and submitted that every effort had been made in the protocol and correspondence with doctors to remind them of their obligation to enrol patients only after the decision to prescribe the product had been made.

The scientific justification for the study was not an issue raised by the complainant. The PMS guidelines (1988) referred to the need for a valid medical reason for undertaking the study. The guidelines for company sponsored safety assessment of marketed medicines (SAMM), published after the study commenced did not refer to scientific justification. The company submitted that to monitor the safety of a new product when it was introduced was an excellent valid medical reason for undertaking the study. The interim data from the study were provided.

APPEAL BOARD RULING

The Appeal Board noted that section 4 of the PMS guidelines (1988) stated that there should be a valid medical reason for undertaking a study. It noted that the term scientific justification had been used in previous cases but accepted that the term valid medical reason was more appropriate. If there was no valid medical reason for carrying out a PMS study, then it would follow that payment to a participating doctor for prescribing the product would be in breach of the Code. The complainant had alleged that the study was a financial inducement to prescribe the product and to deal with such a complaint it was necessary to examine the validity of the study.

The Appeal Board considered that the potential lack of compliance due to the bitter taste was not a safety issue as submitted by the company but an efficacy issue and noted that this was not mentioned explicitly in the protocol, although it was put forward by the company as a specific area of interest in setting up the study. The protocol stated that the purpose of the study was to evaluate the use of the product in every day clinical practice and to establish its safety profile in a large observational cohort of patients treated in general practice. The Appeal Board also considered that the box on the case report form for premature discontinuation was not easy to find.

The Appeal Board examined all the study documentation and noted that it was being carried out on a different patient population taking a new formulation. The Appeal Board considered that, on balance, the study was not unacceptable.

Given that the study was considered to be acceptable, the Appeal Board considered that the £14 fee was reasonable for the amount of work involved in completing the case report form. The Appeal Board ruled no breach of the Code. The appeal therefore succeeded.

Complaint received **5 September 1994**

Case completed **7 December 1994.**

CASE AUTH/210/9/94

GENERAL PRACTITIONER v CYANAMID

Offer of loan of ambulatory BP machine in return for prescribing Monocor

A general practitioner complained about a letter sent by a Cyanamid representative which offered the loan of an ambulatory BP machine in return for switching prescribing of bisoprolol to Monocor. Breaches were ruled as the representative had not maintained a high standard of ethical conduct and the letter constituted an inducement to prescribe. It was also held that it brought discredit upon and reduced confidence in the industry in breach of Clause 2.

The Appeal Board decided to report the company to the ABPI Board of Management. The ABPI Board required that an audit of the company's procedures be carried out and following receipt of the audit report, the company was reprimanded by the ABPI Board of Management.

COMPLAINT

A general practitioner complained about a letter received from a medical representative of Cyanamid (UK) which had been received by a colleague in the practice following a meeting with the representative at which Monocor (bisoprolol) had been promoted. The complainant stated that the meeting had concluded with the representative offering the practice the use of his ambulatory blood pressure machine for six months. There was at no stage in the meeting any mention of the "mutually rewarding agreement" that was mentioned in the letter.

The letter offered the loan of a state-of-the-art ambulatory BP machine to the practice for six months if it was still interested and went on to say:

"In return for this I am sure that your practice and I

could have a mutually rewarding agreement, such that your current prescribing of Bisoprolol could be switched to Monocor - for all existing patients on Bisoprolol therapy and any subsequent patients for which a Beta-blocker, and Monocor, would be the therapy of choice. As you are aware, this would not cost your practice financially, merely affect your generic prescribing percentage within your PACT figures".

The complainant stated that the practice prescribing habits were hospital led in this instance where the local consultant prescribed bisoprolol. Breaches of Clauses 15 and 18 of the Code were alleged.

RESPONSE

Cyanamid was most concerned that a local representative had acted in this manner. The company's representatives were instructed to abide by the Code and the company took the matter very seriously. The representative in question had been reprimanded and in line with the company's disciplinary procedure has been put on a final written warning. Further, a copy of the Code had been issued to all field based personnel advising them that any blatant breaches of the Code would result in disciplinary action by the company. The field managers had also been briefed on the specific situation and advised to re-emphasize the Code.

PANEL RULING

The Panel considered that the loan of the ambulatory blood pressure machine had clearly been offered in exchange for the general practitioner switching his prescribing of bisoprolol to Monocor. The Panel noted that Monocor was the Lederle brand of bisoprolol. The wording of the letter constituted an inducement to prescribe Monocor which was totally unacceptable. The Panel therefore ruled a breach of Clause 18.1 of the Code. Further, the representative had not maintained a high standard of ethical conduct and the Panel therefore ruled a breach of Clause 15.2. The Panel also considered that the representative's conduct brought discredit upon and reduced confidence in the pharmaceutical industry and ruled a breach of Clause 2 of the Code.

The Panel considered whether or not it should report Cyanamid to the Appeal Board in accordance with Paragraph 8.2 of the Constitution and Procedure to see whether further sanctions were warranted. It decided, however, not to make such a report as the representative's conduct appeared to be an isolated incident and Cyanamid had taken appropriate remedial action.

APPEAL BOARD

When the case was completed it was reported to the Appeal Board as is routinely done with all cases which are not appealed. The Appeal Board decided that the circumstances were such that it would report Cyanamid to the ABPI Board of Management under the provisions of Paragraph 11.1 of the Constitution and Procedure for it to consider whether further sanctions should be applied.

REPORT TO THE ABPI BOARD OF MANAGEMENT

Having received the report, the ABPI Board instructed the Authority to carry out an audit of the company's procedures in relation to the Code in order to assist the ABPI Board in reaching a decision.

Having received the audit report, and noting that the Authority considered that it had been an isolated incident, the ABPI Board decided that Cyanamid should be publicly reprimanded in relation to the representative's conduct but that no other action should be taken.

Complaint received	**26 August 1994**
PMCPA proceedings completed	**17 October 1994**
ABPI Board proceeding completed	**14 February 1995**

CASE AUTH/215/9/94

GENERAL PRACTITIONER V ASTRA PHARMACEUTICALS

Pulmicort Turbohaler advertisement in an European journal subject to UK Code

A general practitioner complained that the statement "The unsurpassed combination - for first line treatment of chronic asthma" in an advertisement for Pulmicort Turbohaler misleadingly implied that this combination was better than any other combination. He also alleged that it was a hanging comparison and that there was no prescribing information or statement that further information was available upon request.

Astra contended that the advertisement, which had appeared in the European Respiratory Journal, was not subject to the UK Code and in any event disputed the allegation about the statement complained about.

The Panel ruled that the advertisement did come within the scope of the Code and ruled it in breach. Upon appeal on the question of jurisdiction, the Appeal Board confirmed that the advertisement came within the scope of the UK Code.

COMPLAINT

A general practitioner complained about an advertisement for Pulmicort Turbohaler which had appeared in the European Respiratory Journal and in the conference programme for a meeting of the European Respiratory Society.

The complainant had been surprised to see the wording of the advertising, which claimed "The unsurpassed combination - for the first line treatment of chronic asthma." Clause 1.1 of the Code stated that "The Code applies to the advertising of medicines in professional journals which are published in the UK and/or intended for a UK audience". In the complainant's opinion, the Code should apply to advertising in a journal such as the European Respiratory Journal which had a large number of UK recipients. Astra was misleadingly claiming that this combination of Turbohaler and Pulmicort (budesonide) was better than any other combination. Further, there was no statement that further information was available on request to the product licence holder and there was no prescribing information. A breach of Clause 5.4 was alleged. Finally, the statement in the advertisement was clearly a hanging comparison.

Although the advertisement had appeared under the name of "Astra Draco AB", the complaint was taken up with Astra Pharmaceuticals Limited in the UK.

RESPONSE

Astra Pharmaceuticals said that the advertisement appeared in the European Respiratory Journal and the Conference programme for the European Respiratory Society held in Nice, 1-5 October 1994.

The European Respiratory Journal was a joint UK/Danish venture with approximately 5,000 copies printed and distributed to members of the European Respiratory Society. The journal was only available to members and to a very limited specialist library membership. Conference programmes of the European Respiratory Society were official supplements of the Journal and were available as per the journal itself, ie to subscribing members only. It was of interest that less than 10% of the membership was in the UK and amongst that membership there were, according to the Editor, only one or two general practitioners. Therefore this highly specialist journal had a minimum circulation in the UK and only to *bone fide* members of the European Respiratory Society. It was Astra's view that as 90% of the membership lay outside the UK, it was unreasonable for advertisements to comply specifically with the UK Code. Should the Panel take a different view, this clearly had major implications for all similar European journals and conference programmes.

In relation to the specific complaint, Astra submitted that the phrase "unsurpassed combination" was not a hanging comparison or a breach of Clauses 7.2 and 7.3. It was stated clearly in the text that the clinical efficacy of budesonide was combined with the convenience of an inspiratory flow driven multidose system. Astra was unaware of any combination of an anti asthmatic drug with a delivery system which provided greater clinical efficacy and convenience to patients, ie the combination was unsurpassed. Astra did not state that the combination of Pulmicort and the Turbohaler "is better than any other combination". The text stated that Turbohaler was preferred by asthma sufferers to other inhalation systems. A number of supporting papers were supplied.

PANEL RULING

The Panel decided that advertisements in the European Respiratory Journal, which was published in English, came within the scope of the UK Code. It was published in the UK and went to at least some UK doctors. This was considered to be the inescapable meaning of the supplementary information to Clause 1.1 of the Code. The same applied to the conference programme as this had been circulated as an official supplement to the journal itself.

The Panel noted that unsurpassed meant that there was nothing better. It was not a superlative and nor did the statement amount to a hanging comparison as alleged. It did not mean that the combination was better than anything else, rather that nothing else was better. It was, however, a strong claim.

The Panel ruled that there had been a breach of Clause 7.8 of the Code in relation to the advertisement because the claim implied special merit which had not been justified and was exaggerated. There was also a breach of Clause 4.1 of the Code because of the absence of prescribing information. The advertisement could not be regarded as an abbreviated advertisement due to its size and the amount of information which it contained. Only abbreviated advertisements were required to include a statement that further information was available. It was therefore ruled that there was no breach of Clause 5.4 as alleged.

Noting that the conference programme had been circulated as an official supplement to the Journal itself, the Panel ruled the identical advertisement in that programme to be similarly in breach of Clauses 4.1 and 7.8 of the Code.

APPEAL BY ASTRA

Astra appealed the ruling of the Panel that the advertisements fell within the scope of the UK Code. The company did not appeal the specific rulings of breaches of the Code made by the Panel.

Astra said that the Panel considered that since the journal was published in English, in the UK, and went to at least some UK doctors it was covered under Clause 1.1 of the Code. The journal concerned was not published in the UK alone. It was published in the UK and Denmark. It was available to subscribing members only, ie doctors had to request it. Less than 10% of the membership was in the UK of which the editor believed only two were general practitioners. The circulation list was relatively small and it would be impractical to produce a separate edition which complied with the Code for each country to which the journal was distributed.

Astra's parent company which placed the advertisement was aware of the differing requirements regarding prescribing information and therefore decided not to include the prescribing information from one specific European country but to put the address from which this information could be obtained. In this particular case, Astra believed it would have caused more confusion to doctors if both the UK and the Danish prescribing information had been included in the same advertisement.

APPEAL BOARD RULING

The Appeal Board noted that the appeal related solely to the question of jurisdiction and not the substance of the allegations. Astra had accepted that it would be in breach of the Code if its appeal failed as to jurisdiction.

The Appeal Board observed that the question of the location of "publication" of a journal was not always entirely clear. In the present instance the journal was stated to be published jointly by the European Respiratory Society, the general office of which was in France, and by a Danish publisher, and the editorial staff were located in various countries. The managing editor was, however, in the UK where it was also printed and the publication was in English. The conference programme had been an official supplement to the journal.

The Appeal Board ruled that the journal and its supplement were subject to the UK Code. The appeal accordingly failed.

Case commenced **26 September 1994**

Case completed **3 February 1995**

CASE AUTH/216/9/94

DUMEX v CP PHARMACEUTICALS

Misleading quotation in Diazepam RecTubes detail aid

Dumex alleged that two claims in a detail aid on Diazepam RecTubes referenced to two studies were in breach as the studies were not on the advertised product but on Dumex's product, Stesolid. CP Pharmaceuticals appealed the Panel's rulings of breach on both allegations. The Appeal Board accepted that one of the claims was general and not specific to RecTubes and therefore ruled no breach. The other claim appeared as a quotation in the detail aid and was ruled to be misleading as it would be taken as a reference to the advertised product which was not so.

COMPLAINT

Dumex Limited, a non member company, drew attention to two claims in a detail aid issued by CP Pharmaceuticals Limited for Diazepam RecTubes which were referenced to two separate studies, one by Moolenaar the other by Magnussen.

The first claim at issue, "Absorption of diazepam solution by rectal tube is significantly more rapid than oral, intramuscular or suppository administration", was referenced to Moolenaar and appeared beneath a graph showing plasma concentration for various presentations of diazepam taken from the same study. The second claim, "....the correct use of these tubes might replace the administration of tablets or intramuscular injections, especially when rapid effect is wanted, as in ....pre-anaesthesia", was referenced to Magnussen and appeared as a quotation in the detail aid.

Dumex pointed out that in both studies its branded product, Stesolid, was used and therefore the results obtained and published related to Stesolid. Dumex alleged that unless CP Pharmaceuticals could provide evidence that its rectal tubes were equivalent and had the same pharmacokinetic and pharmacodynamic properties as Stesolid, it was misleading to use the quotations. Breaches of Clauses 7.2 and 7.3 of the Code were alleged.

RESPONSE

CP Pharmaceuticals acknowledged that both studies used Stesolid and stated that it had evidence that Diazepam RecTubes was essentially similar to Stesolid.

In CP's view, the first claim was a general statement relating to the administration of any diazepam solution by any rectal tube compared with administration of diazepam by other routes. It was not a specific claim for Diazepam RecTubes. The company pointed out that the conclusion of the Moolenaar study was "After rectal administration of diazepam in solution form" [in other

words in any solution form of diazepam, not specifically Stesolid] "absorption is extremely rapid. Absorption proceeds significantly ($p < 0.05$) more rapidly than after oral or intramuscular administration of diazepam... For the suppository dosage form, absorption is rather slow..."

CP submitted that the second claim was used with other claims to illustrate potential uses for Diazepam RecTubes. It was a general statement relating to the use of diazepam in any rectal tube formulation in pre medication/minor surgery and was not a specific claim for Diazepam RecTubes. The company similarly submitted that the Magnessen study referred to diazepam solution which meant any rectal tube containing a diazepam solution, not necessarily Stesolid.

PANEL RULING

The Panel had noted that the claims at issue appeared on different pages of the detail aid with each page headed "Diazepam RecTubes". The first claim appeared beneath a subheading "A rapid alternative" and the second claim appeared under a subheading "Uses". The Panel had considered that the reader would assume that the references given for the disputed claims related to studies involving the product being promoted, Diazepam RecTubes, and this was not so. This was particularly misleading with regard to the second claim which was given as a quotation and included the words "these tubes". The Panel had therefore considered that the detail aid was misleading as alleged and ruled a breach of Clause 7.2 of the Code.

APPEAL

CP Pharmaceuticals appealed the ruling. The company submitted that, but for a small difference in specification of no pharmaceutical significance, the two formulations, Stesolid (mark 1) and RecTubes, were qualitatively and quantitatively identical in terms of both active and inactive constituents. The licences for RecTubes were granted on the basis of "essential similarity". A bioequivalence study used to support the licence application was provided. The company submitted that there was therefore essentially no difference between RecTubes and Stesolid (mark 1) rectal tubes from Dumex which were used in the Moolenaar and Magnussen studies.

With regard to the claim "Absorption of Diazepam solution by rectal tube is significantly more rapid than oral, intramuscular or suppository administration" referenced to the Moolenaar study, CP submitted that the statement was not intended as a specific claim for RecTubes but as a general claim for the speed of absorption of diazepam solution given rectally compared to the absorption by other routes. It reflected accurately and clearly the findings and conclusions of the authors.

With regard to the claim "....the correct use of these tubes might replace the administration of tablets or intramuscular injections, especially when a rapid effect is wanted, as in ..... pre-anaesthesia" referenced to Magnussen, the company submitted that the quotation needed to be viewed in the context of the earlier part of the Magnessun's sentence. This read "Our measurements of the concentrations following administration by rectal tube containing a diazepam solution indicates that the correct use of these tubes might replace the administration of tablets or intramuscular injections....". The company submitted that Magnessun used the words "these tubes" to refer to rectal tubes containing diazepam solution in general, not any particular brand of rectal tube. The use of this quotation was meant to refer to diazepam rectal tubes in general and not specifically to CP Diazepam RecTubes.

APPEAL BOARD RULING

The Appeal Board noted that RecTubes and Stesolid were virtually identical products and, although in some circumstances it might be wrong to rely on a study on another product to substantiate claims in promotional material, in this case there was no evidence to show that Stesolid (mark 1) used in the studies and RecTubes behaved differently.

The Appeal Board considered that the claim "Absorption of diazepam solution by rectal tube is significantly more rapid than oral, intramuscular or suppository administration" was a statement about rectal tubes in general and was not specific to Diazepam RecTubes. The Appeal Board did not accept that the use of the Moolenaar study as the reference to the statement was misleading and therefore ruled no breach of the Code.

This aspect of the appeal was therefore successful.

The Appeal Board considered that the quotation as it appeared in the detail aid "...the correct use of these tubes might replace the administration of tablets or intramuscular injections, especially when a rapid effect is wanted as in.....pre-anaesthesia" from the Magnussen study appearing under the headings "Uses" and "Pre-medication/Minor Surgery", was misleading as the words "these tubes" would be taken by readers as a reference to the advertised product Diazepam RecTubes, which was not so. This was misleading notwithstanding the fact that Diazepam RecTubes were essentially similar to Stesolid (mark 1) used in the study. The Appeal Board therefore ruled a breach of Clause 7.2 of the Code.

This aspect of the appeal therefore failed.

Complaint received **27 September 1994**

Case completed **9 January 1995**

CASE AUTH/219/10/94

DIRECTOR v BOEHRINGER INGELHEIM

Promotion of Motens for unlicensed indication in a bulletin

Apparent claims for unlicensed indications for Motens noted by the Panel in its consideration of an earlier case were taken up with Boehringer Ingelheim under Paragraph 16 of the Constitution and Procedure. This was denied by Boehringer Ingelheim and the Panel ruled that a claim referring to Motens "antiproliferative efficacy in the treatment of atherosclerosis" appearing in a summary on the front page of a company produced bulletin constituted the promotion of Motens outside the terms of its licence. No breach was ruled with regard to similar references to Motens in atherosclerosis in a product monograph. Boehringer Ingelheim appealed against the breach ruling but the Appeal Board upheld the Panel's ruling.

COMPLAINT

This case arose from a previous matter (Case AUTH/207/8/94) in which the Panel had identified apparent breaches of Clause 3.2 of the Code which were taken up under Paragraph 16 of the Constitution and Procedure with Boehringer Ingelheim Limited. The alleged breaches of Clauses 3.2 related to a reference to lacidipine (Motens) in the treatment of atherosclerosis in a company produced bulletin Diagnostic and Therapeutic Aspects of Hypertension entitled "Molecular Basis for the Interaction of Dihydropyridine Calcium Channel Blockers with Biological Membranes" and similar references in a chapter on lacidipine and atherosclerosis in a product monograph for Motens.

RESPONSE

Boehringer Ingelheim explained that the bulletin contained a single article approved in its entirety for publication by the author who was expert in the field. The article detailed the unique pharmacokinetic profile of lacidipine and related this to the observed clinical characteristics of the product in the management of hypertension and also to the experimental antiproliferative properties of calcium antagonists as a class. The article clearly related to and was presented under the banner of hypertension with the prescribing information for the product given in the bulletin clearly confirming that hypertension was the licensed indication for Motens. At no point did the author or the company suggest that calcium antagonists as a class or lacidipine in particular were proven to be clinically effective in treating atherosclerosis.

The company submitted that the product monograph was written as a comprehensive source of information on lacidipine. No one reading the document would be under any illusion that the document did not relate to the importance of calcium antagonists as a class in the management of hypertension and to lacidipine, as a new member of that class, in the management of hypertension. The chapter on lacidipine and atherosclerosis was concerned with ongoing work with lacidipine related to known scientific facts about calcium antagonists. It clearly stated that "clinical trials [in atherogenesis] have so far been inconclusive" and further that the hypothesis "is being tested in a multicentre clinical trial".

The company submitted that neither document had the intention of promoting the prescription of Motens in the treatment of atherosclerosis and that neither would be interpreted as doing so. One was essentially a discussion of the molecular properties of lacidipine while the other clearly stated that the possibility of treatment of atherosclerosis with lacidipine was at the clinical investigation stage.

PANEL RULING

The Panel noted that the Diagnostic and Therapeutic Aspects of Hypertension bulletin at issue included the claim in the summary on the front page that "These events influence not only the antihypertensive efficacy of lacidipine, but may also have some bearing on the drug's antiproliferative efficacy in the treatment of atherosclerosis". The Panel considered that this was clearly a clinical claim for the product referring to its use in the treatment of atherosclerosis for which it was not licensed. The Panel therefore ruled there was a breach of Clause 3.2 of the Code as Motens was being promoted outside the terms of its licence.

With regard to the product monograph, the Panel acknowledged that product monographs were designed to provide comprehensive scientific information about a product and that such items could include certain information which would not be acceptable in other promotional material. For example, information, such as in this instance, on ongoing clinical research with the product. The Panel accepted that it was clear from the product monograph that the product was licensed solely for hypertension and that the possibility of treatment of atherosclerosis with lacidipine was still at the clinical investigation stage. Nonetheless, the Panel considered that the presentation of the information in the product monograph which constituted an entire separate chapter of the monograph was on the borderline of acceptability. The Panel decided on balance that the section in the product monograph did not constitute the promotion of Motens outside the terms of its licence and ruled there was no breach of the Code.

APPEAL BY BOEHRINGER INGELHEIM

Boehringer Ingelheim appealed against the ruling of a breach of Clause 3.2. The company reaffirmed its submission to the Panel and explained that the brochure was prepared for distribution only to those doctors with a specialist interest in the area and was not part of the general promotional material for Motens.

In Boehringer Ingelheim's view, the disputed sentence, "These events influence not only the antihypertensive efficacy of lacidipine, but may also have some bearing on the drug's antiproliferative efficacy in the treatment of

atherosclerosis", was a scientific statement and not a promotional claim. The phrase "may also have some bearing on" was clearly a speculation on the possible relevance of the membrane activity of lacidipine to its antiproliferative effect that could be important in the treatment of atherosclerosis. The assessment of the efficacy of lacidipine and the treatment of atherosclerosis based on this antiproliferative effect was presently the well recognised subject of a major clinical trial.

APPEAL BOARD RULING

The Appeal Board considered that the statement appearing in the summary to the brochure, "These events influence not only the antihypertensive efficacy of lacidipine, but may also have some bearing on the drug's antiproliferative efficacy in the treatment of atherosclerosis" was a claim for the use of the product in the treatment of atherosclerosis outside the licence. The Appeal Board therefore ruled there was a breach of Clause 3.2. of the Code.

The appeal therefore failed.

Proceedings commenced	**22 September 1995**
Case completed	**3 February 1995**

CASES AUTH 221/10/94 & 222/10/94

BIOGEN v MEMBER COMPANIES

Newspaper articles on new but unlicensed treatments in a disease area

A complaint from Biogen about two articles which appeared in a newspaper on new but unlicensed treatments for a particular disease was taken up with the two companies whose branded products were named in the articles. The Panel considered that there was no evidence to show that either company had been involved directly or indirectly with the production of the articles in question despite extensive enquiries and therefore ruled there was no breach.

COMPLAINT

Biogen complained about two articles which appeared in a national daily newspaper concerning new but unlicensed treatments for a particular disease. It was alleged that the two companies whose branded products were named in the articles were in breach of Clauses 1.2, 1.3, 2, 3, 7.2, 20.1 and 20.2 of the Code as neither product had marketing authorisation, it was unethical to encourage named patient usage, as in the articles in question, and as the article constituted promotion to the public, raised unfounded hopes of successful treatment and misled as to the safety of the products. Furthermore, one of the articles was incorrect in referring to the licence for one of the products in the US. It was also alleged to be misleading to associate the properties of the two products together as in the articles without appropriate comparative data as they were chemically distinct.

RESPONSE

Both companies advised that they had nothing whatsoever to do with the articles.

RULING

Extensive enquiries were made by the Authority with the newspaper concerned and, in the light of its response, with a public relations agency which had acted for one of the patient groups referred to in the newspaper articles. The Panel considered that there was no evidence to show that either company had been involved directly or indirectly with the production of the articles in question and therefore ruled no breach of the Code.

Complaint received	**12 October 1994**
Case completed	**10 February 1995**

CASE AUTH/223/10/94

HEALTH AUTHORITY QUALITY CONTROLLER v MEMBER COMPANY

Letter to practice nurses and letter in a journal referring to study conducted by complainant

A health authority quality controller complained about statements in letters from a member company, one appearing in a professional journal and one sent to practice nurses, which he considered distorted the results in a report from his department. The Panel ruled the letter in the professional journal was not subject to the Code and with regard to the letter to practice nurses considered that it did not misrepresent the complainant's report. No breach was therefore ruled.

COMPLAINT

A health authority quality controller complained about recent correspondence from a member company which referred to data and information published by himself. He believed that the correspondence misrepresented his views and could reasonably give a false impression of his data and his conclusions.

The first item in question was a letter from the company which had appeared in a professional journal. The letter referred to "substantial differences" which he had observed between certain products but the complainant said that they were not substantial differences and to represent them as such did not reflect the views of the authors.

The second item was a letter which had been sent by the company to practice nurses which stated that three products might behave differently. The complainant said that a statement in the letter misrepresented the data and conclusions of his report.

The complainant had been told that, when referring to published data in promotional literature, pharmaceutical companies should give a balanced view of such data. In the two instances referred to, it was his belief that the company had not done so.

RESPONSE

The company denied in any way misrepresenting the complainant's data or his conclusions.

The letter in the professional journal was in response to a letter published in the same journal and as such ("letters published in professional journals") did not come within the scope of the Code of Practice (Clause 1.2 referred). The definition of "substantial" was a matter of opinion and the company explained why it considered that, by most reasonable criteria, the differences must be considered to be "substantial".

In relation to the letter to practice nurses, the conclusions in this letter were based on the results of two independent studies (the complainant's and another) and not on the complainant's findings alone, a point which the complainant might have overlooked.

The statement complained about was fully justified and a fair and balanced summary of the current state of knowledge as was the letter as a whole.

RULING

The Panel noted that the letter in the professional journal consisted of replies to two previous letters which had appeared in that publication. The Panel ruled that it came within the exemption provided by Clause 1.2 of the Code, distinguishing it from a letter considered in Case AUTH/206/8/94 which had not been considered to have the benefit of the exemption because it went beyond the parameters of a simple reply, and therefore ruled that it was not subject to the Code.

In relation to the letter which had been sent to practice nurses, the Panel accepted that the statement the subject of complaint was based on the data as a whole and not on just the report from the complainant. On this basis, the Panel considered it did not misrepresent the complainant's report and it was ruled that there had been no breach of the Code.

Complaint received 17 October 1994

Case completed 30 November 1994

ANON v SCHERING PLOUGH/LILLY INDUSTRIES/MEMBER COMPANIES

Wine tasting evenings at a general practice

A document giving details of six wine tasting evenings organised at a surgery and sponsored by eight medical representatives from six difference companies was the subject of an anonymous complaint. The wine tastings were to follow formulary meetings.

The Panel ruled no breach of the Code regarding one company which had declined to take part in the meeting. Schering Plough and Lilly Industries were ruled in breach because they had paid for the wine tasting following a genuine educational meeting. Three member companies were also ruled in breach as the Panel considered that it was inappropriate for an educational meeting to be associated with wine tasting irrespective of the fact that the wine tasting had been organised and paid for separately. The Panel considered whether or not there had been a breach of Clause 2 of the Code but as the meetings appeared to be organised by the practice and not by the representatives no breach of Clause 2 was ruled.

The three member companies appealed and the Appeal Board considered that there was no evidence that any of the three companies knew that the meetings would be followed by the wine tasting and on that basis no breach of the Code was ruled.

COMPLAINT

An anonymous complaint was received regarding six wine tasting evenings organised at a surgery and sponsored by eight medical representatives. The information came by way of a one page document headed up with the practice name and address and the names of the partners. The document read:

> "Wine tasting evenings
>
> We have arranged the following evenings for wine tasting at the practice. As before, ... will be our connoisseur. Each evening will be sponsored by a drug rep. and a light snack will be provided."

The document then gave a series of dates and names of representatives and their companies. Schering Plough, Lilly Industries and four other member companies were named.

In accordance with established procedure the matter was taken up with the companies concerned as a complaint under the Code.

Following an enquiry by the Authority, the practice advised that the series of meetings was arranged to look in further detail at the practice formulary. The doctors would normally have a light supper with some wine after an evening meeting and medical representatives would often provide this kind of catering as a matter of course. It was suggested that it would be a more interesting evening if the practice were to invite along a local wine expert enabling the doctors to taste a variety of wines and receive some tutoring. This was a format which had been used by other companies in a variety of situations and it seemed to the doctors to be entirely appropriate. The doctors' understanding was that all the companies felt comfortable with the proposed format and that no need was seen to separate the provision of food and refreshments at supper.

The practice said that the dates initially suggested were set out in draft form on a sheet, one with the clinical content and one with the wine tasting. Copies were provided by the practice. These were not produced for distribution but were merely an aide memoire for the medical staff and hence only a limited number of copies had been printed. The page sent by the complainant was the draft of one page of a two page memo. Some dates were changed and the final version was different from the document which had been sent. Further investigation had revealed that the document had been stolen by a medical representative who had taken it from among some papers on the practice manager's desk. The practice assumed that the role of the ABPI was to ensure that its member companies did not, by contravening its regulations, bring the industry into disrepute. It seemed to the practice that the type of criminal activity carried out by the said representative fell firmly into the category of disreputable behaviour.

Detailed responses were received from the companies concerned.

Case AUTH/224/10/94

Schering-Plough Ltd submitted that the meeting attended by eight doctors and the practice manager was a presentation by the representative on three of its products, Elocon, Clarityn and Cedax. The representative arrived at the surgery at 7.30 pm and after a brief introduction commenced detailing the three products. Each product had approximately 10 to 15 minutes of discussion with a 15 minute question and answer forum at the end of the presentation. After the presentation, the participants adjourned to the surgery's coffee room where a buffet consisting of cold meats and salads was served. The cost of the buffet was £75 and a copy of the invoice was provided. Immediately after the buffet, a wine merchant conducted a short wine tasting, the cost of which, £94, was also paid by the company. A copy of an invoice from the practice manager with instructions that the cheque should be made payable to the doctors was provided.

Schering-Plough submitted that it was clear that the primary purpose of the meeting was educational and this comprised the bulk of the evening's meeting. Provision of food and wine was secondary to the purpose of the meeting.

Case AUTH/225/10/94

Lilly Industries Limited submitted that the representative was allocated 30 minutes at 7.30 pm to make a presentation on Prozac which was followed by a short presentation on Distaclor ending with a very brief mentioning of Axid. The meeting was attended by seven

general practitioners, the fundholding manager and the practice manager. The formal part of the evening was followed by supper and a wine tasting. The total cost of catering for 11 people was £175.98. The evening ended at approximately 10.15 pm.

The company submitted that the procedure followed for the meeting was one which was had been initiated and followed previously by the practice. The two sections of the evening were clearly defined with the pharmaceutical section chaired by the local doctor prior to the social activities.

Upon request, Lilly provided copies of two invoices one for £90 for catering and one for £85.98 from the wine connoisseur for the wines supplied.

Case AUTH/226/10/94

The company submitted that the clinical meeting proposals from its representative were approved by the area manager and the sales manager on the basis that the meetings were genuine clinical meetings with a clear educational content and that the hospitality was modest and secondary to the purpose of the meeting. The estimated cost of providing a buffet from an external caterer would have been approximately £10 per head which was not considered to be out of proportion to the occasion or in excess of that which the recipients would normally adopt when paying for themselves. The attendees were to be the seven doctors in the practice plus the practice manager and one fundholding manager. The practice manager had confirmed that the representative was requested to arrange a buffet for the doctors and the cost of the wine was to be paid by the doctors not by the company.

The company submitted that the documentation was for internal use within the surgery and its existence was unknown to its representative. If both pages of the practice documentation were read it was clear that the representative's role was the formulary talk and the provision of the buffet. This was followed by a wine tasting which was provided by a friend of the doctors and was not arranged by, nor would it be contributed to by, the company's representative.

Case AUTH/227/10/94

The company understood that only the formulary meetings were the subject of sponsorship which included a light snack at the cost of about £5-6 per head. Following this part of the evening the representatives would depart leaving the latter part of the evening to be run by the wine connoisseur. The purpose of the series of tasting was to encourage the doctors to buy wine from the wine agent involved which was clearly stated in the information relating to the meeting in December ie "bring your cheque book as this will be a great time to place your Xmas order".

The company submitted that the formulary meeting it had sponsored was to take place on Friday 2 December with a light snack provided at a cost of £6 per head. The educational meeting was a standard slide presentation regarding a therapeutic area which had previously been approved and certified in the usual manner.

Case AUTH/228/10/94

The company submitted that the representative concerned was approached by the practice manager about the series of meetings while she was visiting the surgery. The representative expressed interest but stated she would check with her regional sales manager before committing to the meeting. However, following discussions with her regional sales manager it was decided that because of budgetary constraints and other priority contacts she could not carry out the meeting.

The representative communicated the decision not to proceed to the practice manager. She had not seen the poster advertising her co-sponsorship of a meeting and was not aware of its existence until the complaint to the ABPI was brought to her attention.

The company submitted that no offer was made and there was merely a breakdown in communication.

Case AUTH/229/10/94

The company submitted that its involvement in the matter had been hindered as the representative concerned and her manager were no longer employed by the company and the event had not actually taken place.

The company was, however, confident that the primary purpose of the proposed meeting, partly sponsored by its representative, was educational. The provision of snacks and any beverages would have been secondary to the purpose of the meeting and not out of proportion to the occasion (c £80, attendance c 10 people). In fact the practice manager informed the company that the final details of what the company would pay for (food alone or food plus wine) had not even yet been agreed between the representative and the practice.

PANEL RULING

The Panel noted from the various submissions that the document at issue had been stolen from the practice manager's desk by a medical representative. If true, this was to be deprecated. The document had, however, come to the attention of the Authority and in accordance with Paragraph 5 of the Constitution and Procedure, the Authority was obliged to take action.

The Panel noted that each evening was to start with a formulary meeting followed by a buffet supper and wine tasting. It appeared to the Panel that the meetings were organised by the practice and not by the representatives working together. It noted that at the time the complaint was made only two meetings, those involving Schering Plough and Lilly, had taken place and the other four meetings had not and nor had they taken place at the time the complaint was considered by the Panel.

The Panel noted that the representative in Case AUTH/228/10/94 had advised the practice manager that she needed to check with her regional sales manager and subsequently decided not to carry out the meeting. As no offer had been made, the Panel ruled no breach of the Code.

The Panel considered that the role of the companies in the formulary meetings was acceptable and that the associated catering costs which had been paid or were to be paid were also acceptable. The Panel also considered that it was not inappropriate, in principle, to provide wine to accompany a supper as long as the hospitality overall complied with Clause 19 of the Code ie it was not out of

proportion to the occasion and the costs involved did not exceed beyond that level which the recipients would normally adopt when paying for themselves. Wine tastings did not come within the category of appropriate hospitality.

The Panel also considered that the impression created by the arrangements for any meeting should be kept in mind and that it was inappropriate for a pharmaceutical company sponsored meeting to be associated with a wine tasting.

The Panel considered that the impression of the document at issue was that the companies were paying for the wine tasting as the document stated that each evening was to be sponsored by a representative. It appeared to the Panel that the existence of the document implied that it had not been made clear to the practice that some of the companies were not paying for the wine tasting. The Panel considered that all the companies had known that the formulary meetings were to be followed by wine tasting. Further, at the two meetings which had taken place, the wine tasting had been paid for by Schering Plough and by Lilly respectively.

The Panel decided that by paying for the wine tasting Schering Plough (Case AUTH/224/10/94) and Lilly (Case AUTH/225/10/94) had provided inappropriate hospitality. A breach of Clause 19 of the Code was ruled.

The Panel considered that it was inappropriate for an educational meeting to be associated with a wine tasting irrespective of the fact that the wine tasting had been organised and paid for separately. The Panel therefore ruled that the companies concerned in Cases AUTH/226/10/94, AUTH/227/10/94 and AUTH/228/10/94 were in breach of Clause 19 of the Code.

The Panel considered whether or not there had been a breach of Clause 2 of the Code. The Panel decided that as the meetings appeared to be organised by the practice and not by the representatives there was no breach of Clause 2.

APPEALS BY THREE RESPONDENT COMPANIES

Case AUTH/226/10/94

The company stated that at the time its representative submitted appropriate forms to his line manager for approval to conduct the clinical meeting at the surgery, he was merely responding to a request to present at two practice formulary meetings and to provide a light buffet afterwards. The fact that the doctors intended to invite a friend to the buffet who would be bringing three different wines to taste and compare and that this would be linked in any way to the company's sponsorship of the meeting was not known to the representative. He did not invite the person nor did he pay for the wine provided. Furthermore he was unaware of the existence of any documents linking his attendance at a formulary talk with a wine tasting.

Case AUTH/227/10/94

The company submitted that the representative had agreed to sponsor the formulary meeting and provide refreshments. The representative was not aware that the wine associated with the modest meal would be presented in the form of the wine tasting. The first knowledge the representative had of this was following the complaint. The meeting had been held and wine tasting was not involved.

The company accepted the opinion of the Panel that wine tasting alone might be an unacceptable form of hospitality but the actual format of the provision of wine in this case led it to disagree with the Panel. The practice stated in a letter to the company that the representative was asked to supply a light supper with a glass of wine to follow the meeting, that some of the doctors were interested in wine and invited a local wine buff to discuss wine with them over supper and that the person who supplied the discussion was not paid for or invited by the representative.

The company submitted that it was clear that the wine tasting was little more than the usual and acceptable provision of wine with food. Therefore, notwithstanding the fact that the representative was not aware that this would have been announced as wine tasting, if these meetings had taken place they would not have breached Clause 19.

Case AUTH/229/10/94

The company submitted that no decision had been taken as to whether it would pay for any wine and therefore at the time of the making and investigation of the complaint it had not made an offer to pay for wine or wine tasting.

Clause 19 of the Code referred to the offer of hospitality. If the making of an offer was essential for the complaint to be made out, the company submitted that it was in an equivalent position to Case AUTH/228/10/94. The company submitted that the Panel was entitled to concern itself with the question of appropriateness of wine tasting as hospitality but was not entitled to concern itself with wine tasting *per se* where it was not in the form of hospitality. The company pointed out that the supplementary information to Clause 19 stated that the hospitality associated with the meeting must be appropriate. No reference was made to social activities associated with meetings having to be appropriate. The supplementary information stated that meetings which were wholly or mainly of a social sporting nature were unacceptable. By implication, meetings not wholly or mainly of a social or sporting nature were not objectionable just because they contained a social or sporting element. The company submitted that the wine tasting was a social element. It was not the whole or main element and there was nothing therefore to bring the wine tasting element within Clause 19.

APPEAL BOARD RULING

The Appeal Board noted that at the time the complaint was received the meetings had not yet been held.

The Appeal Board noted that the letter from the practice to the Authority described the arrangements and stated that "our understanding is that all of the companies felt comfortable with the proposed format and there was no need to separate the provision of the food and refreshments at supper." This implied that the representatives knew about the wine tasting. There was, however, no direct evidence that the three companies knew that the meetings were to be followed by wine tasting.

The Appeal Board noted that the document sent by the complainant had been produced by the surgery to publicise its own meeting. It considered that medical representatives should make sure that they were aware of any activities associated with meetings organised or sponsored by pharmaceutical companies.

The Appeal Board did not accept the submission that the company in Case AUTH/229/10/94 was in a similar position to that in Case AUTH/228/10/94 as that company had decided not to carry out the meeting. The company in Case AUTH/229/10/94 had agreed to carry out the meeting but had not decided whether to provide food or food and wine.

The Appeal Board considered that on the material before it there was no evidence that any of the three companies knew that the formulary meetings were to be followed by the wine tasting. On that basis the Appeal Board ruled no breach of the Code.

The appeals therefore succeeded.

Complaint received		**19 October 1994**
Cases completed	**AUTH/224/10/94**	**13 December 1994**
	AUTH/225/10/94	**19 December 1994**
	AUTH/226/10/94	**12 January 1995**
	AUTH/227/10/94	**12 January 1995**
	AUTH/228/10/94	**21 November 1994**
	AUTH/229/10/94	**12 January 1995**

Case AUTH/230/10/94

NHS TRUST HOSPITAL DIRECTOR OF FINANCE v MEMBER COMPANY

Allegation concerning representative's offer for future tenders

A director of finance with an NHS trust hospital alleged that discussions about the supply of products between a representative and certain medical staff in the hospital which included the possibility of contributions towards training courses were an attempt to undermine the fair competitive tendering process. The Panel did not accept the allegation and on appeal by the complainant, the Appeal Board similarly ruled that there was no breach.

COMPLAINT

The director of finance at an NHS trust complained that a representative from a member company had been in contact with at least two consultants within one of the trust's medical departments offering the supply of the company's products even though the company had not won the 1994/5 tender for the supply of certain products. Furthermore, it was understood that the representative had offered to contribute to the cost of training courses if orders were placed with the company. In the complainant's view, this was an attempt to undermine a fair competitive tendering process.

RESPONSE

The company explained that although it had not been awarded the formal contract, the hospital had continued to place orders throughout the year for the products in question.

The company explained that the director of the hospital department had telephoned the representative and had asked him to meet her at the hospital. The representative also took the opportunity to meet two other consultants in the same discipline at the hospital on the same day. The purpose of these meetings was to discuss the hospital's tendering process and their requirements for the next contract. The representative did not promote specific products or their benefits at these meetings.

The representative did seek views on whether the hospital would prefer the offer of a straight discount off its invoices or a smaller discount plus an educational grant to support the training and education of the staff in the department if the company was asked to quote for the next contract.

The company stated that it should be noted that no formal offer was made and that these exploratory discussions were intended to identify how the company could meet the needs of the hospital most effectively. The representative had discussed these options with three of the consultants at the hospital and was concerned that the provision of any education grant should be legal, conform with the ABPI Code and should be properly authorised by the hospital. The representative had therefore proposed that the consultant should consult the financial department in the hospital to confirm how educational grants should be properly authorised.

PANEL RULING

The Panel noted that there appeared to be some misunderstanding on the part of the complainant as to the circumstances of the representatives' visit. The director of the department at the hospital had in fact requested the visit.

The Panel considered that it was quite acceptable for the company representative to continue contact with relevant personnel within the hospital's department. The fact that the company had not won the tender did not preclude the representative from continuing professional contact with clinicians, particularly given that the company continued to sell products to the hospital.

The Panel noted that the offer of discounts on the supply of medicines was a well established and recognised practice within the pharmaceutical industry which fell outside the scope of the Code, although the offer of pecuniary advantages as inducements to prescribe, supply, administer or buy any medicine were prohibited under Clause 18.1. Certain offers made in association with the sale or supply of a medicine could be ruled unacceptable under that Clause. The Panel felt some disquiet over the offer made of the educational grant in lieu of discount as it could be a means of subverting financial control of the tendering process. The Panel considered that the provision of an educational grant by a company in itself was acceptable and that in the particular circumstances its offer in lieu of a proportion of discount was not unacceptable. The Panel had therefore ruled there was no breach of the Code.

APPEAL BY COMPLAINANT

The complainant stated that the offer to provide an educational grant plus a small discount rather than a straight discount was not acceptable. The trust's tendering procedures did not provide for educational grants or other payments which were outside the process. Furthermore, in the complainant's view, it was not acceptable to charge the trust a higher price (providing only a small discount) so that an educational grant could be made to an individual or a fund which was not part of the NHS.

The complainant also commented that, although the company correctly stated that the trust had bought some products from it since the new contract was awarded to a competitor company, those products were not covered by the contract arrangements.

The complainant advised she had discussed the meetings between the company representative and the trust with the director of the relevant department and understood that the discussion was about "continuing previous arrangements", rather than providing educational grants and that furthermore she understood that the suggestion that any proposals would need to be checked with the finance department came from the trust staff and not from the representative. The complainant advised that if such apparent misunderstandings were to arise then the trust would consider whether to ban visits from the company's representatives altogether.

Finally, the complainant enclosed an extract from the Prevention of Corruption Acts 1906 and 1916. In the complainant's view, it would be anomalous if the Code approved of acts which might contravene statute.

RESPONSE BY COMPANY

The company reaffirmed its initial submission on the complaint and advised that the representative concerned was certain that the suggestion to discuss the proposal with the finance department had come from himself.

Details of the products purchased by the hospital from the company during 1994 were submitted together with details of all direct and indirect payments associated with its commercial activities at the hospital over the last year.

The company had, subsequent to the complainant's request for an appeal, received a letter from the purchasing manager at the hospital inviting it to quote for the supply of certain products for the forthcoming financial year. A copy of this letter was submitted. The company pointed out that the letter did not state educational grants or other payments were unacceptable to the hospital nor did it provide any details of the hospital's tendering process.

APPEAL BOARD RULING

The Appeal Board considered that the view expressed by the complainant that it was inappropriate to make educational grant payments to individuals or funds as these were not part of the NHS was quite incorrect. The training and education of health professionals and other employees of the NHS was very much part of the NHS. Contributions to postgraduate medical education funds were contributions to the NHS.

The complainant was also incorrect in stating that the company had not supplied the products in question during 1994/5. Details of all of the company's products purchased by that trust between January and November 1994 had been supplied to the Appeal Board by the company and this included the purchase of the products in question. Irrespective of the fact that the NHS trust had continued to purchase some of the product from the company, the Appeal Board considered that it would be quite inappropriate to preclude companies which had not obtained a contract from discussing future contracts with the hospital. To do so might well raise questions in relation to competition law.

The Appeal Board also considered that it was quite unacceptable that an official within an NHS trust should seek to stop health professionals from seeing representatives with whom they wished to discuss matters relevant to their professional work.

The Appeal Board considered that the offer of a payment of an educational grant in the circumstances at issue was by no means irregular as long as the offer was referred to the appropriate persons within the trust as had occurred in this instance. The company was not offering anything other than a benefit to the trust with the knowledge of the trust. Corruption was not involved.

With regard to the complainant's comments regarding the Corruption Act, the Appeal Board observed that the key wording in it was the phrase "corruptly gives". In the Appeal Board's view, it was necessary for monies to be offered or given corruptly ie with the intent on the part of the person making that offer or provision to subvert appropriate practice.

The Appeal Board considered that the representative from the company concerned had not in any way acted inappropriately and ruled there was no breach of the Code. The appeal therefore failed.

Complaint received **24 October 1994**

Case completed **12 January 1995**

CASE AUTH/231/10/94, AUTH/232/10/94, AUTH/233/10/94, AUTH/234/10/94, AUTH/235/10/94, AUTH/236/10/94, AUTH/237/10/94, AUTH/238/10/94, AUTH/239/10/94 & AUTH/247/10/94

GENERAL PRACTITIONER v MEMBER & NON MEMBER COMPANIES

Venue & hospitality at meetings organised by a postgraduate medical centre

A general practitioner complained about two meetings organised by a postgraduate medical centre and sponsored by a number of pharmaceutical companies which consisted of round table discussions in a local restaurant. The Panel ruled that there had been no breach of the Code as the nature of the meetings and the hospitality had been within the parameters set by the Code, though it considered that the letter of invitation could have been better phrased. The meeting which had taken place had been in a sectioned off part of the restaurant.

COMPLAINT

A general practitioner complained about pharmaceutical company representatives sponsoring meetings organised by a university's postgraduate medical centre. The complainant alleged that Clause 19.1 of the Code might have been breached because arranging discussions on clinical topics over a gourmet meal in a busy restaurant was not appropriate for a meeting with a clear educational content. Furthermore, the hospitality associated with the meeting which was promoted as an opportunity to meet both hospital and general practice colleagues in an informal atmosphere could be the main attraction for attendance and was used as a financial bond to ensure it.

The complaint was taken up with the ten pharmaceutical companies which had been involved and also with a company providing representatives under contract which had represented three of them. The matter was also taken up with the postgraduate medical centre itself. Most of the sponsoring companies had been involved only with one or the other of the two meetings.

RESPONSES

In response to the Authority's enquiry, the postgraduate medical centre said that the two meetings in question had been arranged specifically to ensure an informal atmosphere to facilitate discussions between general practitioners and consultants. The first meeting was given PGEA (postgraduate education allowance) approval by the postgraduate department. During the evening five groups of five GPs and a consultant sat around five tables to discuss topical clinical issues, guided by a GP chairman. These chairmen were chosen from amongst local GP educationalists. There was deliberately no fixed agenda and the discussion ranged over topics chosen by the group. The structure of the evening was that the groups were convened after a brief reception and spent one hour discussing clinical matters, without any representatives from pharmaceutical companies present. After this period, a meal was served at the table and discussions continued informally. The groups were joined at dinner by representatives of pharmaceutical companies.

The early part of the evening took place prior to the serving of the meal and informal discussions continued over the meal. If the impression had been created that the meeting was entirely over a meal, this was possibly the centre's error in phrasing the letter of invitation. The pharmaceutical companies were not involved in drafting the letter. The hospitality associated with the meeting consisted of a set meal which was served after the main part of the formal discussions. One alcoholic drink was provided for those who wished to have a drink but if participants wished to have further drinks, it was their own responsibility to purchase. There were few restaurants available in the area to hold meetings and the postgraduate medical centre did not have its own facilities. The food was of reasonable quality but the venue would hardly have been described as a "gourmet" restaurant. The meal was a standard set menu and it was consistent with what participants would normally have adopted when paying for themselves.

Responses from the eleven companies involved were broadly in line with the letter which had been received from the postgraduate medical centre. Most of the responses said that the meeting was held in an area of the restaurant which had been partitioned off and was private from the main public area. Some said that the restaurant was otherwise completely closed on the evening in question. The amount of sponsorship paid per company amounted to £200 which had been paid to the postgraduate department though two companies stated that their contributions were only £100 or £150 respectively. Representatives had had an opportunity to promote their products to the doctors involved.

RULING

The Panel noted that one meeting had already taken place and another was planned. About forty persons had taken dinner at the first meeting. The Panel ruled that there had been no breach of Clause 19 of the Code. The evidence suggested that the hospitality had not been overlavish and that this and the nature of the meetings were within the parameters set by the Code. The meeting which had taken place had been in a sectioned off part of the restaurant. In this regard it could be distinguished from Case AUTH/49/5/93 where it had been held to be in breach of the Code to promote medicines at a table in an open restaurant.

The Panel did, however, have some sympathy with the point of view of the complainant. The letter of invitation which had been sent out by the postgraduate medical centre referring to round table discussions said merely that "open discussions will take place over a meal". It was considered that this was in itself misleading and the Panel noted that the

centre accepted that the letter might have been better drafted.

Complaint received 19 October 1994

Case completed 20 December 1994

CASE AUTH/240/11/94

GENERAL PRACTITIONER v MEMBER COMPANY

Statement in journal advertisement & failure to provide copy of study

A general practitioner questioned a statement relating to bioequivalence licensing requirements in an advertisement and complained that he had not been provided by the company concerned with a copy of a study which he had requested. The Panel ruled that there had been no breach of the Code.

COMPLAINT

A general practitioner complained about a series of advertisements issued by a member company. He questioned the veracity of a paragraph which related to the need to demonstrate bioequivalence with the originator product. He had contacted the company direct and he enclosed a copy of its response. He had subsequently requested on several occasions a copy of the bioequivalence study referred to in the company's letter but it had failed to provide him with a copy of the study.

RESPONSE

In relation to the reference to licensing procedures in the advertisement, the company said that the statement was both true and accurate, reflecting the current Medicines Control Agency position with regard to the registration of essentially similar products. The demonstration of bioequivalence had been an integral part of its product licence submission, such information being required in relation to the validity of its submission and, specifically, the validity of indications approved in the marketing authorisation.

In relation to the study which the company had not provided, the company said that the study was mentioned in correspondence and not in the advertisement and, as such, fell outside the scope of the Code. Clause 1.2 excluded from the scope of the Code "replies made in response to individual enquiries from members of the health professions or in response to specific communications whether of enquiry or comment .....". The company provided a copy of a recently published paper dealing with the question of equivalence.

RULING

The Panel considered that the statement relating to the need to demonstrate bioequivalence with the originator product did in fact reflect its understanding of the current licensing requirements and ruled that there had been no breach of the Code.

In relation to the paper which the company had failed to provide to the complainant, the Panel accepted that the letter which had been written to the complainant fell outside the scope of the Code because it was a reply to an individual enquiry from a member of the health professions. The complainant had been supplied by the company with the papers which were referenced in the advertisement.

Complaint received 4 November 1994

Case completed 20 December 1994

CASE AUTH/241/11/94

GENERAL PRACTITIONER v MEMBER COMPANY

Cost information in a leaflet

A general practitioner complained that information relating to monthly cost in a leaflet was misleading due to the layout and use of a qualifying statement. It was not accepted that the presentation of the data was misleading as the basis of the calculation was given clearly. No breach was ruled.

COMPLAINT

A general practitioner complained about a mailing consisting of a "Dear Doctor" letter, a leaflet and a data sheet sent by a member company. The complainant drew attention to a section in the leaflet showing "Monthly Cost" with a figure displayed prominently in a large box. Underneath the box was a qualifying statement with an asterix with the explanation for the asterix appearing underneath. The complainant alleged that it was ingenuous and misleading to state in very large type the cost and then underneath in small type to make the qualification.

RESPONSE

The company explained the basis of the calculation of the monthly cost. Two studies were provided to support the

submission. The company did not accept that the qualification was written in small type and was therefore misleading. It was close to the box which gave the cost and the asterix above the box was prominent.

RULING

The Panel did not accept that the presentation of the data was misleading. The basis of the calculation was clearly given in such a way that it would be noticed by readers. The Panel accepted the submission from the company and considered that the assumptions upon which the calculation was based were not unreasonable. The Panel therefore ruled no breach of the Code.

Complaint received	**7 November 1994**
Case completed	**5 December 1994**

CASE AUTH/242/11/94

DIRECTOR v MEMBER COMPANY

Alleged breach of undertaking

It was alleged that a member company was in breach of its undertaking as a booklet previously ruled to be in breach of the Code was freely distributed at a meeting for general practitioners. The respondent company submitted that although the item had been taken to the meeting it had not been given to doctors or made available to them. The Panel ruled there was no breach as there was insufficient evidence to show that the items had been used again for promotional purposes in breach of an undertaking. This was appealed and the Chairman of the Appeal Board decided to invoke the provisions of Paragraph 4.7 of the Constitution and Procedure and invite both companies to send their representatives present at the meeting in question to give oral evidence to the Appeal Board. This invitation was declined by both companies and the Chairman withdrew the case from the Appeal Board.

COMPLAINT

SmithKline Beecham Pharmaceuticals complained that a booklet from a member company which had been ruled to be in breach of Clauses 4.1 and 15.2 of the Code in an earlier case was being freely distributed at a meeting for general practitioners in breach of the company's undertaking. In accordance with guidance from the Appeal Board, the matter was taken up as a complaint by the Director as the Authority was responsible for ensuring compliance with undertakings.

RESPONSE

The respondent company denied that the booklet was either given to doctors or made available to them at the meeting. The booklet had been taken to the meeting by a representative who was fairly new to the company and who had been left copies of the booklet by her predecessor in the territory, although they should have been destroyed. The representative had taken them in a box of material to the meeting but had checked and confirmed with the other company representative present that the item was that which she had been instructed to destroy in an E mail which had been sent on the matter. The item had therefore been put in the box and put behind the stand out of the way. This was disputed by SmithKline Beecham.

RULING

The Panel ruled there was no breach as there was insufficient evidence to show that the items previously ruled in breach had been used again for promotional purposes in breach of an undertaking. The Panel noted, however, that there was express provision in the Constitution and Procedure (Paragraph 4.7) whereby the Chairman of the Appeal Board could invite persons to attend and give oral evidence where an appeal was concerned with an issue of fact which could not be properly resolved without the oral evidence of the persons directly involved. The Panel considered that, in its view, the matter before it was such an instance.

The Director of the Authority accordingly appealed against the Panel's ruling and the Chairman of the Appeal Board decided to invoke the provisions of Paragraph 4.7 of the Constitution and Procedure and invite both companies to send their representatives present at the meeting in question to give oral evidence to the Appeal Board. This invitation was declined by both companies.

APPEAL BOARD CONSIDERATION

The Chairman advised the Appeal Board that there was insufficient evidence as to what had happened to enable a decision to be made and he accordingly withdrew the case from the Appeal Board. The Panel's ruling of no breach therefore stood and the appeal failed.

Proceedings commenced	**7 November 1995**
Case completed	**2 March 1995**

CASE AUTH/244/11/94

GENERAL PRACTITIONER v MEMBER COMPANY

Claim made by representative

A general practitioner complained about statements made to him by a representative, alleging that they represented a misinterpretation of the supporting studies. The Panel considered that the statements represented a generally accepted view which appeared in the data sheets of more than one company's products. No breach was ruled.

COMPLAINT

A general practitioner complained about a claim relating to a product which had been made by the representative of a member company. He had requested supporting information and various trial papers had been sent to him. Having studied the papers, the complainant could not see how the company could have drawn from them the conclusions put forward.

RESPONSE

The company said that the representative had acted properly. He had used the printed promotional material provided and had referred the resulting question to the company's medical information department. The company believed that its position represented an up to date evaluation of all the evidence. It supplied the papers involved and explained the basis of its claims.

PANEL RULING

Having reviewed the papers, the Panel considered that the proposition was one which was widely accepted. It was noted that similar statements were made in the data sheets for other companies' products of a similar nature. It was ruled that there was no breach of the Code.

Complaint received 11 November 1994

Case completed 17 January 1995

CASE AUTH/245/11/94

NORGINE v GALEN

Omission of legal classification and all embracing claim in abbreviated advertisement for Manevac

A number of allegations were made by Norgine in respect of an abbreviated advertisement for Manevac issued by Galen. The advertisement was ruled in breach by the Panel as it did not include the non proprietary name nor the legal classification of the product and as the words "The choice" in the claim "The choice for overnight relief from constipation" made it all embracing. The Panel did not accept a further allegation that the claim for overnight relief was unacceptable.

COMPLAINT

Norgine Limited, a company not in membership of the ABPI but which had agreed to comply with the Code, complained about an abbreviated advertisement for Manevac issued by Galen Limited which appeared in Pulse, 5 November 1994. It was alleged that the advertisement was in breach of Clause 5.4 of the Code as it did not include the non proprietary name or the legal classification of the product, that it was in breach of Clause 7.8 as the claim "The choice for overnight relief from constipation" was an implied superlative and that the same claim was in breach of Clause 7 as it was not supported by a reference and nor was it covered by the data sheet for the product.

RESPONSE

Galen Limited was not a member of the ABPI but when approached by the Authority agreed to comply with the Code. The company advised that it had considered the complaint and taken action to include the non proprietary name and legal classification of the product forthwith and that the claim "The choice for overnight relief from constipation" had been replaced by the claim "Overnight relief of constipation".

The company submitted that the claim for overnight relief of constipation could be supported. Details of the constituents of the product were submitted and it was pointed out that the usual dosage of Manevac was 1 or 2 level 5ml spoonfuls after supper. Thus taking Manevac at night as indicated should result in a bowel motion the following morning.

RULING

The Panel ruled a breach of Clause of 5.4 of the Code with regard to the failure to include the non proprietary name and the legal classification of the product in the abbreviated advertisement for Manevac in question. A breach of Clause 7.8 of the Code was also ruled with regard to the claim " The choice for overnight relief from constipation" as the words "The choice" made it an all

embracing claim.

The Panel did not, however, accept the allegation that the claim for overnight relief from constipation was in breach of Clause 7. The Panel considered that the claim was not unreasonable in the light of the dosage instructions for the product to take one or two 5ml teaspoons after supper and if necessary before breakfast which clearly implied that it was an overnight treatment for the relief of constipation.

Complaint received	**14 November 1994**
Case completed	**22 February 1995**

CASE AUTH/246/11/94

REGIONAL HEALTH AUTHORITY v MEMBER COMPANY

Offer of samples

It was alleged by a regional health authority executive that an offer of samples was of an excessive quantity and that approaching medical staff without prior consultation with the hospital pharmacy was incompatible with the hospital's expectations.

The Panel considered that the quantity offered was within the limits set by the Code and that the supply of samples could not have been contrary to the hospital's requirements as no samples had in fact been supplied. No breach was ruled.

COMPLAINT

A senior executive in a regional health authority complained about an offer of samples made by a member company. It was alleged that the quantity was excessive and that approaching the medical staff without prior consultation with a senior pharmacy manager was not compatible with the hospital's expectations.

RESPONSE

The member company concerned said that each sample was the smallest size on the market and was sufficient to treat one patient. The number offered had been limited to five per consultant with a maximum of ten per hospital. No samples had been supplied to the hospital. Where samples had been requested, their distribution had always complied with individual hospital requirements. Samples would be supplied to the hospital in question to, and with the agreement of, the department of pharmacy.

RULING

The Panel noted that the quantity offered was within the parameters of Clause 17.2 of the Code which stated that no more than ten samples of a particular medicine could be supplied to an individual health professional in the course of a year. Clause 17.9 stated that the distribution of samples in hospitals must comply with the individual hospital's requirements but since none had been supplied, that had not been breached. It was accordingly ruled that there had been no breach of the Code.

Complaint received	**14 November 1994**
Case completed	**17 January 1995**

CASE AUTH/248/11/94

CHIEF ADMINISTRATIVE PHARMACEUTICAL OFFICER v MEMBER COMPANY

Promotion of a product

A chief administrative pharmaceutical officer complained that a member company was promoting a method of administration and an indication for its product which were not licensed. The Panel noted that the method of administration was well known but not licensed and considered that the company needed to be careful to ensure that its representatives did not advocate use of the product outside the licence. The Panel decided that on balance the company's activities were not unacceptable and ruled no breach of the Code.

COMPLAINT

A chief administrative pharmaceutical officer submitted a complaint on behalf of the chief pharmacists of the NHS trust hospitals within a certain district regarding the promotion of a product by a member company. The complaint alleged that the company was promoting a method of administration for the product which was not within the product licence and queried whether the product was licensed for a particular indication.

RESPONSE

The company concerned submitted that it had never instructed customers that the product should be administered by the method alleged by the complainant. When asked about this method of administration which was well known by specialists in the area to have an advantage, it had been made clear the company did not have a licence and none of the promotional material made any reference to this method of administration.

The company submitted that the product was licensed for the indication queried by the complainant and it could therefore be promoted for such indication.

The company advised that it was in the process of changing the product licence to include the method of administration in question.

The company had sent the complainant copies of the briefing documents given to its representatives.

The the response from the company had been sent to the complainant for further comment. The complainant referred to various meetings between pharmacists and representatives from the company.

RULING

The Panel appreciated the difficulties for the company as the method of administration at issue was well known but was not a licensed method of administration. There was a need for great caution on the part of the company in such circumstances so as to ensure its representatives did not transgress in advocating use of product outside the terms of its licence.

The Panel noted that it was difficult to reach a conclusion in cases like this where there was a conflict of evidence as to what had been discussed at various meetings. There was nothing in the documentation provided by the company to support the allegation.

Taking all the facts into account, the Panel decided that on balance the company's activities were not unacceptable. The Panel therefore ruled no breach of the Code.

Complaint received **16 November 1994**

Case completed **17 February 1995**

CASE AUTH/250/11/94

DIRECTOR v MEMBER COMPANY

Drug & Therapeutics Bulletin article criticising the promotion of a product

Criticism in an article in the Drug and Therapeutics Bulletin of the promotion of a member company's product was taken up as a complaint under the Code. The Panel decided that there was data to support the claims which were not unacceptable and ruled no breach of the Code.

COMPLAINT

An article on a member company's product published in the Drug and Therapeutics Bulletin, referred to claims made for the product and concluded that no clinical evidence could be found for the claims. In accordance with established procedure, the matter was taken up as a complaint under the Code.

RESPONSE

The company submitted that clinical evidence existed regarding the claims criticised and this had been sent to the Drug and Therapeutics Bulletin during the review process of the article. The relevance of the data had been recognised by most experts in the field as well as by the UK regulatory authority. The company considered that it was one thing for the Drug & Therapeutics Bulletin to

disagree with data supplied but to ignore it and suggest that no such data existed was not only incorrect but raised serious doubts about the validity of the review. There were other factual errors in the article.

RULING

The Panel examined the data provided and considered that the claims were not unacceptable and therefore ruled no breach of the Code.

Proceedings commenced	**28 November 1994**
Case completed	**27 January 1995**

CASE AUTH/251/11/94

FHSA PHARMACEUTICAL ADVISER & PRACTICE NURSE FACILITATOR v MEMBER COMPANY

Conduct of a representative at a meeting for practice nurses

An FHSA pharmaceutical adviser and a practice nurse facilitator complained about the conduct of a representative. It was alleged that he had failed to attend a meeting in the manner agreed, that his talk was given in an inappropriate and threatening manner and that he had given inaccurate information. The Panel reviewed the slides used in the presentation and the accompanying script but found no evidence of a breach of the Code. It was difficult to deal with cases of this nature in which there was a conflict of evidence.

COMPLAINT

A Family Health Services Authority (FHSA) pharmaceutical adviser and a practice nurse facilitator jointly complained about the conduct of a representative of a member company at a meeting for practice nurses. It was alleged that he had failed to attend a meeting in the morning and provide a stand as arranged, though he had attended later to give a talk. It was also alleged that in the course of his talk to the practice nurses present at the meeting he had given inaccurate information about the use of his company's products and the relevant disease area. Further he had behaved in an inappropriate and patronising manner and had used inappropriate and threatening sales tactics.

RESPONSE

The company stated that the arrangements had been made through a third party and there had obviously been a misunderstanding. The representative had offered to cancel the arrangements but had been told to proceed and that it was not a problem. The company was surprised to hear the allegations concerning the representative's behaviour, which it considered was not to be expected of the representative concerned. The representative could not understand how his presentation could have been regarded in that light. Nonetheless, the company regretted any offence that might have been caused. The company replied in detail to the allegations about factual inaccuracy and provided a set of the slides used together with the accompanying script.

RULING

The Panel noted the criticisms which had been made about the attitude and behaviour of the representative. Clearly the complainants had been concerned and relationships with the company had been prejudiced. That was not to say, however, that the representative's attitude and the like necessarily amounted to a breach of the Code. In relation to the allegations made about factual content, the Panel reviewed the papers which had been supplied by the company, including the slide presentation script, and viewed those slides relevant to the allegations.

Having considered the comments from both the complainant and the company, the Panel ruled that there had been no breach of the Code. This type of complaint was difficult to deal with because of the conflict of evidence which arose and the difficulty of determining whether particular points had been badly put and the audience misled.

Complaint received	**30 November 1994**
Case completed	**6 March 1995**

CASE AUTH/252/12/94

DIRECTOR v MEMBER COMPANY

"Dear Practice Nurse" letter - matters taken up under Paragraph 16

Two possible breaches of the Code were taken up under the provisions of Paragraph 16 of the Constitution and Procedure in respect of a "Dear Practice Nurse" letter issued by a member company. No breach was ruled by the Panel in respect of one matter identified concerning the use of a particular word in the letter. The Panel ruled a breach in respect of the other matter concerning a recommendation given in the letter which did not specify that the recommendations related to one medicine only. This ruling was reversed on appeal and no breach was found.

PANEL CONSIDERATION

This case had arisen during the consideration of an earlier case (Case AUTH/223/10/94) in which two matters identified as possible breaches of the Code were taken up under the provisions of Paragraph 16 of the Constitution and Procedure. One matter concerned the use of the word "independent" in a reference to "independent data" from two studies discussed in the letter. The Panel had queried whether the description independent was applicable to one of the studies discussed in the letter which had been sponsored by the pharmaceutical company concerned in the case whereas the other study was wholly independent of the company. The other matter queried concerned the second of three recommendations given in the final page of the letter which quoted a recommendation from the second study discussed in the letter which had been carried out by a health services body. It was considered that the letter did not make clear that the recommendations related to one medicine only in the therapeutic area.

The Panel noted that the two studies referred to in the letter were of a different order of independence as one was wholly independent of any link with the pharmaceutical company whereas the other had been directly funded by it. The Panel decided nonetheless that the reference to "independent data" was not misleading in the circumstances as both studies would be accepted as being independent in the general sense and ruled there was no breach of the Code. The Panel considered, however, that the second recommendation in the letter should have specified that the health services body recommendation related to a particular product only and that it was misleading not to do so. The Panel therefore ruled there was a breach of Clause 7.2 of the Code.

APPEAL BY MEMBER COMPANY

The member company appealed the ruling, pointing out that the mailing referred throughout only to the one product with prescribing information for that product alone provided. The quoted recommendation from the health services body was a direct quote which was clearly referenced to it being a paper on the one product with the results being discussed in the text of the letter. In the company's view it was clear that the recommendation was related to the one product only.

APPEAL BOARD RULING

The Appeal Board accepted the submission put forward by the member company that the second recommendation given in the letter was not misleading in omitting to stipulate that it referred to a particular product only and ruled there was no breach of the Code. The appeal therefore succeeded.

Proceedings commenced	**3 November 1995**
Case completed	**2 March 1995**

CASE AUTH/253/12/94

PFIZER v DUPHAR

Cost comparison chart in a Faverin advertisement

Pfizer alleged that the presentation of a suppressed zero in a cost comparison chart for Faverin issued by Duphar was misleading. The Panel considered that the use of the suppressed zero exaggerated the differences between the products even though the graph had been annotated to show the cost of each product and ruled that it was misleading.

COMPLAINT

Pfizer complained about an advertisement for Faverin (ref: FAV-PRJ1/9/94) issued by Duphar Laboratories Limited.

The piece was headed "The only SSRI below the £20 barrier" under which appeared a bar chart comparing the cost of sertraline at £28.40, fluoxetine/paroxetine at £20.77 and Faverin at £19.00. There was no zero on the vertical axis and the horizontal axis was aligned with the £20 mark on the vertical axis. The column for Faverin appeared below the horizontal axis whereas the columns for fluoxetine/paroxetine and sertraline appeared above the horizontal axis.

Pfizer alleged that the presentation employed a graphic with a suppressed zero on the vertical axis and the effect was to maximise the visual differences between the lowest

and highest price products in a disproportionate manner. In addition, the horizontal axis was judiciously chosen resulting in an apparently negative value for Faverin at £19.00. Pfizer alleged breaches of Clauses 7.6 and 7.2 of the Code.

RESPONSE

Duphar stated that the advertisement was aimed at doctors, all of whom were quite capable of understanding the meaning of the graph without the need for the zero to be shown. The chart clearly showed on the vertical axis the figures £20 and £30. Duphar submitted that even if the vertical axis had been extended to zero the difference in price between the Pfizer product and its product Faverin, of £9.40, would not have been any less pronounced. The company drew attention to the heading "The only SSRI below the £20 barrier" and submitted that it was perfectly proper to incorporate the £20 barrier as the horizontal axis.

Duphar referred to Case AUTH/160/5/94 in which it was stated by the Panel that the suppression of the zero on the vertical axis was not an automatic breach of the Code.

Duphar submitted that to allay any possible confusion the bars were individually named, coloured and the bar values emphasized by clearly marking the actual costs. To suggest that the chart gave the impression that Faverin had a negative price was not logical.

The layout of the chart was not chosen with the aim of falsely magnifying the considerable differences in cost between the products.

RULING

The Panel considered that there might be occasions when it was possible to use a graph with a suppressed zero. Such graphs were not ruled out *per se*. The Panel considered, however, that in this instance the use of the suppressed zero exaggerated the differences between the products even though the chart had been annotated to show the costs of each product. The visual impression of the chart was that there was a large difference between the products and if the chart had been drawn without a suppressed zero this difference would not have been so marked. The Panel considered that the chart was misleading and ruled a breach of Clause 7.6 of the Code.

Complaint received **6 December 1995**

Case completed **20 February 1995**

CASE AUTH/255/12/94

DUPHAR v PFIZER

Allegations concerning Lustral detail aid

Four allegations made by Duphar about a Pfizer detail aid for Lustral were considered by the Panel.

An allegation that the title "What distinguishes LUSTRAL from other antidepressants" was all embracing was rejected as it was a question rather than a claim. A claim that "LUSTRAL builds a simple recovery in patients taking other drugs" was considered to be misleading in view of information in the data sheet about drug interactions. A claim that "..... LUSTRAL has a relatively low potential for P450 IID6 inhibition compared to other SSRIs" was ruled to be misleading as it omitted any reference to fluvoxamine which was superior in this respect. Finally, the claim that "LUSTRAL minimises the likelihood of drug interactions" was considered to be an all embracing claim in view of the other findings and was also in breach.

Duphar Laboratories Limited complained about a detail aid issued by Pfizer Limited entitled "What distinguishes LUSTRAL from other antidepressants?" (ref 66141 Oct 94). There were four allegations.

1 All embracing claim in title

COMPLAINT

Duphar alleged that the title "What distinguishes LUSTRAL from other antidepressants?" implied an all embracing claim, the only justification for which was the licensed indication for the prevention of relapse/recurrence of depression. The other aspects referred to did not differentiate Lustral from many other antidepressants. A breach of Clause 7.8 was alleged.

RESPONSE

In Pfizer's view, the title did not constitute an unqualified all embracing claim. It was simply a question which was answered by the statements in the detail aid itself. There were differences between antidepressants and these differences were not only represented by the licensed indications. In the detail aid, the pharmacokinetic properties, the potential for drug interactions and the difference in safety profile obtained from properly designed and conducted clinical trials were described. In Pfizer's view, it was quite clear when a comparison was being made with other products and when the narrative was simply the description of the properties of Lustral.

RULING

The Panel considered that the title of the detail aid "What distinguishes LUSTRAL from other antidepressants?" was a question rather than a statement. It did carry an implication that all elements of its contents were distinctive but the Panel was of the opinion that it should not be regarded as an unqualified all embracing claim as alleged and ruled that it was not in breach.

2 "LUSTRAL builds a simple recovery in patients taking other drugs"

COMPLAINT

Duphar alleged that this claim was all embracing. The Lustral prescribing information specifically warned against use of MAOIs (monoamine oxidase inhibitors). Additionally, it cautioned use with lithium, tryptophan, alcohol and highly protein bound drugs, whilst at the same time admitting that the interaction potential with a number of other drugs had not been fully assessed. This hardly backed up the claim which Duphar regarded as both misleading and exaggerated and in breach of Clause 7.8.

RESPONSE

In Pfizer's view, the statement had to be read in its clear context. The quoted sentence introduced a page on drug interactions, mediated through the hepatic cytochrome P450 IID6. There was no ambiguity in this statement which clearly referred to the drug metabolism through the CYP isoenzymes. There was no suggestion that the product was devoid of any drug interaction and the statement was addressed to a well informed medical profession. In Pfizer's view, there was no possible suggestion about inappropriate use of the drugs eg concomitant with MAOIs or with intoxicating substances like alcohol and Pfizer did not believe that doctors would interpret this statement in that way.

RULING

The Panel considered that the claim "LUSTRAL builds a simple recovery in patients taking other drugs" was somewhat meaningless in itself but had to be read in the context of what followed. Account had not been taken, however, of the specific warning in the data sheet relating to MAOIs. The data sheet also referred to lithium, tryptophan, alcohol and other highly protein bound drugs and also stated that the interaction potential of Lustral with, for example, digoxin, warfarin, propranolol and phenytoin had not been fully assessed. The claim appeared to be based on the hypothesis that the only relevant factor was P450 IID6 inhibition. The Panel noted that the page did not say that there were no interactions but that Lustral minimised their likelihood, but nonetheless considered that the claim, "LUSTRAL builds a simple recovery in patients taking other drugs", as amplified by its associated text, was misleading and in breach of Clause 7.2.

3 "..... LUSTRAL has a relatively low potential for P450 IID6 inhibition compared with other SSRIs"

COMPLAINT

In relation to this claim, Duphar alleged that misleading and selective use of data had been made. Crewe *et al* had shown that sertraline (Lustral) had a greater inhibitory effect, by an order of magnitude, than fluvoxamine (Duphar's product Faverin). By omitting this information and any mention of fluvoxamine, there had been a failure to give an accurate, fair, unambiguous comparison and not all available evidence was reflected, in breach of Clause 7.2. It was also relevant that the major metabolite of sertraline, desmethyl sertraline, was a CYP 2D6 inhibitor in its own right (von Moltke *et al*) and it was present in higher concentrations in the blood than the parent compound (Tremaine *et al*). Desmethyl sertraline might therefore also have a role in potential drug interactions. This was a complex subject and to simplify it in this way was misleading to prescribers and potentially dangerous.

RESPONSE

Pfizer did not accept that the statement was misleading. It clearly related to a comparison in the relevant respect between Lustral and paroxetine and fluoxetine; these three products being listed immediately after the statement in the same box of copy. These three products together represented over 90% of the UK SSRI (selective serotonin reuptake inhibitor) market. Pfizer did not accept that reference was made to any other SSRI and Duphar's comments about fluvoxamine were in its view irrelevant. Pfizer did not accept that its statement was misleading and, in particular, it did not consider it was potentially dangerous. It was clearly based on the literature and the data available at the time. It had used a review by Preskorn which displayed the information clearly and showed that sertraline had the least inhibiting activity of the three SSRIs. There was certainly no claim that sertraline was devoid of any inhibiting activity. Although von Moltke *et al* found that sertraline and its metabolite, desmethyl sertraline, had an inhibitory activity on the cytochrome P450 they concluded that such inhibition was at least five fold less than fluoxetine or norfluoxetine. These data were consistent with those of Preskorn and again confirmed the lower inhibiting potential for sertraline than fluoxetine. Pfizer did not suggest that sertraline or its metabolite were devoid of any drug interaction potential but, as a general statement based on clinical studies in four years post marketing experience, Pfizer considered that its claim was fairly based and acceptable.

RULING

In relation to the claim that "..... LUSTRAL has a relatively low potential for P450 IID6 inhibition compared to other SSRIs", the Panel, while noting that the three products mentioned, paroxetine, fluoxetine and Lustral, had 90% of the market, considered nonetheless that the omission of any reference to fluvoxamine was misleading as Lustral had a significantly greater inhibitory effect than fluvoxamine. It was thus selective use of data to omit fluvoxamine and the Panel ruled that there had been a breach of Clause 7.2 of the Code.

4 "LUSTRAL minimises the likelihood of drug interactions"

COMPLAINT

Duphar alleged that this claim was both a hanging comparison and an all embracing/exaggerated claim, in breach of Clauses 7.2 and 7.8.

RESPONSE

Pfizer did not accept this interpretation of the statement. The statement was taken from the same page as that dealing with the cytochrome P450 IID6 related drug interactions and appeared immediately below the relevant data. Pfizer had taken great pains to develop the story from *in vitro* to *in vivo* results and claimed to have a lower drug interaction potential mediated through this system than with two other SSRIs. This statement should not be taken in isolation but put in the context of the page overall. Since it was at the end of the page dealing with cytochrome P450 it was not, in Pfizer's view, necessary to repeat the wording relating to the cytochrome P450 IID6 metabolism.

RULING

The claim that "LUSTRAL minimises the likelihood of drug interactions" was not considered by the Panel to be a hanging comparison as such, although in the light of the title of the detail aid as a whole it did have a comparative element. Noting the rulings in 2 and 3 above, it was considered that it was an all embracing claim and it was ruled to be in breach of Clause 7.8.

Complaint received 15 December 1994

Case completed 27 March 1995

CASE AUTH/256/12/94

HOSPITAL PHARMACIST v SERVIER LABORATORIES

Review brochure on Coversyl

A hospital pharmacist complained that a brochure on Coversyl issued by Servier Laboratories was misleading on three counts. First, the title of the brochure was "Latest developments in congestive heart failure" while the content referred solely to the one product. Secondly, that a section in the brochure was attributed as being written by someone of IRIS, Slough, which created the impression that it was an independent view instead of which it should have stated that it had been written by someone from Servier. Thirdly, that in the list of contents it claimed that Coversyl prevented mortality caused by ventricular fibrillation post infarction and that neither in the list of contents nor in the body of the text of the brochure did it mention that the claims were based on a study in ten rats. The latter criticisms also applied to a claim that Coversyl reversed structural and functional changes which occurred in heart failure.

The allegations were accepted by the Panel but, on appeal, the Appeal Board considered that on balance the cover of the brochure did not mislead as to its contents as it was clearly a pharmaceutical company item related to one of its products and ruled that there was no breach on that point. The Appeal Board accepted, however, that it was misleading to reference the third section in the brochure as being by someone from IRIS, Slough, as it did create the impression to those not familiar with the term IRIS that the author was independent of the company. A breach was upheld.

With regard to the third matter, the Appeal Board considered that the claims were misleading as, although it could be read in the data provided on the studies in the text of the brochure that they were both based in the rat, both claims were claims for the clinical usage of the product and it was misleading to make such claims based on an extrapolation of animal data. The Appeal Board therefore considered that the claims failed to take into account that they were based on studies in the rat as alleged and ruled they were in breach.

COMPLAINT

A hospital pharmacist complained that a brochure on Coversyl issued by Servier Laboratories Limited was misleading on three counts. First, that the title of the brochure was "Latest Developments in Congestive Heart Failure" while the content referred almost solely to the one product. Secondly, that a section in the brochure stated as being written by someone from IRIS, Slough, created the impression that it was an independent view instead of which it should have stated that it was written by someone from Servier. Thirdly, that in the list of contents it claimed that Coversyl prevented mortality caused by ventricular fibrillation post infarction. Neither in the list of contents nor in the body of the text of the brochure did it mention that the claims were based on a study in ten rats. The latter criticism also applied to a claim that Coversyl reversed structural and functional changes which occurred in heart failure.

RESPONSE

Servier, although not a member of the ABPI, had nonetheless agreed to comply with the Code.

Servier rejected the allegations concerning the title of the brochure which it believed was fully justified. The main subject matter of the brochure was the extension of Coversyl's licence in heart failure to include GP initiation of treatment. With regard to the brochure only mentioning Coversyl, the company submitted that the contents section made this abundantly clear and there had been no attempt to hide the product. It was reasonable to expect readers to look at the contents page as only then they would know what the publication contained.

With regard to the second point, the company advised that the person was an employee of Servier but had written the article whilst on a training course with IRIS (Institut de Recherches Internationales Servier). The company asserted that the "article itself is a mixture of environment and product, but is totally compliant with the Code". It denied that there was any attempt on its part to disguise the origins of the article in question. A telephone or written request for further information regarding IRIS would be answered with a full explanation of the relationship between Servier UK and IRIS.

Furthermore, the origin of the brochure was openly acknowledged both on the front and back covers as being produced by Servier.

With regard to the third issue, the company submitted that the contents page in the front of the brochure listed those studies that appeared in the brochure as summaries. The full scientific title of each study was not given but a short promotional, but fully supportable, phrase was used instead. Within the brochure each study was detailed over two pages with the full referenced title of the study, the aims and methods in brief and the pertinent results quoted and displayed. With both of the studies cited by the complainant, the fact that they were animal studies were patently obvious from both the titles and the methods. No attempt had been made to claim otherwise.

PANEL RULING

The Panel noted that the brochure was entitled "Latest Developments in Congestive Heart Failure for the General Practitioner" with a prominent statement appearing on the cover that it was "An educational service from Servier Laboratories". Although the cover noted that it included formal notification of a data sheet change, the cover did not in itself refer to Coversyl. The Panel considered that the brochure was a promotional item for Coversyl which was concerned solely with that product. The title page which formed the cover of the brochure was therefore misleading and a breach of Clause 7.2 was ruled.

The Panel also considered that it was misleading not to specify that the author of the third section in the brochure entitled "Heart Failure: the challenge of appropriate drug therapy", was an employee of Servier. The author's name was presented as the author of the section together with his qualifications and an unexplained reference to IRIS, Slough, UK. This was the same format given to the author of the first section in the brochure who was described as an independent doctor at a named hospital. The impression given by the presentation of name of the employee of Servier was that he was independent of the company. The Panel therefore ruled a further breach of Clause 7.2.

Finally, the Panel noted, as acknowledged by Servier, that the contents page at the front of the brochure listed the original articles summarised in the brochure by way of a series of promotional claims for Coversyl. These claims were repeated as the prominently displayed headings to each piece in the brochure summarising the original articles. Thus, the contents page and the main heading to the section in the brochure was "Coversyl prevents mortality caused by ventricular fibrillation post infarction" whereas the actual article was entitled "Converting enzyme inhibitors prevent early post infarction ventricular fibrillation in the anaesthetised rate (sic)". Similarly with the second article noted by the complainant, the contents page and the main heading to the section in the brochure was "Coversyl reverses myocardial structural and functional changes which occur in heart failure" whereas the actual article was entitled "Hormonal and cardiac effects of converting enzyme inhibition in rat myocardial infarction". The Panel considered that it was quite misleading to both list these claims as the reference to the articles in the contents page and to repeat them as headings to each section summarising the articles in the brochure when the studies themselves were limited to studies in a small number of rats. The claims did not reflect the limitations on the data in the studies. The Panel therefore ruled there was a further breach of Clause 7.2 of the Code.

APPEAL BY SERVIER

Servier appealed against the Panel's rulings and reaffirmed its submission to the Panel. It was abundantly clear from the cover of the brochure that it was a company produced item and from the reference to the data sheet change on the cover that it was concerned with the company's product. There was no intention to mislead by the reference to IRIS in the third section in the brochure. The acronym IRIS was used in international referencing in published papers in reputable peer reviewed journals. Readers would not be misled by the reference to IRIS as, in the company's view, if they did not understand what it stood for (Institut de Recherches Internationales Servier) that would only raise a query in the mind of the reader rather than put the article in a better light. With regard to the final point, the company considered that the complaint was patently untrue as it was clearly stated in the text of the brochure that the data was derived from the rat.

APPEAL BOARD RULING

The Appeal Board considered that on balance the cover of the brochure did not mislead as to its contents as it was clearly a pharmaceutical company item related to one of its products. The Appeal Board therefore ruled there was no breach. The appeal therefore succeeded on this point.

The Appeal Board considered, however, that it was misleading to reference the third section in the brochure as being by someone from IRIS, Slough, as it did create the impression for those not familiar with the term IRIS that the author was independent of the company. It did not appear that the acronym IRIS was well understood in the UK. The Appeal Board ruled that it was misleading and in breach of Clause of 7.2. The appeal therefore failed on this point.

With regard to the third matter, the Appeal Board considered that Servier had not quite appreciated the point of the complaint. The complainant alleged that the claim "Coversyl prevents mortality caused by ventricular fibrillation post infarction" which appeared both in the list of contents at the front of the brochure and with slightly different wording as the dominant heading in the page discussing the relevant data (the word "reduces" was used instead of "prevents" on the page in which the data was discussed), did not specify that the prevention of mortality referred to data in the rat. This allegation was repeated with the claim that "Coversyl reverses myocardial structural and functional changes which occur in heart failure." The Appeal Board considered that although it could be read in the data provided on the studies that they were based in the rat, both claims were claims for the clinical usage of the product. It was misleading to make such claims based on an

extrapolation of animal data. The Appeal Board therefore considered that the claims were misleading as alleged as they failed to take into account that they were based on studies in the rat and ruled they were in breach of Clause 7.2 of the Code. The appeal therefore failed on this point.

Complaint received 16 December 1994

Case completed 30 March 1995

CASE AUTH/257/12/94

GENERAL PRACTITIONER v 3M HEALTH CARE

Video on angina for patients & follow up market research survey

A general practitioner complained about a video on angina issued by 3M Health Care and publicised in newspapers and a follow up market research survey carried out on recipients of the video. The Panel considered that the combination of the visual comparison of 3M Health Care's product, Minitran, although not mentioned by name as such, with a competitor patch in the video, together with positive statements about the advantages of patches and the lack of balance, meant that the video encouraged members of the public to ask their doctors to prescribe a specific medicine. Further, the Panel ruled that the market research survey constituted disguised promotion.

COMPLAINT

A general practitioner submitted a complaint about a video on angina entitled "Affairs of the Heart" issued by 3M Health Care Limited.

The complainant explained that one of his patients had attended surgery recently requesting patches for angina. The patient had brought a video and informed the complainant that he had been sent it following a request to an address published in a national newspaper. Following the dispatch of the video, a lady claiming to be a medical practitioner had made enquiries regarding the usefulness of the video and advised the patient that he should approach his GP for patches for angina.

The complainant was unhappy about such an approach by a self styled medical practitioner which was clearly against accepted medical ethics and code of conduct.

RESPONSE

3M Health Care Limited submitted that Minitran, its transdermal nitrate patch, was a pharmacy medicine and not a prescription only medicine. The company submitted that its relationships with patients were accordingly somewhat different.

3M submitted that the video was produced as a service to patients. It was publicised via press releases to national and some local newspapers and also through leaflets in doctors' surgeries and in pharmacies. Copies of the video, the script, press releases and articles from various newspapers were provided.

3M advised that following distribution of the video, patients were contacted by telephone to establish whether they had found it useful. The market research was organised by the company responsible for the promotion and subcontracted to a telemarketing company which was experienced in conducting market research by telephone. The questions asked were provided. It was not part of the brief to pretend to be a doctor or to advise patients to visit their own doctor.

RULING

Firstly, the Panel noted that Minitran was a pharmacy medicine and not a prescription only medicine. It considered that Clause 20.1 as currently worded did not apply to a pharmacy only medicine. The Panel considered however, that information to the public on Minitran provided by 3M Health Care should comply with the rest of Clause 20.

The Panel's opinion was that the promotion of Minitran to the public was prohibited under regulation 6 of The Medicines (Advertising) Regulations 1994 SI 1932. Schedule 1 listed cardiovascular diseases as being a disease in respect of which advertisements to the public were prohibited. Minitran would come within this prohibition.

The Panel noted that the box for the video stated that it was for people with angina whereas the leaflet inside the box stated that it was for patients whose angina was controlled by nitrate patches. The articles from newspapers appeared to be offering the video to angina patients generally and not only to those controlled by nitrate patches.

The Panel considered that the video was not balanced as it gave a lot of information about the advantages of transdermal nitrate patches generally, and specifically Minitran, although the product was not mentioned by name as such. Other treatments, these being betablockers, calcium antagonists and treatment with oral nitrates, were only mentioned briefly. The video featured too much on the benefits of the 3M patch.

The Panel noted the requirements of Clause 20.2 that statements must not be made for the purpose of encouraging members of the public to ask their doctors to prescribe a specific medicine. The Panel considered that the combination of the visual comparison of Minitran with a competitor patch in the video, together with positive statements about the advantages of patches and the lack of overall balance, meant that the video encouraged members of the public to ask their doctors to prescribe a specific medicine. The Panel ruled a breach of Clause 20.2 of the Code.

The Panel noted the company's submission that recipients

of the video were contacted by a market research agency whereas the complainant stated that the approach had been made by a medical practitioner. The Panel considered that there might have been a misunderstanding and, lacking definitive evidence on the point, decided to make no ruling on this aspect of the complaint.

The Panel noted that of the five questions asked under the market research survey, two were general relating to whether the person had actually received the video and whether the recipient suffered from angina. The remaining three questions were whether the recipient wore a skin patch for angina, whether the recipient remembered the scene showing the different patches that were available and finally the question "When you next see your GP, do you intend to mention the video and discuss the subject of patches with him/her?".

The Panel did not accept that the questions constituted genuine market research. It was simply a method of reinforcing the messages in the video and encouraging patients to ask their doctors about nitrate patches. The Panel considered that the questions constituted disguised promotion and therefore ruled a breach of Clause 10.1 of the Code.

The Panel then considered whether or not there had been a breach of Clause 2 of the Code as the combination of the video and the questionnaire could be viewed as reducing confidence in the industry by undermining the valuable services provided by the industry in supplying information for patients on disease areas etc. On balance, the Panel decided that the video and questionnaire did not constitute a breach of Clause 2 of the Code.

Complaint received 20 December 1994

Case completed 27 January 1995

CASE AUTH/261/1/95

DIRECTOR/PARAGRAPH 16 v MEMBER COMPANY

Sample request card

The Panel noted during the consideration of an earlier case that a prepaid sample request card did not make provision for the applicant to sign and date it. The matter was taken up under Paragraph 16 of the Constitution and Procedure.

The company concerned indicated that samples would not actually be sent in response to the card and that a signed and dated request would be obtained before samples were supplied. No breach of the Code was ruled.

COMPLAINT

This complaint had arisen during the consideration of an earlier case (Case AUTH/246/11/94) when a possible breach of the Code had been identified under the procedure set out in Paragraph 16 of the Constitution and Procedure.

The Panel had noted that Clause 17.3 of the Code stated that "Samples may only be supplied in response to written requests which have been signed and dated." In the earlier case, the company had stated that its letter to the complainant had said that it was necessary to return an enclosed prepaid card. A copy of this had been provided but it had not been clear that the requirements of Clause 17.3 had been met as there was no indication on it that a signature and date were required.

RESPONSE

The company said that it was true that the card did not make it clear that samples could only be supplied in response to written requests which had been signed and dated. However, the card was only intended to offer information concerning the supply of samples or information on a variety of matters. The company believed that this was clear from the paragraph preceding the various offers. The card in itself was not intended as a vehicle through which samples might be requested or supplied.

The company nevertheless recognised the possibility of confusion and stated that it would ensure that in future communications any reference to the supply of samples would clarify that a written request, signed and dated, was required prior to delivery.

PANEL RULING

The Panel accepted the company's statement that it was not its intention to actually supply samples without a signed and dated written request. It was accordingly ruled that there had been no breach of the Code.

Proceedings commenced 5 December 1994

Case completed 6 January 1995

CASE AUTH/262/1/95

GENERAL PRACTITIONER V MEMBER COMPANY

Letter to practice nurses

A general practitioner complained about a letter sent to practice nurses by a member company, alleging that its tone denigrated other pharmaceutical companies and the industry as a whole and that advertisements for prescription only medicines should not be sent to nurses. It was further alleged that the evidence for statements made in the letter was neither strong nor convincing in what was a controversial and unresolved area. The Panel considered that the letter was not unacceptable in the circumstances and found no breach of the Code.

COMPLAINT

A general practitioner complained about a letter sent by a member company to practice nurses in relation to the administration of medicines in a particular therapeutic area. He considered that the tone and detail of the letter denigrated rival pharmaceutical companies and the industry as a whole. He was concerned about the fact that the letter had gone to practice nurses even though it concerned prescription only medicines and he considered that the evidence put forward in the letter for the statements made therein was neither strong nor convincing. He was unhappy that his practice nurse was being urged to make changes to medication and its administration in this controversial and unresolved area.

RESPONSE

The company explained that the letter had been sent out to give an overall picture of the subject and had also been a response to materials sent to practice nurses and others by another company. The Code allowed appropriate materials to be sent to members of the health professions and these included nurses. The company explained in detail the basis of the statements which had been made in the letter.

RULING

Having reviewed the information provided by the company, the Panel considered that the letter was reasonable in the light of the data and in the context of the continuing debate on the matter. The tone of the letter was strong but not unacceptable under the circumstances, which included material from another company dealing with the same issues. The Panel noted that the Code permitted the promotion of medicines, including prescription only medicines, to nurses, provided that what was sent to them was appropriate as provided for in Clause 12. The Panel did not consider the letter to be unsuitable for sending to nurses. The Panel ruled that there had been no breach of the Code.

Complaint received 11 January 1995

Case completed 2 March 1995

CASE AUTH/263/1/95

GLAXO PHARMACEUTICALS v CHARWELL PHARMACEUTICALS

Claim in brochure for efficacy of Migraleve based on sales data

Glaxo Pharmaceuticals complained about a claim in a Migraleve mailing issued by Charwell Health Care that "Two Migraleve Pink tablets taken early should be sufficient to stop a migraine developing in 60% of cases" based on sales data. The Panel ruled the claim in breach as, although the sales data for Migraleve might have been of some relevence in promoting the efficacy of the Pink tablets in preventing migraine in very general terms, it was not adequate to substantiate a specific claim for efficacy such as the one in question.

COMPLAINT

Glaxo Pharmaceuticals UK Limited alleged that a claim in a Migraleve mailing (ref 5/94/Pn) that "Two Migraleve Pink tablets taken early should be sufficient to stop a migraine developing in 60% of cases" based on sales data was in breach of Clauses 7.2 and 7.3 of the Code. It was unacceptable in Glaxo's view to use sales data to support a claim for efficacy. The standard of proof of efficacy was the clinical trial and to suggest that sales were a valid measure of a specific efficacy claim of 60% was misleading, inaccurate and unbalanced.

Glaxo also criticised a delay of six weeks in Charwell responding to its request for supporting data for the claim.

RESPONSE

Charwell submitted that it was well established that any claim should be taken in its particular context and if a claim was expressed in strong and/or unqualified terms, then usually stronger supporting evidence would need to be supplied. The disputed claim was qualified in that it stated that the two Pink tablets taken early "should be" sufficient to stop migraine developing in 60% of cases.

Furthermore, although the company accepted the view that sales data should not usually be used to support

efficacy claims, it did not consider that sales data was totally irrelevant to efficacy. There could come a stage when particular sales data, over a long period with very large volumes involved, could be a powerful indicator in support of a particular claim.

The company explained that when Migraleve was introduced in 1971, the packed presentation consisted of duo packs (containing Pink Migraleve and Yellow Migraleve tablets in the ratio 2:1) and supplementary packs of Yellow Migraleve tablets. Within a short period of time it became evident that packs of Pink Migraleve tablets alone were required because migraine attacks were being successfully treated and/or controlled by a single dose of two Pink tablets without the follow on Yellow tablets being necessary. Packs of Pink tablets were introduced in 1972 and since then they had been the most rapidly growing of all the Migraleve pack presentations.

Charwell submitted that presuming that the vast majority of users followed the dosage recommendations, it knew from its sales data that two Pink tablets were taken for every 0.8 Yellow tablets, and on this basis, presuming that users of the Yellow tablets only took a single two tablet dose, then more than 60% of users only took Pink Migraleve. Sales data to substantiate this claim were submitted. The company pointed out that the figures for the ratio of Pink:Yellow tablets were remarkably consistent. During the twelve month period ending March 1994, over twenty four million pink tablets were sold representing treatment of up to twelve million migraine attacks.

The company submitted that the sales figures adequately supported its statement, bearing in mind their consistency and volume. Additionally, although numbers of patients in Migraleve clinical trials were relatively small, it could confirm that the data generated were not inconsistent with the statement in the Migraleve brochure.

Charwell commented with regard to the time taken to supply substantiating data for the claim to Glaxo, that apart from an initial delay of just over a month due to the absence of senior personnel on annual leave, it had not been tardy in supplying responses to Glaxo.

RULING

The Panel considered that although the sales data for Migraleve might of some relevence in promoting the efficacy of the Pink tablets in preventing migraine in very general terms, it was not adequate to substantiate a specific claim for efficacy such as the one in question. The expectation from the claim was that Charwell had clinical trial data to show the Pink tablets were effective in 60% of cases in stopping the development of a migraine which was not so. The Panel therefore ruled that the claim was misleading in breach of Clause 7.2 of the Code.

The Panel noted that Glaxo had not specifically made an allegation concerning the delay by Charwell in supplying substantiation of the claim but considered that the delay in responding to Glaxo's request appeared not to be in accordance with the requirements of Clause 7.4 of the Code.

Complaint received	**13 January 1995**
Case completed	**20 February 1995**

CASE AUTH/265/1/95

CONSULTANT CARDIOLOGIST & PHYSICIAN v MEMBER COMPANY

Treatment guidelines issued by pharmaceutical company sponsored continuing medical education organisation

A consultant cardiologist & physician complained about treatment guidelines sent to him by a pharmaceutical company sponsored continuing medical education organisation. The Panel decided that the guidelines were not subject to the Code as the pharmaceutical company was not responsible for them. Although it financed the continuing medical education organisation under whose name the guidelines were produced, it appeared that the college was a separate body run independently of the pharmaceutical company and the guidelines had been produced by an independent body of experts without direct involvement by the pharmaceutical company.

COMPLAINT

A consultant cardiologist & physician complained about treatment guidelines sent to him by a pharmaceutical company sponsored continuing medical education organisation which was accompanied by a letter from the chairman of the panel which had drawn up the guidelines.

The complainant expressed concern that the guidelines failed to take into account more recent studies involving competitor products to that of the sponsoring company. It was alleged that the item was clearly a promotional document and that it was not objective although it had been presented as the result of a consensus conference on the subject and this was unethical and misleading.

RESPONSE

The pharmaceutical company concerned, a member of the ABPI, provided detailed information on the continuing medical education organisation and its relationship with it. It was explained that the guidelines had been produced by a panel of experts following four scientific meetings held under the auspices of the continuing medical education organisation. The guidelines were sent to all invitees to the meetings with a covering letter from the chairman of the panel indicating that the guidelines were not definitive and inviting comments. There was no input by the pharmaceutical company or the continuing medical

education body in the preparation of the guidelines with neither body acting in an editorial capacity or offering comments prior to publication.

The company submitted that the guidelines accurately reflected the discussion at the various meetings which had occurred at that time but agreed that it could be argued that events had overtaken the guidelines to the extent that they were not reflective of current literature and therefore required updating. This would be conveyed to the chairman of the panel of experts.

RULING

The Panel considered the information before it and noted that although the pharmaceutical company was concerned in financing the continuing medical education organisation under whose name the guidelines were produced, it appeared that the organisation was a separate body run independently of the pharmaceutical company. The Panel considered that the guidelines had been produced by an independent body of experts without direct involvement by the company.

The Panel decided in the circumstances that the guidelines were not subject to the Code as the company was not responsible for them and ruled that the guidelines and the accompanying letter by the chairman of the panel of experts which produced the guidelines were outside the scope of the Code. This was without prejudice to the question of whether other material produced by the continuing medical education organisation could come within the scope of the Code.

Complaint received	**23 January 1995**
Case completed	**31 March 1995**

CASE AUTH/266/1/95

GENERAL PRACTITIONER v MEMBER COMPANY

Sponsored journal

A general practitioner alleged that an issue of a journal sponsored by a member company masqueraded as an independent journal whereas it was in fact advertising material for a product. Three allegations were made about the contents.

The Panel noted that the company's sponsorship had been declared and it did not accept that the journal was disguised promotion. No breach of the Code was ruled.

One of the articles had been influenced by the company and that article was considered to be promotional. The Panel decided, however, that overall the journal was not promotional. Nonetheless as it was distributed by the representatives from the company it had been used for a promotional purpose.

With regard to the specific allegations, which related to articles over which the company had no influence, the Panel considered that it would have been desirable if the product highlighted by the complainant had been included in a relative toxicity table but in the circumstances the Panel ruled no breach of the Code. A cost comparison chart was ruled not to be in breach of the Code as it was clear that it referred to the price of branded products. Finally with regard to statements about affects on liver toxicity, the Panel considered that the statements were personal views of the authors and not inconsistent. No breach was ruled.

COMPLAINT

A general practitioner, alleged that a general practice journal sponsored by a member company masqueraded as an independent journal whereas it was in fact advertising material for a member company's product.

The complainant alleged that the journal presented distorted information and cited three instances. Firstly, a chart showing the relative toxicity of a number of products in which the company's product came out best but another product was not included. Secondly, that a cost comparison chart which only showed the cost of branded products was a deliberate attempt to misinform. Finally, there was a discrepancy as one section of the journal stated that a competitor product had some liver concerns whereas elsewhere it stated that it was rare for the class of products to seriously affect the liver.

RESPONSE

The company explained that it was contacted by the publisher which invited the company to sponsor a particular issue of the journal. The company agreed to sponsor the issue on the basis that the journal would include an advertisement for its product and an article reviewing its product. The journal clearly stated that the issue was sponsored by the company. There was an advertisement on the back page of the journal.

The company submitted that with the exception of the article on its product, the articles were independently written by experienced pharmacists and two experts in the field respectively and were not edited by the company. It did, however, supply clinical data to the publisher at its request, which was forwarded to the authors to assist them in their research. Final copies of the articles were sent to the company for information although it had no influence over the content other than the article on its product. The company submitted that it did not have any influence on the layout, subject matter, contents and conclusions in the journal.

The company submitted that the article reviewing its product was written on the basis of clinical data supplied by it and had been edited by the company. Final approval rested with the author. The company submitted that the article was non promotional; however, as a safeguard, it was passed through the company's approval procedure for promotional copy and certified. Prescribing information was provided as a precaution, although the

article itself made no reference to the brand name of the product.

The journal was distributed by the publisher's mailing organisation to current and prospective fundholding GPs and to medical and pharmaceutical advisers. In addition, the company's representatives had been issued with copies of the magazine.

With regard to the specific allegations raised by the complainant, the company submitted that the relative toxicity table was a representative selection of products from a table in a published paper.

With regard to the cost comparison chart, the company pointed out that it was clearly headed that it referred to brands and that the accompanying text stated "These charts are not comprehensive. For example, generic substitutes are available for some of the branded formulations .....".

With regard to the issue concerning affects on the liver, the company submitted that the complainant had quoted from two contributors, and both views were personal views based on experience and should be viewed in that light.

RULING

First the Panel had to decide whether or not the journal was a promotional item in itself. The Panel noted that the whole area of company sponsored publications and reports from symposia etc was not at all clear cut under the Code. Although the Authority received many enquiries about such publications, it had little in the way of precedent. The decision as to whether or not a sponsored publication was promotional had to be taken on the facts of the particular case.

The Panel considered that the fact that a company sponsored an item did not in itself necessarily make that item promotional for that company's products.

The Panel noted that although one article in the journal had been influenced by the company, the other articles were written by independent authors commissioned by the publisher rather than by the sponsoring company and that the only editorial input on the part of the sponsoring company was restricted to sight of the articles before publication.

The Panel decided that the journal was not masquerading as an independent journal as alleged. The company's sponsorship was declared in the front of the journal. The Panel therefore ruled there was no breach of Clauses 9.9 and 10.1.

The Panel considered that the journal was breaking new ground as the item consisted of a number of articles which were not edited by the company, the article which was edited by the company followed by prescribing information and an advertisement on the back page. The Panel decided that overall the journal was not promotional but as the company had some control over one article, that article would be considered as being promotional and subject to the Code. It would have been preferable if the company's involvement in the article had been stated in the heading in order to distinguish it from the other articles in the journal. There was, however, no specific complaint about the content of that article. The complaint concerned articles written by the other authors over which the company had no control.

The Panel decided nonetheless that as the journal was distributed by representatives from the company it had clearly been used for a promotional purpose and its use therefore came within the scope of the Code.

The Panel considered with regard to the relative toxicity table that it might have been desirable for the omitted product highlighted by the complainant to have been included as it was a standard treatment. It noted that the results with the company's product were, however, slightly better than the omitted product. However, the article in which the chart appeared was independently written and in the circumstances the omission was not unacceptable. The Panel therefore ruled no breach of the Code.

With regard to the cost comparison chart, the Panel noted that beside the generic name of each product, the appropriate brand name was given. It was clear that the chart was referring to the prices of branded products and the Panel therefore ruled no breach of the Code.

The Panel considered that comments made with regard to affects on the liver were personal views and were not inconsistent and ruled no breach of the Code.

Complaint received	**26 January 1995**
Case completed	**27 March 1995**

CASE AUTH/267/2/95

ANTIGEN PHARMACEUTICALS v NON MEMBER COMPANY

Claim in a journal advertisement

Antigen Pharmaceuticals alleged that a claim in a journal advertisement issued by a non member company could not be substantiated. The Panel ruled that the advertisement was not subject to the Code as it was for a container and there was no mention of any medicine.

COMPLAINT

Antigen Pharmaceuticals (UK) submitted a complaint regarding a journal advertisement issued by a non member company for a container in which a number of medicines were supplied. Neither company was a member of the ABPI but both had nevertheless agreed to comply with the Code.

Antigen drew attention to a claim in the advertisement concerning sales and alleged that there was no proof to substantiate the claim. Breaches of Clauses 7.3 and 7.4 of the Code were alleged.

RESPONSE

The company concerned submitted that the advertisement did not fall within the scope of the Code. The advertisement was specifically directed towards a container and made no reference in any form to pharmaceutical indications or claims. The claim queried could be substantiated but it was not its intention to provide a competitor with a detailed breakdown of sales.

RULING

The Panel examined the advertisement and noted that it only referred to a container. There was no mention of any medicine. The Panel therefore ruled that the advertisement was not subject to the Code.

Complaint received 2 February 1995

Case completed 24 March 1995

CASE AUTH/271/2/95

PHARMACIA v ALCON

Advertisement in European journal for products not licensed in the UK

Pharmacia complained about an advertisement for Viscoat and ProVisc placed by Alcon International in a European journal, alleging that it failed to include prescribing information, that it failed to include non-proprietary names adjacent to the brand names and that the products did not have product licences at the time of the advertisement. The Panel considered that the advertisement came within the scope of the UK Code and ruled breaches in respect of the absence of prescribing information and the lack of product licences.

COMPLAINT

Pharmacia Ltd complained about an Alcon International advertisement for Viscoat and ProVisc in the December 1994 issue of the European Journal of Cataract and Refractive Surgery. It was alleged that the advertisement did not include prescribing information contrary to Clause 4.1 and that there were no non-proprietary names adjacent to the two brand names used contrary to Clause 5.4 and that neither of the two products had a product licence in December 1994. The complaint was taken up with Alcon Laboratories (UK) Limited.

Neither Pharmacia or Alcon Laboratories were members of the ABPI but both were companies which had agreed to comply with the Code.

RESPONSE

Alcon said that the advertisement had appeared in an international journal and had been placed by the company's international office in Fort Worth, Texas. The advertisement carried neither UK product licence information nor the Alcon UK address and so would not lead anybody to assume that these products were advertised for the UK market. Alcon was sure that this was a situation that occurred on numerous occasions with advertisements being placed in international journals with an element of UK circulation for products that did not have local product licences. Alcon did not believe this to be a valid complaint under the UK Code.

RULING

The Panel noted that the European Journal of Cataract and Refractive Surgery was published in London. It was printed in Northern Ireland and it was in English.

Noting the precedent established in Case AUTH/215/9/94 (published earlier in this Code of Practice Review), the Panel decided that advertisements in the journal came within the scope of the UK Code in accordance with the supplementary information to Clause 1.1. It was ruled that the advertisement was in breach of

Clause 3.1 because neither product had a UK product licence at the time of the advertisement and of Clause 4.1 because of the absence of prescribing information. Clause 5.4 did not apply because the advertisement was not an abbreviated advertisement as it was above the maximum size allowed and the failure to put the non-proprietary names adjacent to the brand names was covered by the ruling of a breach of Clause 4.1.

Complaint received	**24 February 1995**
Case completed	**21 March 1995**

CASE AUTH/273/3/95

GENERAL PRACTITIONER v MEMBER COMPANY

Meetings at a hotel

An anonymous general practitioner alleged that two weekend meetings organised by a member company would be a blatant attempt to promote the company's product and that the venue was not suitable. The Panel accepted that the arrangements for the meeting were appropriate and reasonable and ruled no breach of the Code.

COMPLAINT

An anonymous general practitioner submitted a complaint about weekend meetings held at a hotel organised by a member company. The complainant alleged that the meetings were thinly disguised as clinical meetings on a therapeutic area and stated that if some of the company's other activities were any guide, the meetings would be a blatant attempt to promote the company's product to the exclusion of all others. The complainant alleged that a free weekend at a prestigious golfing hotel was not a suitable or legal venue for a serious clinical meeting.

RESPONSE

The company submitted that it had arranged two meetings. On both occasions the chairman was a university professor of medicine. The company submitted that the venue was a central location for doctors attending who practised in the area. The facilities were those of a normal hotel with conference facilities suitable for holding such meetings. The meetings were to run over two half days, Saturday afternoon and Sunday morning.

The company provided copies of the programmes which were essentially similar although one of two of the speakers differed. The programmes consisted of a series of presentations which were neither specific to nor promotional of the company's product in any way except for one presentation in which a general practitioner investigator provided a report on the large scale safety and efficacy study of the product in general practice. Postgraduate education allowance approval had been obtained with regard to the content of the meetings. A total of 240 general practitioners (120 for each meeting) were invited from the area. The company provided copies of the invitation together with lists of delegates invited and details of the costs etc.

RULING

The Panel noted that the programme consisted of a Saturday afternoon and a Sunday morning of presentations. Overnight accommodation was provided. The presentations covered a range of topics and were not solely promotional of the company's product. The Panel considered that the programme had a clear educational content. It was not unreasonable for the company to promote its product. The Panel considered that the venue was acceptable given that the delegates would be attending what amounted to one full day of lectures. It was reasonable to provide overnight accommodation and the costs were not inappropriate. The invitations stated that it was not possible to accommodate any accompanying persons.

The Panel considered that the meetings and their arrangements were acceptable and therefore ruled no breach of Clause 19 of the Code.

Complaint received	**6 March 1995**
Case completed	**21 March 1995**

CODE OF PRACTICE REVIEW - MAY 1995

CASES

AUTH/169/6/94	Zeneca v Vestar	Medical representative's letter on AmBisome - rescission by Vestar of its agreement to accept the jurisdiction of the Authority	Breach 4.1, 7.10	No appeal
AUTH/177/7/94	Serono v Organon	Normegon booklet for patients & price comparison data	Breach 7.2	Appeal by both complainant and respondent
AUTH/187/7/94 AUTH/189/7/94 AUTH/197/8/94 AUTH/198/8/94	Glaxo/Clinical director of NHS trust v Lederle/SmithKline Beecham	Use of economic evaluation in promotional material for Zoton, unfair comparisons & substantiation of claim in newspaper	Breach 7.2, 7.4	Appeal by both respondents
AUTH/206/8/94	Parke-Davis v Wellcome	Lamictal promotional material & letter to journal	Breach 7.2	Appeal by respondent
AUTH/208/9/94	Wellcome v Parke-Davis	Allegations concerning Neurontin detail aid	Breach 7.2	Appeal by respondent
AUTH/209/9/94	GP v member company	Post marketing surveillance study	No breach	Appeal by respondent
AUTH/210/9/94	GP v Cyanamid	Offer of loan of ambulatory BP machine in return for prescribing Monocor	Breach 2, 15.2 & 18.1	No appeal
AUTH/215/9/94	GP v Astra Pharmaceuticals	Pulmicort Turbohaler advertisement in an European journal subject to UK Code	Breach 4.1, 7.8	Appeal by respondent
AUTH/216/9/94	Dumex v CP Pharmaceuticals	Misleading quotation in Diazepam RecTubes detail aid	Breach 7.2	Appeal by respondent
AUTH/219/9/94	Director v Boehringer Ingelheim	Promotion of Motens for unlicensed indication in a bulletin	Breach 3.2	Appeal by respondent
AUTH/221/10/94 AUTH/222/10/94	Biogen v member companies	Newspaper articles on new but unlicensed treatments in a disease area	No breach	No appeal
AUTH/223/10/94	Health authority quality controller v member company	Letter to practice nurses & letter in a journal referring to study conducted by complainant	No breach	No appeal
AUTH/224/10/94 AUTH/225/10/94 AUTH/226/10/94 AUTH/227/10/94 AUTH/228/10/94 AUTH/229/10/94	Anon v Schering Plough/Lilly Industries & member companies	Wine tasting evenings at a general practice	Breach 19 & no breach	Appeal by three respondent
AUTH/230/10/94	NHS trust hospital director of finance v member company	Allegation concerning representative's offer for future tenders	No breach	Appeal by complainant
AUTH/231/10/94 AUTH/232/10/94 AUTH/233/10/94 AUTH/234/10/94 AUTH/235/10/94 AUTH/236/10/94 AUTH/237/10/94 AUTH/238/10/94 AUTH/239/10/94 AUTH/247/10/94	GP v member & non member companies	Venue & hospitality at meetings organised by a postgraduate medical centre	No breach	No appeal
AUTH/240/11/94	GP v member company	Statement in journal advertisement & failure to provide copy of study	No breach	No appeal

CODE OF PRACTICE REVIEW - MAY 1995

CASES

AUTH/241/11/94	GP v member company	Cost information in a leaflet	No breach	No appeal
AUTH/242/11/94	Director v member company	Alleged breach of undertaking	No breach	Appeal by complainant
AUTH/244/11/94	GP v member company	Claim made by representative	No breach	No appeal
AUTH/245/11/94	Norgine v Galen	Omission of legal classification & all embracing claim in Manevac abbreviated advertisement	Breach 5.4 & 7.8	No appeal
AUTH/246/11/94	Regional health authority executive v member company	Offer of samples	No breach	No appeal
AUTH/248/11/94	Chief administrative pharmaceutical officer v member company	Promotion of a product	No breach	No appeal
AUTH/250/11/94	Director v member company	Drug & Therapeutics Bulletin article criticising the promotion of a product	No breach	No appeal
AUTH/251/11/94	FHSA pharmaceutical adviser & practice nurse facilitator v member company	Conduct of a representative at a meeting for practice nurses	No breach	No appeal
AUTH/252/11/94	Director v member company	"Dear Practice Nurse" letter - matters taken up under Paragraph 16	No breach	Appeal by respondent
AUTH/253/12/94	Pfizer v Duphar	Cost comparison chart in a Faverin advertisement	Breach 7.6	No appeal
AUTH/255/12/94	Duphar v Pfizer	Allegations concerning Lustral detail aid	Breach 7.2, 7.8	No appeal
AUTH/256/12/94	Hospital pharmacist v Servier Laboratories	Review brochure on Coversyl	Breach 7.2	Appeal by respondent
AUTH/257/12/94	GP v 3M Health Care	Video on angina for patients & follow up market research survey	Breach 10.1, 20.2	No appeal
AUTH/261/1/95	Director/Paragraph 16 v member company	Sample request card	No breach	No appeal
AUTH/262/1/95	GP v member company	Letter to practice nurses	No breach	No appeal
AUTH/263/1/95	Glaxo v Charwell	Claim in brochure for efficacy of Migraleve based on sales data	Breach 7.2	No appeal
AUTH/265/1/95	Consultant cardiologist & physician v member company	Treatment guidelines issued by pharmaceutical company sponsored continuing medical education organisation	No breach	No appeal
AUTH/266/1/95	GP v member company	Sponsored journal	No breach	No appeal
AUTH/267/2/95	Antigen v non member company	Claim in a journal advertisement	Outside Code	No appeal
AUTH/271/2/95	Pharmacia v Alcon	Advertisement in European journal for products not licensed in the UK	Breach 3.1, 4.1	No appeal
AUTH/273/3/95	General practitioner v member company	Meetings at a hotel	No breach	No appeal

PRESCRIPTION MEDICINES
CODE OF PRACTICE AUTHORITY

The Prescription Medicines Code of Practice Authority was established by The Association of the British Pharmaceutical Industry (ABPI) in 1993 to operate the Code of Practice for the Pharmaceutical Industry at arm's length from the ABPI itself.

Compliance with the Code is obligatory for ABPI member companies and, in addition, more than fifty non member companies have voluntarily agreed to comply with the Code and to accept the jurisdiction of the Authority.

The Code covers the advertising of medicines to health professionals and administrative staff and also covers information about such medicines made available to the general public.

It covers:

- journal and direct mail advertising
- the activities of representatives including detail aids and other printed material used by representatives
- the supply of samples
- the provision of inducements to prescribe, supply or buy medicines by the gift, offer or promise of any benefit or bonus, whether in money or in kind
- the provision of hospitality for promotional purposes
- the sponsorship of promotional meetings
- the sponsorship of scientific meetings including payment of travelling and accommodation expenses in connection therewith
- the provision of information to the general public either directly or indirectly
- all other sales promotion in whatever form, such as participation in exhibitions, the use of audio-cassettes, films, records, tapes, video recordings, electronic media, interactive data systems and the like.

Complaints submitted under the Code are considered by the Code of Practice Panel which consists of the three members of the Code of Practice Authority acting with the assistance of independent expert advisers where appropriate. Both complainants and respondents may appeal to the Code of Practice Appeal Board against rulings made by the Panel. The Code of Practice Appeal Board is chaired by an independent legally qualified Chairman, Mr Philip Cox QC, and includes independent members from outside the industry.

In each case where a breach of the Code is ruled, the company concerned must give an undertaking that the practice in question has ceased forthwith and that all possible steps have been taken to avoid a similar breach in the future. An undertaking must be accompanied by details of the action taken to implement the ruling. Additional sanctions are imposed in serious cases.

Complaints about the promotion of medicines should be sent to the Director of the Prescription Medicines Code of Practice Authority, 12 Whitehall, London SW1A 2DY (telephone 0171-930 9677 facsimile 0171-930 4554).