PRESCRIPTION MEDICINES
CODE OF PRACTICE AUTHORITY

QUARTERLY REVIEW OCTOBER 1993

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Case Reports

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

A number of cases which remained outstanding from 1992 and which were being dealt with under the old procedure have now been completed and reports of these have been circulated (ref: CODE/93/95 of 1 October).

Price Reductions

A number of enquiries have been received about the amendment of prices in promotional material as a consequence of the need to reduce prices on 1 October in connection with either the renewal of the Pharmaceutical Price Regulation Scheme or the limited, or selected, list. The comments below may be of assistance.

i) It is in the interest of advertisers to indicate the new lower prices on promotional material as soon as possible. In the period 1 October to 31 December, however, promotional material will not be considered to be in breach of the Code if it still carries the previous higher price.

During that period, the PMCPA will not include accuracy of price in its routine scrutiny of advertisements.

ii) Care should be taken, however, to ensure that there is no discrepancy between what representatives say and what is stated on written material left with the doctor etc by representatives.

In such circumstances, representatives should point out that the written material has the old price on it rather than the new price which he or she has quoted or should ensure that the price is corrected on the written material, by hand if necessary. This will avoid the possibility of subsequent criticism that what the representative said and what the doctor subsequently found stated in written material were different.

iii) It will not be acceptable at any time to list comparative prices in promotional material where these involve the new lower price of the advertiser's product and the superseded higher prices of competitor products.

Eighth Edition of the Code of Practice for the Pharmaceutical Industry

The current edition of the Code of Practice for the Pharmaceutical Industry is the Eighth Edition which came into operation on 1 January 1993. We are aware that some executives concerned with advertising are still referring to earlier editions.

The Eighth Edition remains available only in typescript because publication in printed form has been deferred until the United Kingdom implements the EC Directive on the advertising of medicinal products for human use. It is hoped that a printed version will be made available around the turn of the year.

EC Directive on the Advertising of Medicinal Products for Human Use

The EC Council Directive on the advertising of medicinal products for human use (92/28/EEC) should have been implemented by member states by 1 January 1993, but most, including the UK, did not meet this deadline.

Current information is that the Medicines Control Agency intends to reconsult on the question of the implementation of the Directive in the UK and that the document setting out its proposals will be out in October. The Association of the British Pharmaceutical Industry (ABPI) will circulate the consultative document to its members when it comes to hand.

The Eighth Edition of the Code of Practice was drafted with a view to incorporating all of the requirements of the Directive in the form which it was understood they would take when implemented in the UK. It is anticipated that only minor changes to the Eighth Edition will prove to be necessary. It had been hoped to put proposals for any necessary changes to the Half–Yearly General Meeting of the ABPI in October but that will not now be possible and it is likely that a Special General Meeting will be held in December to consider any changes found necessary.

Seminars

An important part of the work of the PMCPA is helping pharmaceutical companies with the training of their staff in the requirements of the Code with a view to maintaining high standards of promotion. In the first nine months of this year, seven seminars on the Code of Practice open to all comers were held by the PMCPA at the Royal Society of Medicine and nineteen seminars were held at individual companies.

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

Monday, 4 October **(fully booked)**
Wednesday, 10 November **(fully booked)**
Friday, 10 December

Open seminars will take place at the Royal Society of Medicine in the early part of next year on:

Wednesday, 26 January 1994
Wednesday, 2 March 1994
Wednesday, 27 April 1994

Further details and booking forms for these seminars will be circulated in November.

Seminars can also be arranged for individual companies.

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

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CASE REPORTS
OCTOBER 1993

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

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AUTH/4/1/93

KABI PHARMACIA LTD v B BRAUN MEDICAL LTD

Unsubstantiated and exaggerated claim in Nutriflex and Lipofundin MCT/LCT journal advertisement

Kabi Pharmacia Ltd complained about a journal advertisement for Nutriflex and Lipofundin MCT/LCT issued by B Braun Medical Ltd which appeared in the January 1993 issue of the "British Journal of Intensive Care". Although neither Kabi Pharmacia Ltd or B Braun Medical Ltd were members of the ABPI, both companies had agreed to comply with the Code of Practice.

Complaint There were two matters of complaint. The first related to the claim for Nutriflex:-

> "If you've ever wished for a parenteral nutrition formulation that was ready-to-use, needed no fuss or compounding and provided:
>
> - Optimum nitrogen content
> - Clinically accepted electrolyte profile
> - High level calorific support
> - All in a low volume of solution
> - Unprecedented flexibility, simplicity, convenience and cost effectiveness (you can cut costs by up to 50% when compared to a 3-litre bag).
>
> Then you were dreaming - until today!"

Kabi Pharmacia alleged that it implied that those properties were possessed by Nutriflex and that this could not be substantiated in breach of Clause 4.4 of the First Revision of the Seventh Edition of the Code.

The second matter was concerned with the claim for Lipofundin MCT/LCT:-

> "Lipofundin MCT/LCT is a fat emulsion containing medium-chain and long-chain triglycerides in equal proportions, providing distinct metabolic advantages and demonstrable clinical benefits compared with conventional LCT in terms of:

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- High oxidation rate for more rapid provision of energy
- Faster clearance of triglycerides from the bloodstream
- Improved protein economy and nitrogen balance
- Favourable influence on liver metabolism and morphology due to significant reduction in fatty infiltration and deposition, so safeguarding liver function during critical TPN.
- Reduced influence on immune function parameters."

Kabi Pharmacia alleged there were breaches of Clauses 4.4, 5.1 and 5.2 of the First Revision of the Seventh Edition of the Code in that the claim for "... demonstrable clinical benefits compared with conventional LCT..." was based on the extrapolation of laboratory and metabolic data. None of the references supplied to substantiate the claim found a clinical advantage for the product.

Response B Braun Medical Ltd denied the allegations and submitted detailed material in support of the claims made in the advertisement.

The Case was considered under the provisions of the Eighth Edition of the Code of Practice of 1 January 1993 as the journal advertisement in question appeared following that date.

Ruling The Code of Practice Panel considered that the disputed claim for Nutriflex listed those desirable properties of a parenteral nutrition formulation which it was claimed were met by Nutriflex in the concluding statement "Then you were dreaming - until today!". All but the fifth point listed in the disputed claim concerned properties for Nutriflex which were not disputed. With regard to the fifth point listed, this was in effect a claim that Nutriflex had outstanding flexibility, simplicity and convenience and that furthermore it was also cost effective. The only data submitted by the company with regard to the latter was cost data which was inadequate to substantiate the claim. Cost effectiveness involved an analysis of cost and the outcome of treatment and not simply cost only. Furthermore, it could be said that flexibility already existed by using many combinations produced by different manufacturers. The Panel therefore considered the claim for "Unprecedented flexibility, simplicity, convenience and cost effectiveness..." had not been substantiated and ruled there was a breach of Clause 7.3.

With regard to the disputed claim for Lipofundin MCT/LCT, the Panel accepted that there was some evidence to show possible clinical advantages with MCT/LCT over LCT alone but considered the claim for "demonstrable clinical benefits" in terms of those points listed in the advertisement overstated the available evidence. The Panel therefore ruled that the claim was exaggerated in breach of Clause 7.8 of the Code.

Complaint received **20 January 1993**

Case completed **2 June 1993**

AUTH/8/1/93

THE DIRECTOR V MEMBER COMPANY

Newspaper article critical of the promotion of a medicine

Complaint In accordance with established practice, a newspaper article critical of the promotion of a medicine by a member company was taken up under the Code. The item was critical of the cost of the product and a university research fellow was quoted as accusing the company of using misleading

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statistics to encourage doctors to prescribe it. The company concerned indicated that it was unable to identify the item which was the subject of complaint and the research fellow was accordingly invited to identify it and to indicate his concerns.

A product monograph which described data from a meta analysis of trials involving the product, another medicine and a placebo, was identified by the research fellow. It was alleged that the data did not support the monograph's suggestion that the product was superior; the analysis described comparisons between each medicine and a placebo but direct comparison between the two groups was not reported and a formal direct comparison of the results did not indicate a statistically significant advantage for the product.

Ruling Having examined the underlying papers in the light of the company's comments on the allegations, the Code of Practice Panel was satisfied that these did derive from studies directly comparing the product itself, another medicine and a placebo. The Panel further noted that the monograph referred to the "possible" superior effects of the product in certain regards. This statement was derived from the summary of a published paper. The Panel considered that the qualified statement was not unreasonable in the light of the evidence and the fact that it appeared in the body of the text in a detailed product monograph which provided the underlying data. It had accordingly been ruled that there was no breach of the Code.

Case commenced **12 February 1993**

Case completed **28 May 1993**

AUTH/19/3/93 & AUTH/32/4/93

HOSPITAL DOCTOR AND PFIZER LIMITED V SMITHKLINE BEECHAM PHARMACEUTICALS UK

Allegations concerning the promotion of Seroxat

A hospital doctor made a number of allegations about the promotion of Seroxat by SmithKline Beecham Pharmaceuticals UK (AUTH/19/3/93). Before consideration of that complaint was completed, a further complaint was received from Pfizer Limited (AUTH/32/4/93). As the two complaints had a number of elements in common they were taken together. The allegations involved various promotional items.

Use with lithium & anti-convulsants A Seroxat booklet reported on two studies, one involving patients on lithium therapy receiving Seroxat and the other involving patients on certain anti-convulsants receiving Seroxat. The doctor alleged that it was implied that it was safe to combine lithium and anti-convulsants with Seroxat which was inconsistent with the data sheet for the product which advised caution. Furthermore, a graph showing the results in a study involving patients on lithium demonstrated that there was a trend towards increased levels of lithium toward toxic levels. Pfizer made a similar complaint.

SmithKline Beecham submitted that the data presented was factually correct, reflected its current data base and was complementary to, but not inconsistent with, the data sheet. The copy of a graph submitted by the doctor was taken from a version of the booklet in which, due to a printing error, the colour codes for Seroxat and lithium shown in the diagram had been reversed thus implying that the lithium levels tended to rise which was not so. This had been identified shortly after its introduction and immediately corrected by oversticking with a correct label.

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The Code of Practice Panel accepted that the data presented in the booklet was an accurate reflection of the data and was information additional to that on which the data sheet was based. Although there was some concern that it should have included some reference to the need for caution in concomitant treatment with Seroxat in such patients, the Panel decided on balance that it was not inconsistent with or misleading as to the statements in the data sheet as it was dealing with the use of the product in special clinical circumstances where particular problems were known to arise. The Panel ruled there was no breach of the Code in this regard. The Panel considered, however, that the doctor had been provided with inaccurate information in the booklet with which he had been supplied due to the incorrect labelling of the graph and ruled that there had been a breach of Clause 7.2 of the Code.

Pfizer also complained that a page headed "Reassurance Every Step of the Way" in another Seroxat booklet gave a clear indication that paroxetine could be given in combination with therapy such as lithium and anti-convulsants without the expectation of problems.

SmithKline Beecham said that this booklet had not been in circulation for some time and had been replaced by the booklet complained about above, the relevant section of which was headed simply "In patients taking other medication". The company reaffirmed its submission outlined above that the data were complementary to and not inconsistent with the data sheet.

The Panel noted that the booklet containing the page headed "Reassurance Every Step of the Way" had not been in use for some time but considered that it implied that there would never be a problem with patients taking lithium or anticonvulsants. The information in this earlier item for Seroxat, unlike that in the current item, had not been sufficiently qualified and the Panel ruled that there had been a breach of Clause 7.2 of the Code.

Use in renal or hepatic impairment A section dealing with the use of Seroxat in patients with renal or hepatic impairment reported on pharmacokinetic studies performed in subjects with renal dysfunction and with liver cirrhosis. The doctor alleged that it implied that Seroxat could be used safely in all degrees of hepatic and renal insufficiency, although it was later stated that the dosage levels should be at the lower end of the dosage end in patients with renal or hepatic impairment.

The Panel accepted the submission from SmithKline Beecham that the statements were consistent with the data sheet and provided accurate information on the use of the product in such patients. The booklet clearly stated that there was no change to the starting dose in renal or hepatic impairment. The Panel ruled there was no breach of the Code.

Safety in Overdose A claim "Full recovery was seen in all patients who took overdoses of Seroxat in clinical trials" was alleged by the doctor to imply that the product could be safely given to depressed patients with confidence that if they did take an overdose they would not die.

The Panel reviewed the data submitted by SmithKline Beecham and considered that the claim was a statement of fact relating to experience with overdosage in clinical trials on Seroxat. Some concern was expressed at the heading to the claim "Safety in Overdose" which the Panel considered came close to implying that it was "safe". The Panel decided, however, that on balance the claim was not misleading and ruled there was no breach of the Code.

Relative Selectivity Pfizer alleged that Seroxat promotional material consistently stated that paroxetine was a more selective inhibitor of serotonin reuptake (serotonin versus noradrenaline, in vitro) than any other available antidepressant. Such claims were inaccurate, unbalanced and did not reflect the full body of current knowledge and responsible opinion.

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SmithKline Beecham stated that there were a number of published studies or reviews which had compared the relative selectivity of paroxetine and sertraline (Pfizer's product Lustral). The most recent of these supported its view of the superior selectivity of Seroxat. In its laboratories, paroxetine was consistently more selective than sertraline in respect of both 5HT: noradrenaline (NA) and 5HT:dopamine (DA) ratios. The selectivity ratios for both (NA) and (DA) were relevant. SmithKline Beecham agreed with Pfizer that the balance of published literature concerning the relative selectivity of the SSRIs was not entirely clear. In recognition of this, and in a spirit of compromise, SmithKline Beecham had agreed that it would not use the specific claim for superior selectivity of Seroxat in relation to 5HT reuptake compared to noradrenaline reuptake in future material.

The Panel considered that the evidence was equivocal on the question of relative selectivity and noted that SmithKline Beecham had accepted that the balance of the published literature on the question was not entirely clear. The Panel ruled that there had been a breach of Clause 7.3 of the Code in relation to claims for Seroxat as being a more selective inhibitor of serotonin reuptake (serotonin versus noradrenaline in vitro) than any other available antidepressant.

Early onset of action Pfizer said that there was a clear implication from a claim "Early onset of action" beneath a heading "On the road to recovery, which antidepressant offers more than Seroxat" in a detail aid that Seroxat worked faster than other antidepressant therapies but the evidence offered to justify this major claim comprised two trials with small sample sizes, one comparing Seroxat with lofepramine and the other comparing it with amitriptyline. In one of the studies the difference in onset of action was not statistically significant and the other was methodologically flawed. Other studies subsequently cited by SmithKline Beecham were inadequate to substantiate the claim and certain studies had shown different results.

SmithKline Beecham said that the title of the detail aid in question was clearly intended to encourage the doctor to think about the issues which might be important when prescribing an antidepressant. It was asking a question not making any promotional claim. It was also intended to illustrate that recovery from a major depressive episode may be gradual but clinically relevant improvements in a patient's condition may occur before "full recovery" is achieved. The claim was that paroxetine started to work early in the course of treatment. This was clearly supported by recent studies demonstrating clinical improvement within two weeks. It was not claiming an earlier onset of action.

The Panel considered that the claim "Early onset of action in lifting depression" was a statement of fact and not an implied claim for earlier onset of action. The Panel ruled no breach of the Code.

The criticisms of the studies involving lofepramine and amitriptyline are dealt with below.

Comparison with lofepramine Pfizer complained about a statement that Seroxat was "More effective than lofepramine in lifting depression in the first two weeks" above a bar chart comparing physicians' clinical global impression (CGI) for the two products.

The Panel examined the study used to reference the claim and noted that three assessments had been undertaken. The MADRS and cognitive function assessments had shown no significant differences between the treatments at any time whereas the CGI assessment had shown a statistically significant difference. The study conclusion had been very general. The Panel considered that the claim was misleading as to the significance of the study in that two of the three assessments had shown no difference between the products and the company had chosen only the assessment which had shown a difference. The Panel had ruled that there had been a breach of Clause 7.2 of the Code. SmithKline appealed against this ruling.

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Upon appeal, SmithKline Beecham said that the ruling of the Panel was based upon the observation that of three variable studies only the CGI was statistically significant. This interpretation was both inappropriate and incorrect. The CGI and the MADRS were the two primary efficacy variables. "Cognitive function" assessment, was not a primary efficacy variable but a side effect variable which was not relevant in this context. The CGI showed a very significant difference in favour of Seroxat as compared with lofepramine at week two and a significant difference at week four. The MADRS data showed no significant differences between the two substances but there were consistent trends in favour of Seroxat, with the difference at week four just failing to reach significance. Extracts from the study's statistical report dealing with the MADRS showed a consistent trend in favour of paroxetine in each of the assessments made and in one assessment this difference achieved conventional significance. The MADRS outcome entirely supported the CGI data.

The Code of Practice Appeal Board considered that the CGI data showed a significant difference between Seroxat and lofepramine and that this was supported by the MADRS data. It was considered that the claim had been substantiated and, the appeal was justified. It was ruled that there had been no breach of the Code.

Comparison with amitriptyline The complainant doctor referred to a bar graph which showed a trend towards an earlier onset of action of paroxetine than amitriptyline. He considered that the statement "These results may suggest a more rapid onset of action by Seroxat compared with amitriptyline" was misleading since no statistical analysis had been shown. The quoted reference actually showed that there was no statistical difference between the two treatment groups. In relation to the same graph, Pfizer alleged that the difference in onset of action was not statistically significant as referred to above.

The Panel ruled the bar chart which compared percentages of patients with an HAMD reduction greater than or equal to 50% for Seroxat and amitriptyline to be in breach of Clause 7.6 of the Code because it was not considered to be a fair representation of the data in the underlying study. Any data presented in graphical form carried the implication that it was based on results which were statistically significant as otherwise it exaggerated the significance of those results. That ruling applied similarly to the statement "These results may suggest a more rapid onset of action by Seroxat compared to amitriptyline" which was ruled to be in breach of Clause 7.2. SmithKline Beecham appealed these rulings.

Upon appeal, SmithKline Beecham said that the graph was a factual representation of the study findings. It had been ruled to be misleading because differences between amitriptyline and Seroxat at weeks one and two had not been tested for statistical significance. The chart, however, showed statistically significant improvement in both treatment groups compared to base line percentages of patients responding at each time point identified on the chart. The text stated that "These results may suggest more rapid onset of Seroxat compared with amitriptyline". The quotation was appropriately qualified and taken from the peer review publication.

The Code of Practice Appeal Board considered that too much was being made of the study upon which the claims were based despite the qualification "may suggest". The fact that a statement was a quotation from a paper did not mean that the company was not responsible for what it said. The study had not shown statistically significant differences between the onset of action of Seroxat and of amitriptyline. It was considered that the bar chart and the statement should be taken together as being a single matter and it was ruled that there had been a breach of Clause 7.2 of the Code. The appeal failed.

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Activity of the sertraline metabolite The complainant doctor referred to the fact that a table in a booklet listed fluoxetine and sertraline as having active metabolites with long half-lives. This might be seen as a detrimental quality of both of these substances. One of the references quoted, however, was a data sheet for sertraline which stated that the metabolite was "inactive in in vivo tests". Fluoxetine and sertraline were quoted as having active metabolites based on in vitro testing. The results of in vitro testing might not be applicable to the clinical setting. Pfizer alleged that the booklet misled doctors by stating that sertraline had an active metabolite with a half-life of three to five days. It clearly implied that sertraline had a similar long acting metabolite as fluoxetine. However, whereas the metabolite of fluoxetine was equipotent with the parent substance, the only significant metabolite of sertraline had one twentieth of the pharmacological activity of the parent substance, was innocuous in toxicology tests and was inactive in in vivo models of depression. There was no evidence that the metabolite would compromise the safety or efficacy of sertraline.

The Code of Practice Panel considered that it was misleading to refer to the sertraline metabolite as being active in vitro with a half life of 3-5 days in view of its very low activity, which could at the most have a slight additive effect, and the fact that the data sheet said that it was inactive in vivo. Furthermore, it was misleading to set this information alongside that for fluoxetine in a chart when the metabolite of fluoxetine was equipotent with fluoxetine itself. The Panel ruled that there had been a breach of Clause 7.2 of the Code. SmithKline Beecham appealed this ruling.

Upon appeal, SmithKline Beecham stated that the metabolite of sertraline, desmethylsertraline (DMS), in in vitro studies showed 5-20% of the activity of sertraline, which was itself very potent. A recently published study clearly indicated that the metabolite was active in vitro. The selectivity of DMS was approximately ten-fold less than that of sertraline but it had a much greater half-life and tended to accumulate. In vivo studies show that DMS had 5-66% of the activity of sertraline, dependent upon the model and the species involved.

The Code of Practice Appeal Board considered that the promotional material complained of was literally true as it did refer to the metabolic activity of metabolites in vitro. However, it was established that such statements should not be made unless they could be shown to have some clinical relevance. It was noted that the points had been made in a relatively low key fashion in a booklet intended to answer hospital doctors' questions. In the light of the evidence which was available the Appeal Board considered that, on the balance of probabilities, the activity of the metabolite of sertraline was of clinical relevance. In these circumstances, the Appeal Board considered the appeal was justified and ruled that there had been no breach of the Code.

Complaints received	**AUTH/19/3/93**	**15 March 1993**
	AUTH/32/4/93	**2 April 1993**
Cases completed		**2 August 1993**

CASE AUTH/20/3/93

THE DIRECTOR V MEMBER COMPANY

Unbalanced promotion

Complaint A letter from a general practitioner critical of the promotion of a medicine by a member company was noted in the "British Medical Journal" and, in accordance with established

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practice, was taken up as a complaint under the Code of Practice. It was alleged that the current advertisement for the product was unbalanced.

Response The company concerned submitted comments in relation to each element of the advertisement in question, providing papers in support when appropriate. The company considered the advertisement to be a balanced description of the action and the long term efficacy of the product. Its features had been stated simply within the terms of the product licence.

Ruling The Code of Practice Panel reviewed each aspect of the advertisement in the light of the company's response and the information in the data sheet. It considered that all were couched in terms which were consistent with the data sheet and with the available evidence. Nothing was claimed for the product which went beyond that permitted by the data sheet. The Panel accordingly ruled that there had been no breach of the Code.

Case commenced **16 March 1993**

Case completed **20 May 1993**

AUTH/21/3/93

GENERAL PRACTITIONER V ALLEN & HANBURYS LIMITED

Mailing on Becodisks

Complaint A general practitioner complained that a mailing on Becodisks and their consistency of dose sent by Allen and Hanburys Limited was misleading. The mailing consisted of a "Dear Doctor" letter and an accompanying leaflet (ref: HM0807-OP/NOV 1992).

There were four allegations in total. The first three allegations concerned what were, in the complainant's view, comparisons in the mailing between Becodisks and Rotacaps (another Allen & Hanburys product). The fourth allegation concerned a comparison of the dose reproducibility of the Diskhaler device with the dry powder device based on two in vitro studies. These two separate studies were referred to in the text of the "Dear Doctor" letter and were presented as graphs in the accompanying leaflet. The complainant alleged that the comparison was dangerous and quite misleading as the studies were quoted as being similar when in the first study 10 Diskhaler devices were tested which meant that the graph produced had no statistical significance whatsoever and in the second study, 120 reservoir powder devices were tested.

Response Allen & Hanburys submitted that there had been a misunderstanding with regard to the three allegations referring to comparisons of Becodisk with the Rotahaler as neither the "Dear Doctor" letter nor the accompanying leaflet referred to the Rotahaler device which was a single dose device. The material compared the Diskhaler with a competitor product, a multi dose reservoir powder device. With regard to the use of the dose reproducibility studies, the company submitted that these used the twin impinger method which had been accepted by the Medicines Control Agency. Each study was conducted on sufficient numbers to produce an accurate estimate of dose reproducibility on each occasion. Due to the wide deviation in dose consistency from the reservoir powder device, there was a need to study considerably more in order to achieve a meaningful result. In contrast, the Diskhaler demonstrated a very narrow band of deviation from the mean and therefore in that particular study there was no need to include a large number in order to achieve a meaningful result. Each study

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therefore produced data which could stand alone and could be compared with similar data for another device under identical test conditions.

Ruling The Code of Practice Panel accepted the response from Allen & Hanburys Limited that there had been some misunderstanding as the complainant's first three allegations concerned comparisons of the Diskhaler device with the Rotahaler device whereas in fact the material compared the Diskhaler with the reservoir powder device. The Panel therefore ruled no breach of the Code with regard to the first three allegations.

With regard to the comparison of the dose reproducibility studies, the Panel noted that the letter did not refer to the number of devices used in the tests although this information was given in the graphs in the accompanying leaflet. The Panel considered that the comparison of the dose reproducibility studies of the Diskhaler device with the terbutaline reservoir powder device in both the letter and the accompanying leaflet was misleading as only 10 Diskhaler devices were compared with 120 reservoir powder devices. The results with 10 Diskhaler devices could be due to chance and were not statistically significant. The Panel did not accept the company's submission and ruled a breach of Clause 7.2 of the Code.

Complaint received **19 March 1993**

Case completed **6 May 1993**

AUTH/22/3/93

DIRECTOR V LUNDBECK LIMITED

Article in "The Sun": conduct of a medical representative

The provisions of the First Revision of the Seventh Edition of the Code of Practice for the Pharmaceutical Industry, January 1991, applied in this Case as the promotional activities in question predated 1 January 1993.

Complaint An article in "The Sun" newspaper of 18 March 1993 reported on an industrial tribunal hearing concerning the dismissal by Lundbeck Limited of a medical representative who had distributed pornographic videos to doctors. In accordance with the usual practice, this matter was taken up as a complaint under the Code of Practice. Lundbeck Limited, although not a member of the ABPI, had agreed to comply with the Code.

Response The company explained that in late 1991 it had received a pornographic video which had been provided to a doctor by one of its medical representatives. Its solicitors had advised that the video was an illegal obscene publication. On interviewing the representative in question, he admitted to supplying hard core pornographic videos to a number of doctors for the previous few years. The company clearly did not condone the supply of pornographic videos by representatives to doctors and the representative had accordingly been dismissed with immediate effect. The representative subsequently made a claim for unfair dismissal which had been rejected unanimously by an industrial tribunal. The company did not accept the conduct of the representative as being in any respect part of his professional duties.

Ruling The Code of Practice Panel considered that it was clear that the company concerned had not condoned the activities of the medical representative in question and had taken appropriate action

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when it became aware of them. The Panel noted, however, that it was a well established principle under the Code that companies took responsibility for the conduct of their representatives during the course of their employment. Although there might be circumstances where a company would not be held responsible if a representative was acting quite separately from the scope of his or her employment, this was not such an instance because the distribution of pornographic videos by the representative took place at the same time as his professional contact with doctors.

The Panel ruled there had been a breach of Clause 17.2 of the Code as the representative in question had failed to maintain a high standard of ethical conduct in the discharge of his duties. The Panel also ruled that there had been a breach of Clause 2 of the Code as the actions of the representative in distributing pornographic videos to doctors brought discredit upon the pharmaceutical industry.

In view of the seriousness of the above rulings, the Panel considered the provisions of Paragraph 8.2 of the Constitution and Procedure under which the Panel could report to the Appeal Board any company whose conduct in relation to the Code warranted further consideration. The Panel decided that such a report was not justified in the circumstances of this Case as the company had not condoned the action of the representative in question and had acted promptly and appropriately on discovering the misconduct in question.

Matter taken up **19 March 1993**

Case completed **28 April 1993**

AUTH/23/3/93

HOSPITAL DOCTOR V ALLEN & HANBURYS LIMITED/"DEAR DOCTOR" LETTER ON BECODISKS

Misleading use of references

The provisions of the First Revision of the Seventh Edition of the Code of Practice for the Pharmaceutical Industry, January 1991, applied in this Case as the promotional material predated 1 January 1993.

A hospital doctor complained about a "Dear Doctor" letter on Becodisks issued by Allen & Hanburys Limited. There were four heads of complaint:

Inappropriate use of a reference Firstly, the complainant drew attention to a statement "The Diskhaler overcomes technique problems associated with conventional metered dose inhalers" referenced to a 1982 paper written by the complainant. That paper described only the problems patients have using pressurised aerosol inhalers and made no mention of the Diskhaler or any other dry powder device. It was alleged that the reference had been inappropriately used in the letter to infer that the reference stated that the Diskhaler overcame metered dose inhaler technique problems.

Allen & Hanburys stated that the paper had been referenced because it highlighted many of the potential errors of aerosol inhaler use, the majority of which involved problems of synchronisation of actuation and co-ordination. The reference was used to highlight the problem itself and did not imply that the paper specifically mentioned the Diskhaler.

The Code of Practice Panel took the view that it was misleading to reference the paper to the statement "The Diskhaler overcomes technique problems associated with conventional metered dose

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inhalers" as it implied that it referred to the Diskhaler as overcoming these problems and this was not so. It was therefore ruled that there had been a breach of Clause 4.3 of the Code.

Use of quotation Secondly, the complainant referred to the use of a quotation from another paper written by the complainant "[The reservoir powder device] may become less efficient in situations where the ambient humidity is high. With a relative humidity of 85% the available dose may decrease to 25% ...." which appeared in a section in the "Dear Doctor" letter discussing the Diskhaler system and the protection against humidity it provided because it had individually sealed blisters. The complainant pointed out that in the paper that information was referenced to a paper by another author and that other paper should have been used as the reference in the "Dear Doctor" letter. The complainant's main concern, however, was that mention of ambient humidity with regard to the efficiency of the reservoir powder device was misleading as ambient humidity affected all dry powder devices to the same extent.

Allen & Hanburys pointed out that it accurately quoted from the paper except that a brand name had been changed to "reservoir powder device". The company did not accept that humidity affected all dry powder devices to the same extent. The reservoir powder device was to some extent protected by the cap but there was data to show that the cap did not fully protect against moisture. This might lead to a reduction in the dose which could be taken into the lungs.

The Panel noted that the quotation had been edited to remove the concluding comment "However, in most countries ambient humidity should not alter the efficiency of any DPI's" (dry powder inhalers). The Panel considered that the quotation had been used in a misleading manner in omitting the concluding comment and by not referencing the origin of the information quoted in the complainant's paper and that its significance had been exaggerated. The Panel therefore ruled that there had been breaches of Clauses 4.3 and 5.2 of the Code.

Reference to lactose carrier Thirdly, it was alleged that a statement that "Becodisks utilises a lactose carrier so that patients may taste when the dose has been taken" *(emphasis added by complainant)* was not true as the Diskhaler system would not work without a lactose carrier or vehicle.

Allen & Hanburys said that there were many technical and pharmaceutical reasons for adding the lactose carrier. The first dry powder system which was launched by Allen & Hanburys included lactose mainly for technical reasons. It became clear from handling studies with patients however that they did find reassurance that the dose had been taken from the lactose taste. With this in mind, when the Diskhaler was developed the lactose was intentionally retained, not just for pharmaceutical reasons but because patients benefited from the reassurance that the lactose gave. The company was merely emphasising the benefit derived from the lactose carrier without exploring the other less relevant technical and pharmaceutical formulation details.

The Panel took the view that while lactose might well have the benefit claimed, it was not true to imply that it was the only reason why lactose had been included in the formulation as in the disputed statement. It was ruled that there had been a breach of Clause 4.3.

Effects of breathing into the Diskhaler Finally, it was alleged that a statement "Furthermore, if the patient accidentally breathes into the Diskhaler, only one dose may be affected by moisture" inferred that more than one dose of other dry powder devices would be affected and this was not true.

Allen & Hanburys stood by the statement that only one dose was affected in the Diskhaler and the allegation that this would also be the case for the reservoir powder device was not supported by the evidence. Three papers in this regard were submitted.

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The Panel was of the opinion that the statement "Furthermore, if the patient accidentally breathes into the Diskhaler, only one dose may be affected by moisture" clearly implied, in the context of the letter, that more than one dose could be affected with the reservoir powder device.

The Panel considered that there was some evidence to support the inference that more than one dose could be affected in the reservoir powder device and ruled that there had been no breach of the Code in that regard.

Complaint received **22 March 1993**

Case completed **17 May 1993**

CASE AUTH/24/3/93

CONSULTANT GERIATRICIAN AND DRUG INFORMATION OFFICER V PARKE-DAVIS & CO LIMITED/JOURNAL ADVERTISEMENT FOR LOPID

Claim qualified elsewhere in text of advertisement in breach

Complaint A consultant geriatrician and a drug information officer submitted a complaint about an advertisement for Lopid issued by Parke-Davis & Co Limited appearing in, for example, "Hospital Doctor", 28 January 1993.

It was alleged that a headline claim that Lopid reduced coronary heart disease by 72% was misleading as the reference for the claim indicated that the figure was derived from a study of 23,000 Finnish men between the ages of 40 and 55 of which 164 received Lopid in the subgroup that suffered a 70% reduction in coronary heart disease events. Furthermore, coronary heart disease was usually silent until an event took place. It was therefore misleading to claim that the disease process was reduced rather than the events were reduced. It might be that these events were merely delayed beyond the period of the study.

Response Parke Davis & Co Limited submitted that the claim "Lopid 600 raised HDL, lowers LDL, cuts CHD by 72%" was qualified as it was indicated elsewhere in the advertisement in emboldened text that the reduction in coronary heart disease occurred in high risk patients who had an LDL/HDL ratio >5 and triglycerides>2.3 mmol/L. Further, it was clearly stated in the prescribing information, adjacent to the body of the advertising, that Lopid was indicated for the primary prevention of coronary heart disease in men between 40 and 55 years of age with hyperlipidaemias who had not responded to diet and other appropriate measures. A copy of the reference supporting the claim was provided.

The company submitted that despite coronary heart disease often being silent until an event took place it was fully justified in claiming Lopid reduced coronary heart disease. This was also done by the authors of the Helsinki Heart Study who stated in the published paper on the study that it showed a reduction in the incidence of coronary heart disease having used fatal and non fatal myocardial infarction and cardiac death as the principal end points, rather than coronary angiograms.

Ruling The Code of Practice Panel accepted that it might be possible to claim a reduction in coronary heart disease based on a study reporting cardiac events provided sufficient information was given for interpreting the results. It noted that 154 men had received Lopid and not 164 as stated by the complainant.

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The Panel considered that the claim "Prescribing Lopid 600 raises HDL, lowers LDL, cuts CHD by 72%" was exaggerated and all embracing as it was not sufficiently qualified as Lopid was only indicated for men between 40 and 55 years of age with hyperlipidaemias who had not responded to diet and other appropriate measures and that the 72% figure was derived from data involving patients with certain defined hyperlipidaemic profiles. The fact that the company had indicated in emboldened text elsewhere that the claim applied to high risk patients with certain profiles and the indications for Lopid appeared in the advertisement did not make the claim acceptable. It was a well established principle that one could not correct a misleading or inadequate statement by qualifying it in the small print. In any case the emboldened statement was not very noticeable.

The Panel also considered that the claim was misleading as it failed to reflect the study to which it was referenced. In this regard, the Panel noted that the study stated "Caution is also necessary in the interpretation of these findings, as they are based on a post hoc analysis of subgroups not defined in the original study plan" and "It is important to note that our conclusions are based on a cohort of initially healthy, hyperlipidaemic middle-aged men and are not necessarily generalizable to other populations". Further, it appeared that the claim failed to reflect all the available evidence as another reference supplied by the company stated that "in the Helsinki heart study, a randomised 5 year double blind trial, a 34% in the reduction in the incidence of coronary heart disease (CHD) was observed in dyslipidemic men treated with gemfibrozil".

The Panel therefore ruled that the claim was in breach of Clauses 7.2 and 7.8 of the Code.

Complaint received **26 March 1993**

Case completed **14 May 1993**

AUTH/25/4/93, AUTH/26/4/93 & AUTH/27/4/93

GP V MEMBER COMPANIES

Plain envelopes used for mailings alleged to be disguised

Complaint A general practitioner complained about two plain envelopes sent to her enclosing promotional mailings from ABPI member companies which she alleged to be in breach of Clause 7.5 of the Code (First Revision of the Seventh Edition) in that she could not identify from the outside that they were advertisements. One of the mailings was a joint promotion by two companies and thus it was taken up separately with each of the companies.

As the mailings were sent after 1 January 1993, the attention of the companies concerned were drawn to Clause 10.1 on disguised promotion under the Eighth Edition of the Code of 1 January 1993 which was the equivalent provision to Clause 7.5 of the old Code.

Subsequently, a further complaint was received from another general practitioner about one of the envelopes. As the complaint was the same as that made by the complainant in this Case it was not taken up as a separate matter.

Ruling The Code of Practice Panel noted that under the previous edition of the Code there was reference in the supplementary information to Clause 7.5 on disguised promotional material to doctors resenting promotional material being sent in the guise of personal communications, such as when advertisements were enclosed in plain envelopes, or addressed in real or facsimile handwriting on

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letters or postcards. Under the Eighth Edition of the Code, the prohibition on disguised promotional material remained but the supplementary information had been reworded to delete the reference to the use of plain envelopes as had the reference to the prohibition on the use of first class post. Thus, it was now permitted to use a plain envelope to send promotional material provided that it was not disguised as a personal communication.

The Panel considered that neither of the mailings complained about was disguised as a personal communication. One of the mailings was sent in an envelope with a typewritten address bearing a reference number and was franked second class postage and that the other mailing was sent in a plain window envelope bearing a second class postage paid symbol with a typewritten address showing through. The Panel did not consider they were disguised in any way and therefore ruled there was no breach of the Code.

Complaint received **1 April 1993**

Cases completed **14 May 1993**

AUTH/28/4/93

GP V KNOLL LTD/MAILING ON SECURON SR

Wording on envelope constituted disguised promotional material

Complaint A general practitioner complained about 3 envelopes sent to her which she alleged to be in breach of Clause 7.5 of the Code (First Revision of the Seventh Edition) in that she could not identify from the outside that they were advertisements. One of the mailings was a "Dear Doctor" letter sent by Knoll Ltd in association with the promotion of Securon SR. The other envelopes were those referred to in Cases AUTH/25/4/93, AUTH/26/4/93 and AUTH/27/4/93 above.

The envelope enclosing the Securon SR mailing bore the Ordnance Survey logo on the outside together with the wording "It's a Question of Scale!". The envelope was otherwise plain.

As the mailing had been sent after 1 January 1993, the attention of Knoll Limited was drawn to Clause 10.1 of the Eighth Edition of the Code of 1 January 1993 which was the equivalent provision to Clause 7.5 of the Old Code.

Response Knoll Limited explained that the Ordnance survey logo and the slogan "It's a Question of Scale!" related to a map offer inside the envelope made in association with the promotion of Securon SR.

Ruling The Code of Practice Panel considered that the use of the Ordnance Survey logo and the wording "It's a question of Scale!" was misleading as to the contents of the envelope as it implied that it was something sent by the Ordnance Survey and not a pharmaceutical company.

The Panel therefore decided that it constituted disguised promotional material and ruled there was a breach of Clause 10.1 of the Code.

Complaint received **1 April 1993**

Case completed **6 May 1993**

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AUTH/29/4/93 and AUTH/30/4/93

GENERAL PRACTITIONER V MEMBER COMPANIES

Alleged imitation of another company's promotional logo

Complaint A general practitioner complained that a logo used by one member company in the promotion of its product was similar to a sticker bearing a similar logo provided by another member company when promoting another product. The complainant alleged that it would seem that one company was contravening Clause 7.8 (First Revision of the Seventh Edition) which prohibits promotional material from imitating the devices, copy, slogans or general layout adopted by other companies in a way that was likely to mislead or confuse.

As the promotion in question had taken place since 1 January 1993, the attention of the companies concerned was drawn to the provisions of Clause 9.3 of the Eighth Edition of the Code of 1 January 1993 which was the equivalent requirement to Clause 7.8 in the old Code.

Response The company concerned in Case AUTH/29/4/93 explained that the particular logo had been used in association with the promotion of its product since its launch some years ago and was hence strongly associated as the brand image for the product. The competitor product on the other hand had been launched subsequently and at no time throughout its promotion had there been any association of it with the logo in question.

The company concerned in Case AUTH/30/4/93 explained that the sticker in question was a reflective safety sticker given out as a promotional aid to general practitioners. The image used on the sticker was generic and selected purely to enhance its general appeal and thereby encourage its use as an aid to safety. There was no intention to associate the image with the product and no advertising material for the product bore the image used on the sticker.

Ruling The Panel considered that the first company could not be held to have contravened the requirements of Clause 9.3 in any way as it was the first of the two companies to use the logo in question. The Panel therefore ruled there was no breach.

The Panel noted the circumstances of the use of the logo by the second company and, in particular, that it was not used in any advertising material for the company's product and that the sticker itself did not contain any reference to any medicine or pharmaceutical company. Furthermore, the Panel noted that the particular logo was not an original image but a well recognised device used outside the pharmaceutical industry.

The Panel did not consider that the use of the logo by the second company on the sticker was likely to mislead or confuse in any way and ruled there was no breach of Clause 9.3 of the Code.

Complaint received **1 April 1993**

Case completed **19 May 1993**

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AUTH/31/4/93

DIRECTOR V SMITH & NEPHEW PHARMACEUTICALS LIMITED

Failure to implement undertaking

Complaint At a Code of Practice Familiarisation Seminar held at the Royal Society of Medicine, it was noted by the Prescription Medicines Code of Practice Authority that, in an exhibition in an adjacent area, Smith & Nephew Pharmaceuticals Limited had a stand which, inter alia, bore a panel advertising Ditropan with the claim "Gives them the bladder control they want" prominently displayed. It was recalled that this claim had been ruled by the Code of Practice Committee in Case 1085/1/92 to be in breach of Clauses 4.3 and 5.2 of the Code and Smith & Nephew had accepted this ruling and had given the usual undertaking and assurance.

The Code of Practice Appeal Board had been consulted as to the appropriate course of action to be taken when there had apparently been a breach of an undertaking and the Appeal Board had advised that it should be taken up as a fresh case. Accordingly, the matter had been taken up as a complaint with reference being made to Clauses 7.2 and 7.8 of the Eighth Edition of the Code. In addition, the company was advised that Clause 2 was now relevant because of the apparent failure to comply with the previous undertaking.

Response Smith & Nephew Pharmaceuticals Limited said that the last use of the original advertisement had been in May 1992. A new campaign had been developed using a sailing boat visual and this was also used on new exhibition panels, a photograph of which was provided. Unfortunately an old panel which had not been destroyed was used at the exhibition in question. The mistake has identified a weakness in the company's system concerning the withdrawal of old panels which it had now modified. The fact that the company had changed the advertisement and modified its exhibition panels showed that the company had responded to the original complaint. It regretted the silly error whereby an old panel was not destroyed and subsequently used again by mistake. The company apologised most sincerely for any inconvenience caused by its oversight.

Ruling The Code of Practice Panel ruled that the use of the claim "Gives them the bladder control they want" on the exhibition panel was in breach of Clauses 7.2 and 7.8 of the Code for reasons identical to those in Case 1085/1/92. That is to say that it was exaggerated and misleading as it implied that the product would give absolute bladder control to all patients with urge incontinence and this was not so.

The Panel considered whether there had also been a breach of Clause 2 of the Code in view of the fact that use of the claim represented a failure to comply with the undertaking and assurance previously given. It was noted that the company had taken steps to implement its undertaking and assurance and that the use of the old exhibition panel had been in error. It was considered that these circumstances could be distinguished from those of a previous case where a detail aid had not been withdrawn from use by representatives and a particularly serious view had been taken of the lack of action on the company's part (Case 834/7/89). The Panel ruled that there had been no breach of Clause 2.

Nonetheless, it remained a serious matter for a company to fail to implement an undertaking and assurance and the Panel decided to report the matter to the Code of Practice Appeal Board in accordance with Paragraph 8.2 of the Constitution and Procedure.

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Report to the Appeal Board Having considered the matter and having heard representatives of the company, the Code of Practice Appeal Board decided that in view of the circumstances it was not necessary to take further action and the matter should therefore be regarded as closed.

Case commenced **1 April 1993**

Case completed **19 May 1993**

AUTH/33/4/93 & AUTH/34/4/93

GENERAL PRACTITIONER V MEMBER COMPANIES

Plain envelopes used for mailings alleged to be disguised

Complaint A general practitioner complained that three promotional mailings sent to him by ABPI member companies in plain envelopes were in breach of Clause 7.5 of the Code (First Revision of the Seventh Edition) as there was no indication of what was inside them or who had sent them. As one of the envelopes had already been complained about on the same grounds (Case AUTH/27/4/93) it was not taken up as a separate matter.

As the mailings were sent after 1 January 1993, the attention of the companies concerned were drawn to the provisions of Clause 10.1 on disguised promotion under the Eighth Edition of the Code of 1 January 1993 which was the equivalent provision to Clause 7.5 of the old Code.

Ruling The Code of Practice Panel noted its rulings in Cases Auth/25/4/93, Auth/26/4/93 and Auth/27/4/93 and ruled there was no breach of the Code in relation to the two mailings in question as they were not disguised as personal communications or in any other way. Both envelopes were franked second class post; one mailing bore a typewritten address with an identifying reference number whilst the other mailing was a window envelope displaying a typewritten address and identifying reference.

Complaint received **4 April 1993**

Cases completed **14 May 1993**

CASE AUTH/35/4/93

DIRECTOR OF MEDICAL SERVICES OF A FAMILY HEALTH SERVICES AUTHORITY V ROCHE PRODUCTS LIMITED

Misleading claim

Complaint The director of medical services of a family health services authority complained about a mailing for Vascace (ref: M970083 3/93) sent by Roche Products Limited in March 1993 to its general manager. The complainant considered this misleading, particularly in the assertion that Vascace "has the lowest range of prices for recommended doses..". The normal adult dose according to the data sheet for Vascace was 2.5 mg to 5 mg once daily at a cost of between £10.67 and £17.91 per month at MIMS prices, which compared unfavourably with, for example, ramapril (Tritace) at equivalent normal doses of £7.70 to £9.79 per month. Vascace had a large range of prices because of

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its large range of doses but the mailing would be taken by the average reader to imply that Vascace was the cheapest of the ACE inhibitors to use in normal dosage.

Response Roche Products Limited submitted that data sheet statements on recommended dosage did not represent equivalence of efficacy and in the absence of such data the fairest way to compare prices was to define the patient population and to show the range of doses and prices which may be prescribed. A table comparing prices and doses of Vascace with a number of other ACE inhibitors was submitted.

Ruling The Code of Practice Panel accepted that the claim ".... Vascace has the lowest range of prices for recommended doses of ACE inhibitors in adult (including elderly) patients ....." was factually correct but it considered that it was misleading in that it implied Vascace was the cheapest product at usual adult doses which was not so. The Panel therefore ruled a breach of Clause 7.2 of the Code.

Complaint received **5 April 1993**

Case completed **12 May 1993**

AUTH/37/4/93

THE DIRECTOR V PFIZER LIMITED

Letter in "The Pharmaceutical Journal" concerning an error in a Zithromax dosage card

Complaint A letter from a hospital pharmacist and a consultant paediatrician, published in "The Pharmaceutical Journal" of 20 March 1993 pointed out that a Zithromax dosage card (ref: 70269 Jan 93) issued by Pfizer Limited included an obvious error. The dosage in children under 3 years was given as 0.25 ml per day whereas the dosage according to the prescribing information in the dosage card stated that the dose was 0.25 ml per kg per day.

A reply from Pfizer was also published in "The Pharmaceutical Journal" in which the company accepted that there was an error in the dosage card. The error was noticed before the card was widely distributed. The dosage information was given correctly in the prescribing information. All representatives had been told to destroy their supplies of the item and a new dosage card had been issued.

In accordance with the usual practice, this matter was taken up as a complaint under the Code.

Response Pfizer Limited submitted that it had little to add to the reply published in "The Pharmaceutical Journal". The error was isolated, inadvertent and had quickly been corrected. Copies of the dosage card at issue and of the replacement card were provided.

Ruling The Code of Practice Panel ruled a breach of Clause 7.2 of the Code as the dosage recommendations for children under 3 years old given in the dosage card were inaccurate as acknowledged by the company.

Complaint proceedings commenced **13 April 1993**

Case completed **2 June 1993**

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AUTH/38/4/93

SCOTIA PHARMACEUTICAL LTD V NORGINE LIMITED

Promotion of a medicine with a suspended licence

Complaint A non member company, Scotia Pharmaceuticals Ltd, submitted a complaint regarding an announcement issued by Norgine Limited and appearing in "Chemist and Druggist" of 17 April 1993, concerning the withdrawal of its product Unigam.

Scotia alleged that two paragraphs in the announcement:-

> "UNIGAM was to be the first dual indication gamolenic acid product licensed for both mastalgia and atopic eczema.
>
> The significance to doctors of the introduction of UNIGAM was twofold. Firstly, they could prescribe a single product for both mastalgia and atopic eczema. Secondly, that at a basic NHS price of £17.50 for a pack of 240 capsules, the cost savings provided by UNIGAM of at least 30% compared to other brands, meant doctors could offer the benefits of gamolenic acid to more patients for the same costs."

were in breach of Clause 3 of the Code since they related to the promotion of a product in the absence of a marketing authorization permitting its sale or supply.

Scotia explained that towards the end of 1992 it became aware that Norgine had been granted a product licence for Unigam capsules. The complainant had reason to believe that Norgine had not obtained the licence on the basis of a full product licence application and that the abridged procedure had been used. The complainant considered that as some of the requirements of the abridged licence procedure, which relied upon the published literature exemption, had not been fulfilled the exemption should not apply. The complainant commenced proceedings for a judicial review on the basis that the licensing authority had acted in breach of the EC provisions in granting the licence. On 7 April 1993 the High Court made an order suspending the product licence for Unigam until the hearing of the judicial review application (fixed for July 1993) which effectively meant that the licence was completely suspended until that time.

Response Norgine Limited although not a member of the ABPI had agreed to comply with the Code. The company pointed out that the launch of the Unigam in April 1993 had been planned for some time and it was unaware of any attack on the licence until 1 March 1993. When the subject of the launch was first raised, the April edition of "MIMS" was already in print showing the introductory details of the product.

Following the decision to suspend the licence until the full case could be heard the company acted immediately to withdraw Unigam from all wholesalers and to notify the pharmaceutical and medical professions. There were four announcements in total. The company submitted that it could not be promoting the use of an unlicensed product as it had been withdrawn from wholesalers thus preventing any use during suspension of the licence. The purpose of the announcements was to comment on the effect of the court proceedings launched by Scotia and was headed "Product Withdrawal". The grant of the licence pre-dated the announcement in the Chemist & Druggist by eight months and the Court hearing in July could not result in the "grant" of a licence only in the dismissal of Scotia's application or the quashing of the licence.

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The company submitted that it had acted in good faith throughout and that the Department of Health was now producing evidence in support of its decision to grant a licence. The company fully expected the suspension of the licence to be lifted at the hearing in July.

Ruling The Code of Practice Panel examined the announcement and decided that it went beyond the usual product withdrawal notice due to the claims made for Unigam, such as that it was the first dual indication gamolemic acid, its significance to doctors and the cost savings for the product compared to other brands which appeared in the paragraphs highlighted by the complainant. The Panel noted that the company expected the suspension of the product licence to be lifted in July at the court hearing. The Panel considered that the announcement was promoting the product in anticipation of it becoming available.

The Panel was of the opinion that the clear principle behind Clause 3.1 of the Code was that products which did not have a licence should not be promoted. The Panel considered that as the announcement promoted Unigam, a product which had had its licence suspended, it was in breach of Clause 3.1 of the Code. The Panel therefore ruled a breach of that Clause.

Complaint received **23 April 1993**

Case completed **25 May 1993**

AUTH/39/4/93

GENERAL PRACTITIONER V ORGANON LABORATORIES LTD

Mailing constituted disguised promotion

Complaint A general practitioner submitted a complaint about a mailing for Mercilon sent by Organon Laboratories Ltd. The complainant was irritated by a misleading statement on the envelope "Equipment grant competition" which she alleged was presumably printed to ensure that she read the already familiar contents.

The mailing provided by the complainant consisted of a leaflet on Mercilon and a reply paid card. There was no reference to an equipment grant competition.

Response Organon Laboratories Ltd submitted that the mailing at issue was a general information mailing on Mercilon and should have been sent in a normal plain envelope. Unfortunately the mailing house had used the wrong envelope. The envelope used had been intended for a series of further mailings in relation to a competition. The company submitted a copy of a letter from its advertising agency which accepted full responsibility for the error by the mailing house.

Ruling The Code of Practice Panel considered that, even though it had been unintentional, the mailing had been disguised as the envelope referred to an "Equipment grant competition" and it did not contain any information relating to this competition. The Panel therefore ruled a breach of Clause 10.1 of the Code.

Complaint received **26 April 1993**

Case completed **14 May 1993**

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AUTH/40/4/93

HOSPITAL PHARMACIST V SERVIER LABORATORIES LIMITED

Letter sent by a representative

Complaint A hospital pharmacist complained about a letter which he had received from a representative of Servier Laboratories Limited. He considered that it made unsubstantiated claims for Coversyl, Natrilix and Diamicron. The letter also referred to Adifax and he pointed out that no data sheets had been enclosed for any of the four products although claims were made.

Response Although not a member of the ABPI, Servier Laboratories Limited had agreed to comply with the Code. The company said that the letter had not been sent with its authority and/or approval. It was an entirely personal initiative undertaken by the representative in the process of notifying his impending change of address. He had acted completely outside the guidelines and standards laid down in his training programme. An internal review was being conducted and the company was taking steps to reinforce the control measures applied to medical representatives. A detailed rebuttal of the allegations was submitted in relation to each of the product claims made by the representative.

Prescribing Information The Code of Practice Panel noted that it was clearly established that companies had to take responsibility for their representatives when acting in the course of their employment even if not acting in accordance with their instructions.

It was ruled that there had been a breach of Clause 4.1 of the Code because of the failure to include prescribing information for the four products.

Diamicron The representative's letter had stated that it was "a sulphonylurea for non insulin dependent diabetes which has been shown to have a low incidence of hypoglycaemia and secondary failure in comparative trials."

The complainant queried with what Diamicron had been compared.

The Panel considered that the evidence submitted by Servier indicated that hypoglycaemia problems occurred no more frequently with gliclazide than with glibenclamide or placebo and less frequently than with some other antidiabetic agents. It was considered that the claim had been substantiated and ruled that there had been no breach of the Code in this respect. In this context it was not necessary to name the comparators.

Coversyl The representative's letter had stated that Coversyl (perindopril) was "An ACE-inhibitor licensed in both hypertension (first line) and congestive cardiac failure which is noted for vascular remodelling and a low incidence of first-dose hypotension."

The complainant had alleged that the licence did not mention a low incidence of first dose hypotension or "vascular remodelling".

The Panel observed that the fact that particular aspects of the properties of a product were not mentioned in the data sheet did not mean that they could not be used in promotional material, provided that the promotional material was not inconsistent with the data sheet.

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In relation to the question of first dose hypotension, the Panel, having reviewed the papers submitted by Servier, considered that there was some evidence that perindopril produced a lesser early lowering of blood pressure than two other ACE-inhibitors but considered that the evidence did not support the claim that the incidence was "noted" for being low as it implied that it was a recognised feature of the product and did not reflect the limited nature of the available evidence. It was observed that warnings regarding first dose hypotension appeared in the data sheet.

In relation to the claim that Coversyl was "noted for vascular remodelling", the Panel considered that the evidence made available by Servier, some of which referred to animal studies, did not give adequate support for the clinical significance of the claim that Coversyl was "noted" for vascular remodelling. Although there was some evidence regarding Coversyl in relation to vascular remodelling, this was limited and did not support the unqualified claim.

The claims made by a representative in respect of Coversyl had been exaggerated and the Panel ruled that there had been a breach of Clause 7.8 of the Code. Servier appealed against this ruling. Upon appeal, the company submitted a number of papers in support of its contention that Coversyl was "noted for vascular remodelling. The company acknowledged that it might be a class effect. It had not claimed that the product was necessarily the best but that it was noted in this regard.

The Code of Practice Appeal Board considered that the claim was stronger than was warranted by the available evidence. Many substances exhibited some degree of vascular remodelling. For such a statement to be made there must be some evidence of clinical advantage and this was lacking. The Appeal Board rejected the appeal on this aspect of the case and confirmed that there had been a breach of Clause 7.8 of the Code.

In relation to the claim that Coversyl was noted for "a low incidence of first-dose hypotension", the company referred to a number of published studies. In relation to the reference in the data sheet and prescribing information to the risk of first dose hypotension, the representatives said that this was included as a class effect warning at the time of the grant of the product licence. It was not unreasonable to include such a warning whilst, at the same time, observing that in regular clinical practice the actual incidence of first-dose hypotension was low.

The Appeal Board considered that the appeal was justified as it appeared that Coversyl was noted for a low incidence of first-dose hypotension and this was widely recognised. It was ruled that there had been no breach of the Code in relation to this claim.

Natrilix The representative's letter had stated that Natrilix was "a highly effective antihypertensive which is as effective as a calcium antagonist (at half the cost) and which regresses left ventricular hypertrophy by a similar amount".

The complainant had queried the expressions "highly" effective, "as effective as a calcium antagonist" and "regresses ventricular hypertrophy".

The Panel accepted that there was some evidence that Natrilix was as effective as a calcium antagonist and that it regressed left ventricular hypertrophy by a similar amount. No evidence had been provided, however, that this was true of Natrilix in comparison with all calcium antagonists as implied by the claim made by the representative. The Panel did not consider that the expression "highly effective" had been substantiated. It ruled that the claims that Natrilix was "a highly effective antihypertensive which is as effective as a calcium antagonist (at half the cost) and which regresses left ventricular hypertrophy by a similar amount" were in breach of Clause 7.3 of the Code. Servier appealed against this ruling.

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Upon appeal, the company pointed out that the claim that it was as effective as a calcium antagonist was a reference to a published study. It had not been stated that it was as effective as all calcium antagonists and it was not correct to suggest that the representative's letter so implied. Natrilix had been compared to the reference calcium antagonist, nifedipine. The product was to be regarded as "highly effective" as studies which the company outlined to the Appeal Board showed. The company accepted that there were other products which could be described as highly effective.

The Code of Practice Appeal Board did not accept the submission by the company that the wording "a highly effective antihypertensive which is as effective as a calcium antagonist ..." meant that it was in comparison with one calcium antagonist only. In the context of the claim "a calcium antagonist" was a reference to calcium antagonists as a class. The Appeal Board accepted, however, that as the actual comparison in question was with the reference calcium antagonist, nifedipine, then the claim was not unsubstantiated on the basis that a comparison with the significant member of a class of medicines could be regarded as a comparison characteristic of the whole class.

The Appeal Board considered that the wording of the claim would have been better if it had specified that the basis of the comparison was between Natrilix and one calcium antagonist, nifedipine, but decided that on balance the claim was not unacceptable. The Appeal Board therefore considered that the appeal was justified and ruled that there had been no breach of the Code in respect of the statement as a whole.

Complaint received **29 April 1993**

Case completed **2 August 1993**

AUTH/41/5/93

CONSULTANT PHYSICIAN v MEMBER COMPANY

Complaint about conduct of sponsored nurse in general practice and arrangements for sponsorship scheme

Complaint A consultant physician complained about the conduct of a specialist nurse sponsored by a member company to work in general practice in her district. The complainant explained that although she had initial reservations as to why the company was interested in sponsoring a specialist nurse to work in general practice in the area, she had nonetheless agreed to meet with the nurse specialist to discuss the proposals. The complainant was extremely concerned to be presented prior to that meeting with a letter which the nurse in question intended to send around to local GPs before any consultation with the complainant who was responsible for supervising treatment in the local district.

The complainant queried the arrangements of the scheme and the actions of the company and the nurse in question.

In writing to the company concerned it was pointed out that it was not clear how the matters raised by the complainant would fit within the scope of the Code. Nevertheless, the company was invited to bear in mind the provisions of Clauses 2 and 9.1 of the Code.

Response The company concerned explained that its project had been developed in the light of the "Health of the Nation" White Paper and the rapid increase in the number of specialist clinics operating in primary care in this particular disease area. The project was provided as a service to

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professionals involved in the care of these patients and involved the provision of a team of trained and experienced specialist nurse advisers managed by an independent agency. There was an established procedure for the employment of this team which involved consultation by the nurse adviser with the FHSA and the relevant consultant and care team in the local hospital prior to any approach to targeted GPs. The procedure was being followed in this case. The letter sent to the complainant about which she took objection was a draft letter which had been sent to her for a comment. It was at no point sent to local general practices nor was there any intention of sending it without the endorsement of the complainant. The nurse adviser had not and neither was it the company's intention for her to be active in general practice in the locality without consultation with the complainant. Details of the scheme were provided.

Ruling Having reviewed the information before it, the Code of Practice Panel concluded that there had been no apparent breach of the Code in relation to the matters in question. There had, however, clearly been a communication failure between the company and the complainant. The company needed to make sure that the appropriate people were kept properly and fully informed at all times of all aspects of the arrangements and any proposed implementation of the scheme.

Complaint received **5 May 1993**

Case completed **10 June 1993**

AUTH/43/5/93

ALLEN & HANBURYS LIMITED V FISONS PHARMACEUTICALS

Journal advertisement for Aerocrom inhaler

Complaint Allen & Hanburys Limited submitted a complaint regarding an advertisement published in "Pulse", 3 April 1993, for a new product, Aerocrom, issued by Fisons Pharmaceuticals. The advertisement in question made a series of claims for the product, "The relief they want The protection they need In a therapy they'll take".

Allen & Hanburys alleged that the claim "The relief they want" was not justified in terms of the product licence. The prescribing information in the advertisement stated that Aerocrom was "not for use in acute attacks. Patients may need a separate bronchodilator aerosol to control breakthrough wheezing". The claim was also misleading and inaccurate as the commonly accepted terminology in asthma was to describe three different types of therapeutic intervention: "relievers" for use to treat the symptoms of wheeze as and when they arose and "preventers" and "protectors" were for regular use to try to provide maintenance control between attacks. Breaches of Clauses 3.2 and 7.2 of the Code were alleged. Further the company alleged that the use of the word "the" in the series of claims "The relief they want The protection they need In a therapy they'll take" implied that the product had a special property and was the best in terms of relief and protection. The claims were exaggerated and all embracing by suggesting that the product would provide all patients with both relief and protection and furthermore that all patients would comply with their therapy. A breach of Clause 7.8 of the Code was alleged.

Response Fisons Pharmaceuticals submitted that the claim "The relief they want" was not inconsistent with the data sheet. Salbutamol whether prescribed for use "when required" or regularly in combination with a "preventer", as with Aerocrom, would relieve the symptoms of asthma. The convention of using the term "reliever" for bronchodilator medication did not only imply usage when

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required for acute relief of symptoms but could equally apply to regular maintenance therapy of any bronchodilator medication. The company did not accept that the claim might represent a danger to patients as the prescriber was fully aware of the need for a second bronchodilator to control breakthrough wheezing as stated in the prescribing information.

With regard to the series of claims "The relief they want The protection they need In a therapy they'll take" the company submitted that the statements which started with "the" were merely statements describing the constituents of the product. Thus the patient prescribed Aerocrom sought symptom relief from the salbutamol and the doctor was aware of the need for the preventer (sodium cromoglycate) for protection by his decision to prescribe the product. The combination of the two in a single inhaler encouraged patients to take the therapy. Prescription audit data revealed that in practice many patients prescribed a bronchodilator and anti-inflammatory relied on their bronchodilators and used them regularly.

Panel Ruling The Code of Practice Panel considered that the claim "The relief they want" implied that the product could be used in acute attacks and this was not so. It noted that the prescribing information stated that patients might need a separate bronchodilator aerosol to control breakthrough wheezing. The Panel considered that the claim was misleading and therefore ruled a breach of Clause 7.2 of the Code. The Panel did not accept that the claim constituted a breach of Clause 3.2 of the Code.

With regard to the series of claims "The relief they want The protection they need In a therapy they'll take", the Panel noted that it had already made the ruling above in relation to the claim "The relief they want". With regard to the claim "The protection they need", the Panel did not accept that it implied that 100% protection would be achieved with Aerocrom. It considered that it was implicit in the treatment of asthma that it might be necessary to progress treatment at any time and therefore ruled no breach of the Code. With regard to the claim "In a therapy they'll take", the Panel considered that this was not unreasonable and therefore ruled no breach of the Code.

Fisons appealed the ruling of the Panel that there had been a breach of Clause 7.2 in relation to the claim "The relief they want".

Appeal Fisons reaffirmed the response it had made to the Panel and submitted that care had been taken to avoid ambiguity in the advertisement. Patients would get relief from symptoms of asthma both from acute or long term regular use of bronchodilators. The convention of using the term "reliever" for a bronchodilator medication did not preclude the use of the word "relief" to describe the outcome of the regular use of salbutamol. The company submitted that published clinical studies referred to bronchodilator medicines taken regularly in terms of providing relief from symptoms and that "relief" did not simply refer to symptom relief of acute attacks. Symptom relief had also been applied as a description of the clinical effects of conventional "preventer" medicines such as budesonide and beclomethasone. Fisons did not accept that doctors would perceive the advertisement as suggesting the use of Aerocrom for acute attacks. Market research reports on the attitudes of doctors were made available to the Code of Practice Appeal Board.

Appeal Board Ruling The Code of Practice Appeal Board noted that there was no indication in the body of the advertisement that the product was not for use in acute attacks although this information did appear in the prescribing information. The Appeal Board accepted that "relief" could be used to describe all treatments for asthma. The Appeal Board considered, however, that the claim "The relief they want" implied that the product could be used in acute attacks and this was not so. The Appeal

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Board considered that the claim was misleading in breach of Clause 7.2 of the Code and therefore rejected the appeal.

Complaint received **13 May 1993**

Case completed **2 August 1993**

AUTH/44/5/93

GENERAL PRACTITIONER V MEMBER COMPANY

Patient leaflet

Complaint The Medicines Control Agency referred a complaint from a general practitioner about a patient leaflet on a certain skin condition issued by a member company. The leaflet in question was designed to be left in surgery waiting rooms for patients and contained the name and address, telephone and facsimile number of a relevant patient organisation on the back. It did not mention any product or company by name.

The complainant alleged that a cursory glance at the leaflet would lead patients to the conclusion that it was information put out by the patient organisation but the patient organisation involved had confirmed that it had nothing to do with the leaflet in question. The complainant also alleged that the leaflet was a thinly disguised advertisement for the member company's product in that it effectively rubbished other treatments whilst urging patients to see their doctors about the latest developments in treatment.

Response The company concerned submitted that the leaflet did not constitute advertising to the public as there was no reference anywhere to its products, trade marks or company name. The statements in the leaflet did not encourage patients to ask their doctor to prescribe a specific medicine as it referred to the latest developments which could be the right treatment for the patient. It was left to the doctor to decide which of the several recently introduced new treatments or formulations for the condition should be prescribed. The company submitted that it had a close working involvement with the patient association referred to in the leaflet and provided evidence that it was happy to have its name appear on the back of the patient leaflet in question.

Ruling The Code of Practice Panel accepted that the reference to the patient association had been with its knowledge and permission. The Panel considered that it was not the case that just because a leaflet did not mention a product or company by name then it was necessarily non promotional. The Panel considered, however, that the leaflet in question did not constitute the advertising of a particular product to the public and that it would not encourage members of the public to ask their doctors to prescribe a specific medicine. The Panel also considered that, on balance, the inference of a certain statement in the leaflet that latest developments in treatments "could be just right for you" was sufficiently qualified so as not to raise unfounded hopes of successful treatment. The Panel did not accept that the leaflet was disparaging of competitor products. The Panel therefore ruled there was no breach of the Code.

Complaint received **17 May 1993**

Case completed **20 July 1993**

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AUTH/48/5/93

GENERAL PRACTITIONERS V ASTRA PHARMACEUTICALS LTD

Provision of hospitality to receptionists

Complaint A group of general practitioners submitted a complaint regarding the activities of representatives from various pharmaceutical companies in relation to meetings held with another group of doctors and their staff.

The complainants alleged that pharmaceutical companies were providing hospitality to the doctors, their receptionists and practice manager at various, often expensive, restaurants. It was alleged that the meetings took place at approximately fortnightly intervals and were seen by staff as a reward for hard work and were in effect practice administration meetings. The complainants also alleged that the doctors had been cultivating friendships with various representatives who would be providing substantial help towards equipping the doctors' new premises. Two examples were cited and these were taken up with the companies concerned.

This case concerned an allegation regarding a meeting where a representative from Astra Pharmaceuticals Ltd had provided meals for receptionists at a local restaurant. The complainants enclosed a note on paper printed with the name of an Astra representative with a handwritten message giving details about arrangements to take the "girls" out for a meal.

Response Astra submitted that the meeting in question consisted of an audio-visual meeting, held in the surgery, and was made up of a slide presentation lasting approximately one hour which covered three respiratory products, demonstrations on how to use the devices and a discussion of asthma therapy. It was not possible or appropriate for catering to be arranged at the surgery premises given the particular circumstances prevailing there. It was agreed with the doctors that a meal would be provided at the restaurant where the establishment of an asthma clinic and how the representative could assist would be discussed. The company submitted that one of the general practitioners had invited two of the practice receptionists to attend the meal. The general practitioner offered to pay for the receptionists but the representative was embarrassed by the situation and did not insist that this was done. The cost of the meal was £21.60 per head.

Astra did not accept that the hospitality was inappropriate nor did it exceed the level which the recipients would normally adopt when paying for themselves. With regard to the receptionists, the company advised that the representative had been severely reprimanded for the breach of the Code and of its procedures. The handwritten note was not written by the Astra representative and the day and the time shown were incorrect. The company said that there had been no provision of equipment to the surgery and no intention to do so in the future.

Ruling The Panel accepted that the arrangements for the meeting were not inappropriate and that it was acceptable for hospitality to be provided in a restaurant given the circumstances.

The Panel accepted that the level of hospitality offered was not inappropriate. It considered, however, that it was not appropriate for the company to pay for the receptionists' meals at the restaurant as in these circumstances receptionists did not come within the definition of "appropriate administrative staff

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in hospitals and health authorities and the like". The Panel therefore ruled a breach of Clause 19 of the Code.

Complaint received **25 May 1993**

Case completed **20 July 1993**

CASE AUTH 51/6/93

FISONS PHARMACEUTICALS V MEMBER COMPANY

Allegations concerning promotional material

Complaint Fisons Pharmaceuticals complained about the promotion of a product by another member company which it alleged was disparaging of its product in breach of Clause 8.1 of the Code. A breach of Clause 9.3 was also alleged as Fisons considered that a promotional aid offered by the competitor company was an imitation of a similar promotional aid offered by Fisons.

Ruling The Code of Practice Panel did not accept that the various claims in the promotional material were disparaging of the Fisons product nor did it accept that the offer of a similar promotional aid by the respondent company constituted a breach of Clause 9.3 of the Code as it did not constitute the imitation of a device, copy, slogan, etc. in a way which would mislead and confuse as prohibited under that Clause. The Panel therefore ruled that there was no breach of the Code.

Complaint received **4 June 1993**

Case completed **6 July 1993**

AUTH/52/6/93

GENERAL PRACTITIONER V MEMBER COMPANY

Advertisement feature

Complaint A general practitioner complained about an article which had appeared on the back page of a magazine intended for display in the surgery waiting room and queried whether it was an ethical method of advertising to the public. Although the so-called "advertisement feature" did not actually mention any product by name, it did imply that a condition could be treated in a particular way.

Response The company concerned said that the material in question had been produced by it about two years previously and had been made available to various consumer magazines for individual editors to use if they wished. In this particular instance, however, the entry had been paid for.

The aim was to refute a number of commonly held misconceptions about a particular condition and its treatment. Great care had been taken to ensure that it was both factual and well balanced and it avoided mention of specific products or of any special features of a product that would allow patients to ask specifically for that product. It had been stated that it was for the doctor to advise as to the best treatment.

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Ruling The Code of Practice Panel considered that although the article mentioned various forms of treatment and gave some of the advantages and disadvantages, it did nonetheless favour a particular form of treatment. It had to be recognised, however, that that method did offer certain advantages. The Panel noted that the product of the company concerned was not the only product of its type which was available. Neither the product name nor the company name had been mentioned.

The Panel decided that the article could not be regarded as unbalanced. The Panel considered that the article might lead patients to ask their doctors to prescribe a particular form of medicine but it could not be held to encourage patients to ask for a particular medicine. It was accordingly ruled that there had been no breach of the Code.

Complaint received **8 June 1993**

Case completed **12 July 1993**

AUTH/55/6/93

CONSULTANT PHYSICIAN V ABBOTT LABORATORIES LIMITED

Selective quotation

Complaint A consultant physician complained about a mailing for Klaricid relating to community-acquired pneumonia issued by Abbott Laboratories Limited (ref: X01 19386). The advertisement quoted from the "Guidelines for the management of community-acquired pneumonia in adults admitted to hospital" which had been published by The British Thoracic Society. The quotation used was that "New macrolides such as clarithromycin and azithromycin appear to be better tolerated and have better activity against some of the organisms responsible for community-acquired pneumonia than erythromycin". The next sentence in the guidelines: "Their place in the standard management of pneumonia awaits further experience" had been omitted. It was alleged that this selective quotation was contrary to Clause 11.2 of the Code. The comparison with erythromycin was potentially misleading and contrary to Clause 5.5 of the Code.

Response Abbott Laboratories Limited stated that it believed that the quotation was an acceptable stand alone statement and was not in any way misleading. It did not believe that omitting the final sentence changed the meaning of the quotation. The company had in fact enclosed a reply paid card offering hospital doctors a full copy of the guidelines so there was no intention to mislead.

Ruling The Code of Practice Panel was of the opinion that it was misleading to use the sentence quoted in the advertisement without also including the further sentence which clearly qualified it. The fact that a full copy of the guidelines could be obtained by returning a reply paid card was not considered to repair the omission. It was accordingly ruled that there had been a breach of Clause 11.2 of the Code.

Complaint received **21 June 1993**

Case completed **12 July 1993**

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CODE OF PRACTICE FOR THE PHARMACEUTICAL INDUSTRY

NUMBER		SUBJECT	BREACH
4	Kabi Pharmacia v B Braun	Journal advertisement	7.3, 7.8
8	Director v Member company	Newspaper article	NoB
19} 32}	Hospital doctor} v SmithKline Beecham Pfizer }	Promotion of Seroxat	7.2, 7.3 (A)
20	Director v Member company	Letter published in medical journal	NoB
21	General practitioner v Allen & Hanburys	Mailing to doctors	7.2
22	Director v Lundbeck	Newspaper article	2, 17.2*
23	Hospital doctor v Allen & Hanburys	"Dear Doctor" letter	4.3, 5.2*
24	Consultant geriatrician & Drug information officer v Parke Davis	Journal advertisement	7.2, 7.8
25} 26} 27}	General practitioner v Member companies	Use of plain envelopes	NoB NoB NoB
28}	General practitioner v Knoll	Mailing envelope	10.1
29} 30}	General practitioner v Member companies	Use of a logo	NoB NoB
31	Director v Smith & Nephew	Failure to implement undertaking	7.2, 7.8 Report to Appeal Board
33} 34}	General practitioner v Member companies	Use of plain envelopes	NoB NoB

KEY

* First Revision of the Seventh Edition, January 1991 of the Code applies
(A) Appeal

CODE OF PRACTICE FOR THE PHARMACEUTICAL INDUSTRY

NUMBER		SUBJECT	BREACH
35	Director, Medical Services, FHSA v Roche	Mailing	7.2
37	Director v Pfizer	Letter in pharmaceutical press	7.2
38	Scotia v Norgine	Product withdrawal announcement	3.1
39	General practitioner v Organon	Statement on envelopes	10.1
40	Hospital pharmacist v Servier	Letter sent by representative	4.1, 7.8 (A)
41	Consultant physician v Member company	Sponsorship of nurses	NoB
43	Allen & Hanburys v Fixons	Journal advertisement	7.2 (A)
44	General practitioner (via MCA) v Member company	Patient leaflet	NoB
48	General practitioners v Astra	Hospitality to receptionists	19
51	Fisons v Member company	Promotional material and promotional aids	NoB
52	General practitioner v Member company	Magazine article	NoB
55	Consultant physician v Abbott	Mailing	11.2

KEY

* First Revision of the Seventh Edition, January 1991 of the Code applies
(A) Appeal