PRESCRIPTION MEDICINES
CODE OF PRACTICE AUTHORITY

CODE OF PRACTICE REVIEW

FEBRUARY 1995

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

NEW FORMAT

It is hoped that the new printed format which has been adopted for the Code of Practice Review will make the case reports easier to read. Each report is now preceded by a short summary giving the main features of the case.

For the present, publication will remain on a quarterly basis and the next issue will therefore come out in May 1995. It is possible, however, that publication will move to a two-monthly basis, i.e. six issues a year rather than four. Any views on this would be welcome.

A further feature which the Authority would like to introduce into the case reports is the naming of the respondent companies and products involved even when no breach of the Code has been found. Outside observers find it difficult to understand why names are given only when a breach is found, and it is a bar to the openness which is needed for a successful self-regulatory system. Whether this change can be made depends, however, on whether the ABPI is prepared to accept it.

It is intended shortly to make the review available on disc for those who wish to incorporate the case report in a database, and details will be sent out in the near future.

New Telephone and Facsimile Numbers

The dialling code for the Authority is now 0171. The telephone number is 0171-930 9677 and the facsimile number is 0171-930 4554.
Direct lines can be used for the three members of the Authority.

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

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

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

As anticipated when the new Code and procedures were introduced at the beginning of 1993, a review of the system is to be carried out now that two years' experience of it has been gained to see whether any changes are needed. The Code itself will be reviewed again, as will ancillary matters such as whether the fees payable to the Authority should be raised to make it self-supporting. At present the Authority is subsidised by the ABPI.

During the review, account will be taken of the requirements of the new edition of the IFPMA Code of Pharmaceutical Marketing Practices and of the Medicines (Advertising) Regulations 1994 to see whether these necessitate any changes.

ABPI member companies and other companies which have agreed to comply with the Code and its procedures have been invited to send in their views on the current Code and procedure.

Mailing to General Practitioners

The mailing which was sent out by the Authority in August to 11,902 general practices in the UK detailing the changes which had been made to the Code and inviting them to apply for a copy has resulted in nearly 2,800 copies being requested and dispatched so far.

The purpose of the mailing was to increase the profile both of the Code itself and of the Authority established by the ABPI to administer the Code. The Authority is responsible for the provision of advice, guidance, conciliation and training on the Code of Practice as well as for the complaints procedure.

Price Comparisons

Companies are reminded that price comparisons involving other companies' products are essentially ephemeral in nature and that it is therefore unwise to embody them in material which is intended to be used over a period of time.

Companies which are being disadvantaged by erroneous price comparisons in other companies' promotional materials cannot be expected to take a benevolent view of the situation, and such materials will have to be withdrawn from use.

DOCTORS AND ROOM RENTAL

As you will be aware, Clause 19.2 of the Code states that 'Payments may not be made to doctors or groups of doctors, either directly or indirectly, for rental for rooms to be used for meetings'.

Companies are reminded of two points. Firstly, that payment of room rental to doctors or groups of doctors is not permissible even if such payment is made to equipment funds or patients' comforts funds and the like or to charities or companies. Secondly, that payment can be made for room rental to postgraduate medical centres and the like.

Any companies that identify doctors who are insisting on payment of room rental are invited to notify the Authority, which will write to the doctors concerned about the matter without identifying the companies providing the information.

CODE OF PRACTICE TRAINING

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

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

Forthcoming Code of Practice seminar dates are:

Monday, 20 March
Friday, 28 April
Thursday, 11 May
Friday, 16 June

Further dates for 1995 will be notified in due course.

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

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

Complaints submitted under the ABPI Code of Practice for the Pharmaceutical Industry are considered by the Code of Practice Panel which consists of the three members of the Code of Practice Authority acting with the assistance of independent expert advisers where appropriate. Both the complainant and the respondent in a case may appeal to the Code of Practice Appeal Board against rulings made by the Panel. The Code of Pratice Appeal Board is chaired by an independent legally qualified Chairman, Mr Philip Cox QC, and includes independent members from outside the industry. Details of its composition may be found on pages 30 and 32 of the Code of Practice.

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

CASE AUTH/163/6/94

DIRECTOR v BAYER

Criticism of Ciproxin promotion in British Medical Journal letter

A letter published in the British Medical Journal criticised the promotion of Ciproxin. The authors queried whether the claim "Ciproxin achieves > 95% clinical success in bronchitis" could be substantiated and concluded that Ciproxin was not a suitable agent for use in general practice for the blind initial treatment for chest infections and should not be so promoted.

Breaches of Clause 7.2 of the Code were ruled by the Appeal Board on appeal by Bayer as the prescribing information was misleading as it did not include a reference to the use of the product "pending sensitivity results" and as there was insufficient data to support the claim for >95% clinical success. It was accepted that Ciproxin could be promoted as first line treatment for both chronic and acute bronchitis.

COMPLAINT

A letter in the British Medical Journal, 28 May 1994, criticised the promotion of Ciproxin (ciprofloxacin) by Bayer plc. The authors noted that patients with chest infections had been treated with ciprofloxacin in general practice and the slower resolution of their *Streptococcus pneumoniae* infection required a change of antimicrobial agent and one patient had died. The authors understood, however, that ciprofloxacin was not promoted as first line treatment in general practice for community acquired chest infection but some general practitioners in the area had provided promotional material that did so. This material contained data showing that 14.4% of bacterial pathogens in acute exacerbations of chronic bronchitis were *S pneumoniae.*

The authors referred to a study by Bantz *et al* cited in Bayer's promotional material which mentioned a greater than 95% resolution rate but compared only doxycycline with ciprofloxacin and made no reference to bacterial pathogens. In the same supplement to the American Journal of Medicine, however, other papers gave less favourable views, for example, "the activity of ciprofloxacin against *Streptococci* and *Enterococci* is marginal, at best". The only other reference concerning efficacy cited in the promotional leaflet was a study by Hoogkamp-Korstanje of just 34 patients. Those with *Haemophilus influenzae* rapidly recovered and these organisms were not culturable beyond three days. Of those with *S pneumoniae* infection, five still had positive results after three days, five after eleven days and one after twenty five days. Five patients had a relapse and were then treated with either amoxycillin or co-trimoxazole and clinically recovered. Six patients acquired *S pneumoniae* infection during or after treatment and three required treatment. Two patients had rising minimum inhibitory concentration to ciprofloxacin in *S pneumoniae* with the organisms being isolated further into ciprofloxacin treatment. In the same issue of the Journal of Antimicrobial Chemotherapy a leading article on quinolones in chest infections concluded that there was little reason for optimism about the role of quinolones in chest infections mainly because of the problems with resistance, recurrence and reinfection with *Pseudomonas aeruginosa* and *S pneumoniae.* The authors concluded that ciprofloxacin was not a suitable agent for use in general practice for the blind initial treatment of chest infections and should not be so promoted.

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

RESPONSE

Bayer plc assumed that the complaint related to a mailing to general practitioners dated January 1994. The company submitted that it was not advocating first line treatment in all forms of bronchitis. The mailing stated "she gets bronchitis" referring clearly to recurring bronchitis, it did not say "she has bronchitis" or "she has a cough". The text went on to indicate that bronchitis could be a greater problem to the elderly than younger patients and that respiratory defences may not be as robust as they used to be and that in recurrent bronchitis in such vulnerable patients a further exacerbation may worsen the patient's overall condition.

Bayer submitted that it was adhering to its long standing policy that Ciproxin was intended for grades IIb, III and IV of the chronic bronchitis classification. The original classification was as follows:-

I Previously healthy patient with post-viral tracheobronchitis - no treatment required

IIa Intermittent chronic bronchitis - alternative established antibiotics

IIb Intermittent chronic bronchitis in patients with co-existing illness eg emphysema, diabetes, heart failure etc

III Chronic bronchitis with frequent lower respiratory tract infections

IV Chronic bronchial sepsis

Bayer referred to its data showing that 14.4% of bacteriological pathogens in acute exacerbations for chronic bronchitis were *S pneumoniae*. The figure came from a paper by Aldons *et al*. It would be misleading to omit the least sensitive organism from the chart in the material which showed the causative organisms in acute exacerbations of chronic bronchitis. High levels of clinical efficacy had been shown in infections caused by *S pneumoniae*. The company submitted that *S pneumoniae* infections were not a contraindication to ciprofloxacin and the statements in the mailing that "Ciproxin is highly active against most respiratory pathogens" and "Ciproxin achieves higher concentrations in respiratory tissue", with a greater than 95% clinical success rate in bronchitis did not mislead in any way.

Bayer drew attention to the prescribing information in the mailing that "Ciprofloxacin is recommended for the treatment of the following infections caused by sensitive bacteria" and the list included respiratory tract infections. It was stated clearly that ciprofloxacin was not recommended as first line treatment of pneumococcal pneumonia, ie lobar pneumonia caused by *S pneumoniae*, or the treatment of acute tonsillitis. The prescribing information also referred to the data sheet which pointed out the intermediate sensitivity of *S pneumoniae* to ciprofloxacin and quoted the approved indications in respiratory tract infections. The data sheet did not mention first or second line therapy in respiratory tract infections.

With regard to the paper by Bantz, the company accepted that there was no reference to organisms but there was nothing sinister or highly unusual in this respect. The paper showed that 96.4% of the patients benefitted from treatment by conventional definition. The paper quoted by the authors was an *in vitro* study of ciprofloxacin in gram positive cocci. Ciprofloxacin's principal activity was against gram negative organisms.

With regard to the data by Hoogkamp-Korstanje *et al*, the information in the published letter was not as presented in the actual study, where only two patients relapsed, one with *S pneumoniae* and one with *H influenzae*. The paper stated " The clearance of pneumococci from the sputum was significantly slower than that of *Haemophilus* during therapy, but there were no differences between the two patient populations concerning clearance of leucocytes, clinical results, infection scores or incidences of relapses at day twenty five and four months. Each group had one relapse to be treated". The authors of the letter appeared to concentrate on the most negative aspects of the study with a short term response rate of 97% (cure 70.6%, improvement 26.4%).

Bayer had reviewed twenty key and representative publications relating to the use of ciprofloxacin in pneumonia and varying forms of bronchitis and set out points from those papers.

The company submitted that there would be occasions when Ciproxin was prescribed empirically for the vulnerable bronchitic for logistically it was not always possible to culture sputum seven days a week round the clock and there remained considerable scepticism regarding the value of sputum culture *per se*.

CODE OF PRACTICE PANEL RULING

The Panel examined the mailing and noted that the front page of the mailing stated that "She gets bronchitis". Inside there were a number of claims and two charts. One gave the incidence of bacterial pathogens causing acute exacerbations of chronic bronchitis, the second showed the worldwide results of the efficacy of ciprofloxacin in RTI which appeared beneath the claim that Ciproxin eradicated more than 90% of the common respiratory pathogens *in vivo*.

The claim "Ciproxin achieves > 95% clinical success in bronchitis" was referenced to the studies by Bantz and by Hoogkamp-Korstanje. The Panel noted that the Bantz paper did not give a bacteriological confirmation of the infecting organism and there was no reference to *S pneumoniae*. It was therefore not relevant to the efficacy of Ciproxin against *S pneumoniae*. With regard to the Hoogkamp-Korstanje study, the Panel noted that it was only carried out in thirty four patients with acute exacerbations of chronic bronchitis. The study stated "the only sign of a less optimal response was the slower clearance of pneumococci from the sputum" and that the authors did have reservations about the use of Ciproxin in the treatment of infections of unknown origin.

The Panel noted that the prescribing information for the product stated that "Ciprofloxacin is not recommended as first-line therapy for the treatment of pneumococcal pneumonia but may be used for treating Gram-negative pneumonia and "Although not recommended as first-line treatment for pneumococcal pneumonia, where considered appropriate, a dose of 750mg twice daily". The data sheet stated that "Ciprofloxacin is less active against the following organisms. Sensitivity testing should be performed before treatment is made" and this was followed by a list of organisms including *S pneumoniae*.

The Panel considered that the mailing was misleading as it failed to take account of the statement in the data sheet regarding sensitivity testing prior to commencing treatment. The qualifications in the prescribing information and the data sheet had not been included in the main body of the mailing which the Panel considered gave the overwhelming impression that the product could be used successfully for bronchitis irrespective of the organism causing the condition including *S pneumoniae*. This was not in accordance with the data sheet. Furthermore, there was insufficient data to support a claim for >95% clinical success in bronchitis. The Panel ruled that the mailing was misleading in breach of Clause 7.2 of the Code.

APPEAL BY BAYER

The company submitted that it had decided to avoid the use of Ciproxin in uncomplicated acute bronchitis and had therefore used the chronic bronchitis classification grades. This decision was taken with a view to encouraging responsible prescribing. It had never been mandatory for Bayer to impose such a restriction as the

product licence listed both acute and chronic bronchitis as approved indications.

Bayer submitted that with regard to the issue of sensitivity testing prior to treatment, it was self evident that all antibiotics were more effective with certain organisms than with others. The data sheet for Ciproxin stated that:

"The extensive tissue penetration of ciprofloxacin combined with its enhanced antibacterial activity (including anti-pseudomonal activity), enables ciprofloxacin to be used alone (pending sensitivity results) ....."

Bayer pointed out that sensitivity testing was also referred to in Ciproxin's data sheet for certain organisms in respect of which Ciproxin was acknowledged to be less active. A review of the data sheets of other comparable products demonstrated similar conclusions. As there was no single total spectrum antibiotic, it was good clinical practice for a physician taking any antibiotic prescribing decision to carry out sensitivity testing to assess whether the antibiotic was suitable. The prescribing information in the material at issue stated under the heading "Uses":

"Ciprofloxacin is recommended for the treatment of the following infections caused by sensitive bacteria: severe systemic, respiratory tract, urinary tract, skin and soft tissue, gastro-intestinal, eye, biliary tract, intra-abdominal, bone and joint, pelvic infections and ear, nose and throat infections. Ciprofloxacin is not recommended as first-line therapy for the treatment of pneumococcal pneumonia, but may be used for treating Gram-negative pneumonia"

The company submitted that this was more than adequate notice to the practitioner that he should, in accordance with good clinical practice, carry out sensitivity testing as recommended in the data sheet, which was referred to immediately following the prescribing information in the mailing.

Bayer submitted a number of papers to support the claims that "Ciproxin achieves > 95% clinical success in bronchitis." The claim was referenced to papers by Bantz *et al* and Hoogkamp-Korstanje and Klein. Bayer pointed out that the Panel had criticised the Bantz paper as it did not identify the causative organism. However, that criticism did not affect the validity of the statistical conclusion in terms of clinical success rate.

Bayer submitted that the effectiveness of Ciproxin against *S pneumoniae* was not an issue as it was not mentioned specifically in the material in question although it concerned the authors of the published letter. The Ciproxin data sheet stated that Ciproxin was less active against *S pneumoniae*. This did not mean that Ciproxin was not active against *S pneumoniae*. Bayer summarised its database which related to 201 respiratory tract *S pneumoniae* isolates from various underlying conditions including pneumonia which indicated that clinical resolution occurred in 71.6% and improvement in 19.4% giving a clinical success rate of 91%.

The company provided two tabulated summaries of the trial publications relating to Ciproxin in respiratory tract infections. The tabulations related to the relevant literature selected on the basis of patient population and the general authoritativeness of the study. The company was confident that the cited papers supported the statement that Ciproxin had been found to achieve > 95% clinical success in bronchitis. Five of the seven published trials tabulated in lower respiratory tract infections had a clinical success rate (resolution plus improvement) of > 95%, two had 100% success rate. Eight of the thirteen trials tabulated in bronchitis had a clinical success rate exceeding 95% of which three had 100% success rate. Bayer had arranged a weighted average of 1911 patients from all published studies relating purely to bronchitis which showed a clinical success rate of 94.3%.

APPEAL BOARD RULING

The Appeal Board examined the data sheet for Ciproxin and noted that it was indicated for the treatment of single infections or mixed infections caused by two or more susceptible organisms. It accepted the submission from Bayer that the product could be promoted as first line treatment for both chronic and acute bronchitis.

The Appeal Board noted a paragraph appearing in the "Uses" section of the data sheet that:

"The extensive tissue penetration of ciprofloxacin combined with its enhanced antibacterial activity (including anti-pseudomonal activity), enables ciprofloxacin to be used alone (pending sensitivity results) or in combination with an aminoglycoside or with beta-lactam antibiotics...".

It considered that this paragraph meant that a doctor could initiate treatment with Ciproxin whilst awaiting results from sensitivity testing.

The Appeal Board noted that in the promotional material no reference was made to "pending sensitivity testing" although the prescribing information in the material stated that:

"Ciprofloxacin is indicated for the treatment of single infections or mixed infections caused by two or more susceptible organisms."

The Appeal Board considered that the prescribing information should have included the reference to "pending sensitivity results" which appeared in the data sheet. The omission of this meant that the prescribing information was misleading as to the use of the product. It was not sufficient simply to refer readers to the data sheet. The Appeal Board therefore ruled a breach of Clause 7.2 of the Code.

The Appeal Board examined the data provided by Bayer to support the claim that "Ciproxin achieves > 95% clinical success in bronchitis". It noted that the studies were on small numbers of patients but accepted that given the condition this was not inappropriate. However, a number of the papers submitted by Bayer gave clinical success as below 95%.

The Appeal Board considered that there was insufficient data to support the claim that "Ciproxin achieves > 95% clinical success in bronchitis". The Appeal Board ruled that the claim was misleading in breach of Clause 7.2 of the Code.

Proceedings commenced **1 June 1994**

Case completed **2 November 1994**

CASES AUTH/165/6/94 & AUTH/166/6/94

ASTRA PHARMACEUTICALS v LEDERLE LABORATORIES/ SMITHKLINE BEECHAM PHARMACEUTICALS

Promotion of Zoton - various claims & medical information brochure

Astra made a series of allegations concerning various promotional items for Zoton jointly promoted by Lederle and SmithKline Beecham. A claim that Zoton gave "Faster symptom relief than .....omeprazole" was ruled by the Panel to be misleading as although there was some evidence it was insufficient to support an unqualified claim for faster relief. That ruling was upheld on appeal. Both companies successfully appealed against a Panel ruling concerning a claim "30% higher bioavailability than omeprazole". The Appeal Board considered that although it was a general principle that the presentation of any data in promotional material which was not derived from patient studies should be labelled accordingly, there was an exception for circumstances where it was patently obvious that the data was not derived from patient studies. Bioavailability data came into this category.

Other rulings made by the Panel were that claims regarding the uniqueness of the Zoton molecule and its clinical significance were exaggerated and that a claim for "Over 90 per cent healing rates in both duodenal ulcer and reflux oesophagitis" was also exaggerated. Pie charts used to show results for acid suppression between Zoton and omeprazole and their correlation with healing were also ruled misleading. The Panel considered that it was unacceptable, as with these pie charts, to base claims on a hypothetical scientific model. No breach was ruled in relation to an allegation concerning a claim on cost efficacy used as a heading in a detail aid.

A breach of Clause 2 ruled by the Panel in relation to a brochure on Zoton and *Helicobacter Pylori* issued by Lederle's medical information department was rejected on appeal. The brochure had also been ruled in breach of Clause 3.2 as it promoted the product outside its licence but this ruling was not appealed. (The rulings on the brochure applied only to Lederle as the brochure was not used by SmithKline Beecham.)

Astra Pharmaceuticals complained about the promotion of Zoton, a new proton pump inhibitor, by Lederle Laboratories. The company referred to a number of items, which included two detail aids ZOT 100 & ZOT 081, various leaflets and mailings ZOT 053, ZOT 108 and ZOT 044, a journal advertisement and a brochure ZOT 125. As the product was jointly promoted with SmithKline Beecham Pharmaceuticals, the complaint was also taken up separately with that company.

Lederle Laboratories' submission in response to the complaint was endorsed by SmithKline Beecham as also representing its view on the complaint except in relation to the promotional item ZOT 125, (see 7 below).

1 Pharmacokinetic data

COMPLAINT

Astra made a series of allegations regarding a number of claims appearing in the detail aids for Zoton. These were that:

- the claim "30% higher bioavailability than omeprazole" was not supported by a direct comparative study of lansoprazole (Zoton) versus omeprazole in the same individuals nor did it indicate that the data was from healthy volunteers
- the claim "Faster sulphenamide formation than omeprazole" was an *in vitro* study in hog gastric mucosa and this was not made clear in the material
- the claims "More complete binding to and inhibition of the proton pump" and "3 vs. 2 proton binding site advantage over omeprazole" did not state that they were based on *in vitro* data
- in the detail aid ZOT 081 the latter claim was referenced to Ringam *et al* which did not support the claim.

Breaches of Clause 7.2 of the Code were alleged.

RESPONSE

Lederle said that it was unaware of any requirement for comparisons of pharmacokinetics to be made in head to head comparative studies. It was reasonable to allow comparative statements based on data from different pharmacokinetic studies where the methodologies employed were similar and the end points were objective. The company explained that the presentation of the *in vitro* data was an attempt to explain the *in vivo* findings of superior acid suppression of lansoprazole v omeprazole (considered under 2 below).

PANEL RULING

The Panel considered that, although in general comparative claims on clinical efficacy should be based on direct comparative studies, it was not unreasonable for comparative statements relating to pharmacokinetics to be taken from separate studies which employed similar methodologies and were well conducted.

The Panel noted that the references submitted by Lederle (Cederberg *et al* and Gerloff - data on file) in support of the bioavailability claim were not those cited in the promotional literature. Both ZOT 081 and ZOT 100 referenced the claim to a study by Oates and Wood which was a review article on omeprazole. The referencing to the material was inadequate.

The Panel nevertheless considered that the data submitted did support the claim for "30% higher bioavailability than omeprazole" and ruled there was no breach in this regard. The Panel considered, however, that it should have been made clear in the material that the claim was referring to data in healthy volunteers and ruled that it was misleading in breach of Clause 7.2 of the Code. This ruling equally applied to the allegations concerning the claims for "Faster sulphenamide formation than omeprazole", "3 vs. 2 proton pump binding site advantage over

omeprazole" and "More complete binding to and inhibition of the proton pump" which were based on *in vitro* data. It was a well established principle under the Code that any claim in advertising was automatically read as referring to data in patients and, if this was not the case, then the position should be made clear in the advertisement.

With regard to the incorrect reference to Ringham in ZOT 081 to the claim "3 vs. 2 proton pump binding site advantage over omeprazole", the Panel considered this was misleading as it implied that the paper substantiated the claim and ruled there was a further breach of Clause 7.2 of the Code. The claim had been correctly referenced in the detail aid ZOT 100 to the appropriate study by Simon *et al.*

APPEAL BY LEDERLE AND SMITHKLINE BEECHAM

Lederle and SmithKline Beecham appealed against the Panel's ruling that the claim "30% higher bioavailability than omeprazole" was misleading in breach of Clause 7.2.

Lederle pointed out that the bioavailability studies were always conducted in healthy volunteers except with cytotoxics or where specific studies were required in special cases. The Committee on Proprietary Medicinal Products (CPMP) Guidelines required bioavailability studies to be carried out in human volunteers and if they were not, an explanation was required as to why this was so. The company submitted that as it was normal accepted practice for bioavailability data to be obtained in healthy volunteer subjects it was not misleading to make a factual claim about the bioavailability of Zoton without specifying the point.

APPEAL BOARD RULING

The Appeal Board accepted that bioavailability data was generally taken from healthy volunteer studies and that this was accepted practice. Although it was a general principle under the Code that the presentation of any data in promotional material which was not derived from patient studies should be labelled accordingly, there was an exception for circumstances where it was patently obvious that the data was not derived from patient studies. Bioavailability data came into this category.

The Appeal Board therefore considered that the fact that the claim "30% higher bioavailability than omeprazole" was not labelled as being healthy volunteer data was not misleading and ruled there was no breach of the Code. The appeal therefore succeeded.

The Panel's rulings regarding the i*n vitro* data presented in the detail aids stood.

2 "Faster symptom relief than ....omeprazole...."

COMPLAINT

Astra alleged that the above claim was exaggerated in breach of Clause 7.8 as it did not specify the doses used or the condition treated and that it was in breach of Clause 7.2 as it did not take into account all the scientific evidence. There was clinical trial data by Petite showing no differences between lansoprazole and omeprazole in respect of symptom relief ie time to pain relief and furthermore, the study by Ekstrom to which the claim was referenced concluded that "no major differences were seen in the healing rates, symptom relief and adverse events" between the two products. A study by Corallo *et al* showed in 145 patients with reflux oesophagitis that at 14 days all patients were without symptoms and noted that, although in animal studies lansoprazole had been shown to be more potent than omeprazole, there was no difference in the study in the symptom relief or healing.

RESPONSE

Lederle submitted that there were seven pivotal studies of lansoprazole versus omeprazole and that in five of these lansoprazole was shown to have faster symptom relief which was statistically significant. Only two of the seven available head to head comparative studies failed to show a statistically significant advantage, but even these two studies showed a trend in favour of lansoprazole.

PANEL RULING

The Panel considered the studies submitted by Lederle showing statistically significant faster symptom relief with lansoprazole than omeprazole but did not accept that the five studies cited by Lederle as showing statistical significance did in fact do so.

The Panel considered although there was some evidence to support the claim that Zoton provided "Faster symptom relief than ..... omeprazole.....", it was insufficient to support an unqualified claim for faster symptom relief as in the promotional material for Zoton. Furthermore, the claim was misleading as to the relative clinical effectiveness of the products as there was no difference between the two products in terms of final outcome of treatment. The Panel therefore ruled that the claim for faster symptom relief was misleading in breach of Clause 7.2.

APPEAL BY LEDERLE & SMITHKLINE BEECHAM

Lederle stated that in the first instance it was important to recognise that symptom relief was a critical goal in the management of patients with upper GI disorders, but that in pivotal healing studies it was always the secondary end point. There had been twelve studies conducted in various indications versus omeprazole. In ten of these an attempt was made to document the onset of symptom relief. Of these studies, seven showed a difference in favour of Zoton (in two studies statistically significant) and in the remainder there was no difference. No study showed a benefit in favour of omeprazole. In view of this and in conjunction with studies which document a more rapid healing for Zoton (ie increased healing rates in earlier time points) the companies considered there was justification for the claim made.

APPEAL BOARD RULING

The Appeal Board considered that although there was some evidence to show that Zoton provided faster symptom relief than omeprazole, the evidence was not without its limitations. Only two of the studies, those by Langworthy and Hatlebakk, showed statistical significant differences in symptom relief in favour of Zoton. The

claim for Zoton that it provided "Faster symptom relief than.... omeprazole", was without any qualification and did not reflect limitations on the data available.

The Appeal Board therefore upheld the Panel's ruling that the claims for "Faster symptom relief than....omeprazole" were misleading in breach of Clause 7.2 as although there was some evidence it was insufficient to support an unqualified claim for faster relief. It therefore followed that the claim was misleading as to the relative clinical effectiveness of the products as there was no difference between the two products in terms of final outcome of treatment.

The appeal therefore failed.

3 Over 90 per cent healing rates in both duodenal ulcer and reflux oesophagitis

COMPLAINT

Astra alleged that the above claim for Zoton was in breach of Clause 7.2 as it failed to specify the duration of lansoprazole treatment and as it did not reflect all the scientific evidence. Various studies showed healing rates of lansoprazole less than 90%.

RESPONSE

Lederle supplied two tables setting out a summary of the trials conducted in duodenal ulcer with the percentage healing rates at week two and four and a summary of trials conducted in reflux oesophagitis with percentage healing rates at week four and week eight. The company submitted that there would always be some studies in which lower healing rates were obtained. The vast majority of healing rates were over 90% at four and eight weeks respectively.

RULING

The Panel noted that in the summary of trials conducted in duodenal ulcers none reached over 90% healing rate at two weeks and not all achieved over 90% at week four. With regard to the summary of trials conducted in reflux oesophagitis only one study had reached over 90% healing rate at week four and one third of the studies had not reached over 90% healing rate at week eight.

The Panel considered that the claim was exaggerated as it implied that over 90% healing rates were achieved in all instances with both duodenal ulcer and reflux oesophagitis. Furthermore, the claim did not specify the duration of treatment to which the measurement of healing rates applied. A breach of Clause 7.8 was ruled.

4 "The clinical significance of the unique Zoton molecule" "Unique molecular design - the clinical significance"

COMPLAINT

Astra alleged a breach of Clause 7.8 of the Code as on the basis of all the available data, the claimed clinical benefits of the Zoton molecule over omeprazole were exaggerated and thus the claim that the Zoton molecule was unique could not be supported.

The claims for clinical significance were:

- Consistent acid suppression over 24 hours
- Faster symptom relief than either omeprazole or ranitidine (also considered under 2 above)
- Over 90 percent healing rates in both duodenal ulcer and reflux oesophagitis (also considered under 3 above)
- Simple dosage regimen - 30 mg once daily.

RESPONSE

Lederle's submissions in relation to the points considered above were also relevant to this allegation.

RULING

The Panel considered the claims "The clinical significance of the unique Zoton molecule" and "Unique molecular design - the clinical significance". The Panel noted that it could be argued that different molecules were by definition each "unique" but considered that the use of the word in the context of the detail aids in question was to imply that the molecule had special qualities which conferred significant clinical advantages upon the product. In view of the Panel's rulings of breach in relation to two of the claimed clinical advantages, the use of the word "unique" was not justified. The Panel therefore ruled that the claims for uniqueness were exaggerated in breach of Clause 7.8 as alleged.

5 Pie charts on acid suppression correlating with healing

COMPLAINT

Astra alleged there was a breach of Clause 7.2 of the Code with regard to two pie charts appearing on a page headed "Zoton, a choice of efficacy" in detail aid ZOT 100 underneath a graph comparing acid suppression with lansoprazole and omeprazole. The pie charts showed acid suppression results for omeprazole at 61% and Zoton at 72% with alongside each graph the claims "Correlates with 85% healing" and "Correlates with 90% healing" respectively. The claims were referenced to a paper by Burget *et al.* Astra alleged that the information given was incomplete as the dose and duration of treatment were not stated nor the condition treated. It was not clear what it was which correlated with healing. If it was acid suppression then it was not stated how it was estimated. The reference to which the material was cited was a complex theoretical model which contained only data on omeprazole and not lansoprazole. Moreover the healing rates of omeprazole in the paper did not work out at 85% as cited in the promotional literature. Details of published healing rates of over 90% for omeprazole were submitted.

RESPONSE

Lederle advised that it had already made a decision to delete the pie charts as they proved difficult to explain to customers in practice. The model used was a theoretical model to illustrate the anticipated healing rate from the graph showing comparative pH levels appearing above the pie charts in the detail aid.

RULING

The Panel noted that attempts to correlate the pie charts and accompanying healing percentages with the Burget paper was extremely difficult and no explanation had been provided by Lederle as to how this was done.

The Panel considered that it was quite unacceptable to base promotional claims on a hypothetical scientific model and ruled that they were misleading in breach of Clause 7.2.

6 **"Zoton. A simple, cost effective treatment regimen for patients with known or suspected duodenal ulcer or reflux oesphagitis".**

COMPLAINT

Astra alleged that the above claim appearing as a heading to a section on cost efficacy in ZOT 081 was in breach of Clause 7.6 as the data presented looked only at the cost of symptom free patients rather than healed patients as referred to in the heading. Lansoprazole was licensed for healing.

RESPONSE

Lederle submitted that it was clear in the data presented that it referred to costs of symptom free patients. This was an acceptable measurement as GP's who prescribed the majority of these products measured effectiveness of treatment on the fact that patients' original symptoms were gone. Calculating the cost per patient healed would lead to precisely the same conclusions.

RULING

The Panel considered that it was not unacceptable to use costs calculated per symptom free patient as a measurement of effectiveness in this context and that it was clear from the actual data presented in the detail aid that this was the basis of the calculations for cost efficacy. The Panel therefore considered that the heading "Zoton. A simple, cost-effective treatment regimen for patients with know or suspected duodenal ulcer or reflux oesphagitis" was not misleading and ruled that there was no breach.

7 **Brochure headed Medical Information on Zoton and *Helicobacter Pylori* (Ref ZOT 125)**

This aspect of the complaint did not apply to SmithKline Beecham as the document involved did not bear that company's name nor had it been used by SmithKline Beecham.

COMPLAINT

Astra alleged that although the brochure in question was headed "Medical Information" and there was a statement on the back page that Zoton was not currently licensed for the eradication of *Helicobacter pylori*, it was a promotional item in breach of Clause 3.2 of the Code.

RESPONSE

Lederle explained that the brochure was a medical information summary provided only at the request of doctors for information on the use of lansoprazole in *H pylori* eradication. It was well known that the place of an antisecretory agent in *H pylori* eradication regimens was in controlling pH at a level where antibiotics could work.

The company's representatives had been instructed not to promote in *H pylori* in any way suggesting that lansoprazole eradicated *H pylori* on its own. Company representatives explained that the company did not have a licence but if a doctor requested information, and only then, the doctor would be provided with the brochure at issue.

PANEL RULING

The Panel noted that the exemption under the Code for replies made in response to individual enquiries from members of the health professions as referred to in Clause 1.2 was restricted to individual answers to questions posed by enquirers. The preparation of a brochure dealing with a specific issue which was routinely made available to the field force to deal with enquiries was clearly not exempt from the Code. The brochure itself apart from being headed Medical Information with a medical symbol printed on it with the words Department of Medical Affairs around it, gave the overwhelming impression of being a piece of promotional literature for the product. The brochure was on glossy paper with the layout and graphics looking very much the same as information presented in a detail aid. The brand name was repeatedly used throughout the document.

The Panel noted the statement appearing in bold type at the end of the brochure that "Zoton is not currently licenced for the eradication of *H pylori*, and the above is provided for information purposes only". The Panel considered that it was well established that it was not possible to make something non promotional or acceptable under the Code by use of a disclaimer.

The Panel considered that the brochure was clearly a piece of promotional literature for Zoton which promoted it outside the terms of its licence and ruled there was a breach of Clause 3.2 of the Code. The Panel further considered that the production and use of such a brochure to promote the use of a product outside its licence brought discredit upon the industry and also ruled there was a breach of Clause 2 of the Code.

APPEAL BY LEDERLE

Lederle appealed against the ruling of breach of Clause 2.

The company pointed out that the whole issue of *Helicobacter pylori* eradication was highly topical with it being the most common query raised by doctors in relation to Zoton. The company's medical information department was trying to improve its service and response times to requests for information in line with its total quality plan. In view of the volume of enquiries it was receiving on the subject, even before the product was launched, the brochure was prepared in good faith.

The company accepted that it might be construed as promotional material and it had withdrawn it from use. It further agreed that the use of a disclaimer did not protect a company from the Code but submitted that the intention of the statement was not as a disclaimer but as a reminder to its sales force that this was not an indication in which they should promote the product. The company explained the process by which the brochure was provided.

Lederle advised that it was mailed only to doctors in response to enquiries. It had not been made available to representatives.

APPEAL BOARD RULING

The Appeal Board considered the information before it and noted the submission by Lederle that the document was handled by its medical information department only for direct submission to doctors in response to enquiries and that it had not been made available to representatives. The Appeal Board did not consider that the use of the brochure constituted a breach of Clause 2 and ruled that there was no breach of that clause. The appeal therefore succeeded.

Complaint received 3 June 1994

Cases completed AUTH/165/6/94 16 November 1994
AUTH/166/6/94 11 November 1994

CASE AUTH/172/6/94

GENERAL PRACTITIONER v MEMBER COMPANY

Claim in promotional material

A general practitioner complained that an advertisement was misleading and that the claims could not be substantiated. The Panel accepted that there was sufficient information to substantiate the claims and no breach was ruled.

COMPLAINT

A general practitioner submitted a complaint about an advertisement for a product issued by a member company. The complainant pointed out that specific claims were made for the product and there was no evidence supplied in the advertisement, nor in any of the references given in the advertisement to substantiate the claim. The complainant alleged that the advertisement was misleading in breach of Clause 7 of the Code.

RESPONSE

The company said that the advertisement was fairly broad ranging and covered a variety of topics. There was no requirement under the Code to provide references in advertisements, provided the claims could be substantiated. However, if the complainant were to contact the company with a request for substantiation of any specific claims, the company would be pleased to provide the relevant data. The company enclosed three references to substantiate the claims. The company also provided copies of references quoted in the article.

PANEL RULING

The Panel noted that companies were not required to include the substantiation in the actual promotional material. The Code only required that claims, information and comparisons, be capable of substantiation.

The Panel decided that the claims at issue had not been substantiated by the three studies provided by the company and therefore ruled a breach of Clause 7.3 of the Code.

APPEAL BY RESPONDENT COMPANY

The company provided additional clinical data to support the claims and referred to the licensed indications of the product.

APPEAL BOARD RULING

The Appeal Board examined the additional material. It considered that given the information which was before it, the Panel's decision had been reasonable. The Appeal Board accepted that the additional information now provided was sufficient to substantiate the claims. The Appeal Board ruled no breach of the Code. The appeal therefore succeeded.

Complaint received 23 June 1994

Case completed 19 October 1994

GENERAL PRACTITIONERS v MEMBER COMPANY

Company sponsored disease management survey in a journal

Five separate complaints from general practitioners were received about a survey alleged to be disguised promotion which was published in a medical journal. The Panel noted that there was no mention that the survey had been sponsored by a pharmaceutical company but did not accept that the survey was disguised promotion. No breach was ruled.

COMPLAINT

Five complaints were received from general practitioners about a survey published in a medical journal.

The complaints were that although the survey appeared to be independent, the leading questions amounted to disguised promotion by the company concerned. It was not clear whether the survey findings would be made available or whether the article was company sponsored. Criticisms were made of the survey questions.

RESPONSE

The company concerned said that the survey arose out of a discussion between the editors of the journal and the company from which it was clear that both parties had interests in finding out more about doctors' attitudes to, and views on, guidelines in a particular disease area. The company had agreed to sponsor a market research survey to be run by the journal which retained complete editorial independence over the survey. There was no promotion of any products and no leading questions. The survey was conducted according to market research parameters and was not a promotional item under the Code.

The final analysis of the survey would be made available both to the company and to the journal for publication. The introduction to the survey stated that the results were to be published in a future issue.

RULING

The Panel examined the survey in question and noted that there was no mention that it had been sponsored by the company concerned. The survey did not therefore appear to be fully in accordance with Section 4.2 of the Guidelines on Pharmaceutical Market Research issued jointly by the ABPI and the British Pharmaceutical Market Research Group which required that "A survey should not, however, imply that it is independent of the pharmaceutical industry if it is, in fact, commissioned by, or for, one or more particular companies."

The Panel noted the requirements of Clause 10.2 of the Code, that market research activities must not be disguised promotion, and considered that if a market research survey was not disguised promotion then it did not come within the Code even if the survey itself was not beyond criticism.

The Panel accepted that the purpose of the survey was to investigate attitudes to the guidelines. The Panel did not consider that the survey was disguised promotion and therefore ruled no breach of Clause 10.2 of the Code.

Complaints received 8,11,11,19 July & 8 August 1994

Cases completed 25 August 1994

CASE AUTH/178/7/94

PHARMACEUTICAL SERVICES DIRECTOR v MEMBER COMPANY

Letter sent to chief executive of NHS Trust regarding hospital manufacture of medicines & conduct of representatives

A letter sent by the chief executive of a member company to the chief executive of an NHS Trust expressing strong concern at the manufacture of certain medicines by the trust hospital pharmacy department, was complained about by the pharmaceutical services director at the hospital. The complainant also alleged that he had been told that representatives from the company had been visiting clinicians casting doubt upon the quality of the products manufactured at the hospital.

The Panel had reservations about what was actually said in the letter but accepted that, although it was related to the company's product, it was not fundamentally promotional in nature. The letter was a business communication expressing concern about certain activities undertaken by the hospital. It was therefore ruled that it was outside the scope of the Code. In the absence of any evidence, no breach was ruled in respect of the allegations concerning the conduct of representatives from the company.

COMPLAINT

The pharmaceutical services director with a hospital complained that a letter sent by the chief executive of a member company to the chief executive of the NHS Trust concerned, was in breach of Clause 8 of the Code as it appeared to be calculated to cause alarm and to cast doubt upon the capabilities and professionalism of employees of the trust.

The letter expressed strong concern at the continuing manufacture of certain medicines by the trust hospital pharmacy department even though the pharmaceutical company had obtained a licence for the medicine. The letter stated that it was accepted practice that once a product was licensed it should be the one used and the need for the production of specials should cease. Attention was drawn to incidences which had occurred at another hospital where two children had died as a result of contamination in their intravenous feeding systems produced by a hospital pharmacy department. Copies of newspaper clippings and an article in the Pharmaceutical Journal on the matter were enclosed. The letter pointed out that should any untoward event occur with the hospital concerned, liability would rest with the trust.

The letter stated that the company's concerns were exacerbated by the fact that it had analysed the hospital product and found that it would not pass quality standards imposed by the Medicines Control Agency (MCA). The letter concluded by pointing out that discussions on the situation had been held with both the Department of Health and the MCA which had been copied with the correspondence.

The complainant advised that it was only after asking representatives from the company for information as to where the hospital's product had fallen short of the company's quality standards that it was informed of the supposed short comings. In the complainant's view, this was hardly the action of a company concerned with patient safety. A retest on the retention samples held by the hospital had confirmed that the product was still within specification.

Further, the complainant advised that he had been told that representatives from the company had been visiting clinicians casting doubt upon the quality of the product manufactured in the hospital.

RESPONSE

The company submitted that the correspondence did not come within the scope of the Code. Firstly, it was not promotional. The correspondence discussed the concerns of the company regarding the principle of the hospital's manufacture of the medicine on a specials basis when a licensed product existed. Secondly, the company's analysis of the hospital product indicated that the product was not of the quality which could be released according to the specification of the MCA. The company felt duty bound, both commercially and professionally, to draw this discrepancy to the attention of the chief executive responsible for the NHS trust. The MCA had been notified of the results of the testing.

The company contended that even if the letter did come within the scope of the Code, the remarks to which the complainant objected were acceptable on the basis that they were accurate, balanced and fair.

With regard to the conduct of its representatives, the company expressed its disappointment that the Authority saw fit to take up valuable management time by asking a company to account for hearsay. The company denied that its representatives had been visiting clinicians making disparaging remarks about products manufactured by the hospital involved and advised that it did not have any representatives' briefing material or literature available relating to the issue.

RULING

The Panel had reservations about what was actually said in the letter to the chief executive of the NHS Trust but accepted that, although it was related to the company's product, it was not fundamentally promotional in nature. The letter was a business communication expressing concern about certain activities undertaken by the hospital. The Panel therefore ruled that it was outside the scope of the Code.

In the absence of any evidence, the Panel did not accept the allegations made by the complainant in respect of the conduct of the representatives from the company. It was therefore ruled that there was no breach. It did, however, consider that the Authority had been entirely justified in asking the company to comment on the allegations.

Complaint received 15 July 1994

Case completed 2 September 1994

CASE AUTH/180/7/94

PROCTER & GAMBLE v NON MEMBER COMPANY

Telephone helpline for the public

Procter & Gamble alleged that information provided on a telephone helpline for the public about a disease area promoted a prescription only medicine to the general public and implied that the product had a 100% cure rate. The Panel did not accept the allegations and no breach was ruled.

COMPLAINT

Procter & Gamble Pharmaceuticals UK Limited submitted a complaint about a surgery poster sent to all general practitioners as an insert in a medical journal. On one side of the poster was a "Dear Doctor" letter with the other side intended for display in surgery waiting rooms providing a list of symptoms together with details of a telephone helpline which contained prerecorded information on a particular disease. The poster stated that an information leaflet was available on request and that doctors could give advice. It also stated that it was sponsored by an educational grant from the non member company concerned.

Procter & Gamble alleged that the telephone helpline promoted a particular prescription only medicine to the public and intimated that the product had a 100% cure rate. Breaches of Clauses 1.1, 7.3 and 20 of the Code were alleged.

RESPONSE

The company concerned, although not in membership of the ABPI, had nevertheless agreed to comply with the Code. The company submitted that the condition was a common problem for which patient information was often sought. A transcript of the prerecorded telephone helpline and a copy of the accompanying patient leaflet was provided. The company submitted that these were prepared with great care to provide a balanced and factual overview of the subject. The material tried to cover all aspects including diagnosis, self-help and prevention. On no occasion was the product mentioned by name. The availability of the single dose treatment was mentioned. There were no efficacy claims for any products.

RULING

The Panel noted that Clause 1.1 of the Code could not be breached as it related to the scope of the Code and the definition of certain terms.

The Panel examined the transcript of the prerecorded telephone helpline and the patient leaflet. Both gave general information about the condition and made various suggestions as to methods of relieving the symptoms. No products were mentioned by name, either brand or generic.

The Panel noted the requirements of Clause 20.2 that information about medicines made available to the general public must be factual and presented in a balanced way so as to avoid the risk of raising unfounded hopes of successful treatment or of misleading with respect to the safety of the product and that statements must not be made for the purpose of encouraging members of the public to ask their doctors to prescribe a specific medicine. The Panel considered that the materials provided by the company to the general public complied with the requirements of the Code. It did not accept that the prerecorded telephone helpline intimated that the single dose therapy had 100% cure rate as alleged. The Panel did not accept that either the leaflet or the telephone helpline advertised the product. The Panel therefore ruled there had been no breach of the Code.

Complaint received **19 July 1994**

Case completed **30 August 1994.**

CASE AUTH/184/7/94

SANOFI WINTHROP v SEARLE

Promotion of Zydol - various promotional items

Sanofi Winthrop made six allegations about five promotional items for Zydol issued by Searle. The Panel ruled a breach of Clause 3.2 of the Code in relation to an initial dose recommendation being inconsistent with the data sheet. Breaches of Clauses 9.1 and 10.1 of the Code were ruled as a special front page attached to a daily newspaper failed to recognise the professional standing of the recipient and was disguised promotion. No breach of the Code was ruled with regard to an allegation that a claim that Zydol had superior efficacy to "co-whatsamols" was unsubstantiated. A quiz, although on the limits of acceptability with regard to the nature of the questions and the prizes on offer, was ruled not to be in breach of the Code.

The Appeal Board ruled no breach of the Code with regard to an allegation, appealed by Searle, that Zydol was more effective than codeine. The Appeal Board also ruled no breach of the Code with regard to Sanofi Winthrop's appeal in relation to the term "co-whatsamols" which was alleged to be a slang expression which did not recognise the special nature of medicines and was disparaging of the products of other pharmaceutical companies.

Sanofi Winthrop Limited submitted a complaint regarding the promotion of Zydol (tramadol) by Searle.

The promotional items in question were: a special front page attached to a daily newspaper, a journal advertisement published in Pulse, 25 June 1994, a "Dear Doctor" letter (ref ZYGPLLDM 594 May 1994), a "Dear Pharmacist" letter (ref ZYRML 694 June 1994) and an audio tape issued by a third party.

There were six allegations which were considered as follows:

1 Claim that Zydol was "more effective than codeine"

This claim appeared in the journal advertisement and in the "Dear Pharmacist" letter.

COMPLAINT

Sanofi Winthrop said that the reference provided by Searle to support the claim (Mehlisch *et al*) was an abstract which stated that tramadol 150mg was significantly superior to codeine 60mg in dental extraction pain; however the information was irrelevant as a 150mg dose of Zydol was in excess of the data sheet recommended dosage of 50 - 100mg. The abstract also stated that tramadol 75mg was superior to codeine 60mg but did not indicate whether this was statistically significant. Sanofi Winthrop alleged that the claim was unsubstantiated in breach of Clause 7.3.

RESPONSE

Searle submitted that the dose of Zydol of 150mg was not in excess of the data sheet recommended dosage. The data sheet stated "For acute pain an initial dose of 100mg is usually necessary". The company submitted that the use of doses higher than 100mg was not precluded. Further, it was stated under the heading "Dosage and Administration" that ".... the dose of Zydol should be adjusted according to the severity of the pain and the clinical response of the individual patient". This statement was included to allow flexibility of dosage, recognised by pain specialists as essential for effective analgesic therapy within the range of the lowest and highest recommended doses (50mg - 400mg). The 150mg dose was well within this range.

Searle submitted that the Mehlisch study was one of nine dental extraction pain studies conducted as pain models to assess the relative analgesic efficacy of a range of tramadol single doses (50, 75, 100, 150, 200mg) and placebo and codeine (60mg) and certain combination analgesics. A meta-analysis of the data demonstrated that single doses of 100, 150 and 200mg tramadol were all superior to codeine 60mg with regard to certain pain intensity and pain relief scores. The lowest doses of tramadol (50mg and 75mg) were equivalent in efficacy to codeine. This was to be expected as the higher recommended dose of codeine was being used. In the same clinical trial programme, eight single dose studies in post operative pain were conducted with similar protocols. A meta-analysis was provided. In these studies, tramadol 75mg was superior to codeine 60mg.

Searle submitted that the additional data provided substantiated the claim at doses of 75mg, 100mg and 200mg as well as at 150mg.

PANEL RULING

The Panel noted that the dose of 150mg was not covered by the data sheet which stated that the initial dose was 50 or 100mg depending on the severity of the pain.

The Panel noted that the data sheet did state "As with all analgesic drugs, the dose of Zydol should be adjusted according to the severity of the pain and the clinical response of the individual patient". However, another section headed "Oral administration" stated that "Depending upon the severity of the pain the initial dose is 50 or 100mg followed by 50 or 100mg four to six hourly. For acute pain an initial dose of 100mg is usually necessary". This section also stated that a total oral daily dose of more than 400mg was not usually required.

The Panel considered that although the data sheet stated that the dose should be adjusted, it was reasonable to expect substantiation of the claim at the initial dose of 50 or 100mg as stated in the data sheet. The data for a 150mg dose of Zydol was not sufficient on its own to substantiate the claim. The Panel noted that Searle had some evidence in single dose studies to show that Zydol 100mg was superior to codeine 60mg and that Zydol 50mg and Zydol 75mg were equivalent to codeine 60mg. Searle also had evidence in post operative pain studies that Zydol 75mg was superior to codeine 60mg, although in this meta-

analysis the Panel noted that Zydol 100mg was found to be no more effective than codeine 60mg.

The Panel decided that there was some evidence that Zydol was more effective than codeine but considered that it was not sufficient to substantiate the unqualified claim that Zydol was "more effective than codeine". The Panel therefore ruled a breach of Clause 7.3 of the Code.

APPEAL BY SEARLE

Searle submitted that pain was not a unidimensional experience and that quantitative assessment of analgesic effect was difficult. Although single dose studies were currently the optimum accepted model by regulatory authorities, they did have limitations and some allowance had to be made for this when considering the results.

The company submitted that there were problems with the pain studies as strong analgesics would be effective for mild pain and therefore it was difficult for a strong analgesic to show superiority to a weak analgesic at the mild end of the pain spectrum. The company submitted that equivalence was the most likely outcome. In order to show a real difference, the severe end of the pain spectrum should be investigated. Ethical reasons usually precluded the use of weaker analgesics in this situation. The company submitted that because of the inherent problems involved in comparative pain studies, the full body and spectrum of clinical data should be considered in relation to the claim. In this regard Zydol had been demonstrated to have efficacy at the most severe end of the pain spectrum and was licensed for severe pain. This was not the case for codeine which was licensed for mild to moderate pain. The available clinical data and licensed indications for codeine indicated that Zydol could effectively be used for pain of a more severe nature and could therefore be regarded as "more effective than codeine".

Searle submitted that the specific study meta-analyses of the direct comparisons of Zydol and codeine demonstrated superior efficacy of Zydol at 100mg and 75mg doses in statistically significant terms over codeine 60mg and in numerical terms for three of the four studies results comparing Zydol 50mg to codeine 60mg. The company submitted that comparing Zydol 50mg and codeine 60mg was not a comparison of like with like as the minimal effective dose of Zydol was being compared with the highest recommended single dose of codeine.

The company submitted that the studies with codeine were done for regulatory purposes and were used to position the product. The company maintained that it was not advocating the use of Zydol instead of codeine only that Zydol represented the next step up the pain ladder.

APPEAL BOARD RULING

The Appeal Board acknowledged that it was more appropriate to compare Zydol with analgesics used for severe pain than with codeine. The Appeal Board accepted the submission from Searle and decided that the company had sufficient evidence to substantiate the claims that Zydol was "more effective than codeine". The Appeal Board therefore ruled no breach of the Code. The appeal therefore succeeded.

2 Inference that Zydol has superior efficacy to "Co-whatsamols"

This allegation applied to the journal advertisement which stated that "Where co-whatsamols might fall short ..... and morphine is over the top".

COMPLAINT

Sanofi Winthrop alleged that the claim inferred that Zydol had superior efficacy to "co-whatsamols" which was taken to refer to all combined analgesics with the prefix co as part of their generic name. Sanofi Winthrop alleged that the claim was all embracing and not substantiated by the reference provided by Searle (Sunshine *et al* 1992). No other comparative data with "co-whatsamols" were given. Sanofi Winthrop alleged that the claim was in breach of Clauses 7.3 and 7.8 of the Code.

RESPONSE

Searle submitted that it was not the purpose of the advertisement to infer that Zydol was superior in efficacy to "co-whatsamols". The marketing position for Zydol was not as a substitute for co products which were licensed for mild to moderate pain as this would be inappropriate use of a medicine indicated for moderate to severe pain. The company's view was that Zydol should be used for pain of such severity that the co products would not have sufficient analgesic effect or might fall short.

Searle provided a number of studies and submitted that the data did show efficacy for Zydol at the more moderate end of the pain spectrum and the efficacy extended into the more severe end of the pain spectrum.

PANEL RULING

The Panel considered that the claim did infer that Zydol was superior to the "co-whatsamols" and noted that there was a difference in the indications for use between Zydol and "co-whatsamols". "Co-whatsamols" were indicated for mild to moderate pain whereas Zydol was indicated for moderate to severe pain. Further there was data comparing Zydol with various "co-whatsamols" to support the claim. The Panel ruled that there was no breach of the Code.

3 The initial dose of Zydol

COMPLAINT

Sanofi Winthrop pointed out that the initial dosage recommendation in the "Dear Doctor" letter and the audio tape was "one capsule tds". Sanofi Winthrop alleged that the recommended dose was inconsistent with the data sheet which stated that the initial dose was 50 or 100mg, four to six hourly. Apart from implying a longer half life for Zydol than the data sheet inferred, recommendation for a lower dose than was covered by the data sheet would reduce the cost of therapy and was likely to reduce the frequency of side effects. A breach of Clause 3.2 of the Code was alleged.

RESPONSE

Searle submitted that the Zydol data sheet provided for a broad range of dosing schedules. Flexibility of dosing was a well recognised requirement in order to tailor suitable analgesic regimens to the needs of individuals. The "Dear Doctor" letter provided one example of a possible initial dose which was one that had been used effectively in a controlled clinical trial setting. It was a low dose in accordance with good medical practice of taking a low dose and working upwards. Furthermore, it was clear from the data sheet that the minimum dose a patient could take was 50mg and the maximum was 400mg in a twenty four hour period. The recommendation "one capsule tds" was consistent with the data sheet.

Searle submitted that no inference about half life or side effects was intended.

PANEL RULING

The Panel noted the requirements of Clause 3.2 of the Code that the promotion of a medicine must not be inconsistent with the particulars listed in its summary of product characteristics or data sheet. The Panel considered that to advocate an initial dosage of one capsule three times a day was inconsistent with the data sheet which stated that the initial dose was 50 or 100mg followed by 50 or 100mg four to six hourly. The Panel therefore ruled a breach of Clause 3.2 of the Code.

4 Special front page attached to a daily newspaper

The special front page promoted Zydol and was attached to a daily newspaper.

COMPLAINT

Sanofi Winthrop alleged that the feature was disguised promotional material which failed to recognise the professional standing of its recipients in breach of Clauses 9.1 and 10 of the Code.

RESPONSE

Searle submitted that it had advised Sanofi Winthrop of a PMCPA circular to companies which stated that advertisements in the form of daily newspapers had been ruled in breach of Clauses 9.1 and 10 of the Code. Searle submitted that it was unreasonable for Sanofi Winthrop to retain this as an item of complaint in the knowledge that a breach would be ruled. Had the company received the advice prior to the publication of its advertisement it would not have proceeded.

Searle submitted that the feature was clearly and prominently marked "Advertisement feature for the medical profession only". The various items presented were topical issues and relevant to medical practice. They were also scientifically valid and written to a good standard.

PANEL RULING

The Panel noted that the use of a special front page to the daily newspaper had been the subject of previous complaints before it (Cases AUTH/151/5/94 and AUTH/153/5/94) in which the Panel had ruled breaches of Clauses 9.1 and 10.1 of the Code.

The Panel noted that had Searle received notification prior to the publication of its advertisement it would not have proceeded with it. The Panel considered that its ruling in the previous cases nonetheless had to apply here. It therefore ruled breaches of Clauses 9.1 and 10.1 of the Code as the feature failed to recognise the professional standing of the audience and it was disguised promotional material.

5 The term "co-whatsamols"

This appeared in the special front page attached to a daily newspaper and in the journal advertisement.

COMPLAINT

Sanofi Winthrop alleged that the term "co-whatsamols" was a slang expression and to use it in promotional material did not recognise the special nature of medicines. It was considered to represent a disparaging reference to the products of other pharmaceutical companies. Breaches of Clauses 8.1 and 9.1 were alleged.

RESPONSE

Searle submitted that during market research investigations the term "co-whatsamols" was recognised by doctors as an entirely appropriate description of a group of generic analgesics prefixed with "co", the standard terminology introduced by the UK authorities for the very purpose of easy recognition of this group of products.

PANEL RULING

The Panel did not accept that the use of the term "co-whatsamols" was disparaging of other companies' products nor did it fail to recognise the professional standing of the recipients. The Panel therefore ruled no breach of the Code.

APPEAL BY SANOFI WINTHROP

Sanofi Winthrop objected to the use of the term "co-whatsamols" as it was a slang expression. The company pointed out the Shorter Oxford Dictionary defined slang as "The special vocabulary used by any set of persons of a low or disreputable character; language of a low or vulgar type". Sanofi Winthrop maintained that the use of such slang expressions in promotional material failed to recognise the special nature of medicines. Sanofi Winthrop noted Searle's submission that during market research the term "co-whatsamols" was recognised by doctors as an entirely appropriate description of a group of analgesics prefixed with "co". Sanofi Winthrop pointed out that the English language contained many slang expressions which market research might reveal to be recognisable and at times appropriate. The fact that the term was recognisable did not, however, preclude the term from being derogatory or disparaging in nature and did not indicate that it would be appropriate terminology for a pharmaceutical company to use in reference to ethical medicines.

Sanofi Winthrop pointed out that the prefix "co" was introduced by the UK authorities not for the purpose of easy recognition of a group of analgesics, but as a description of certain compound products which extended beyond generic analgesics to a broad range of other therapeutic areas including antibiotics, diuretics, antihypertensives and medicines used in Parkinsonism. This highlighted the confusion to which the use of undefined terminology might lead and thus such expressions were inappropriate in the promotion of medicines.

RESPONSE

Searle submitted that all the comments made to the Panel were valid and substantiated why the term "co-whatsamols" was not disparaging. The term had been originally coined by a palliative care physician. The company submitted that there were many different definitions of slang and that by no means all of these definitions stated that slang was disparaging. Sanofi Winthrop itself had a second definition of slang namely "undefined terminology".

APPEAL BOARD RULING

The Appeal Board did not accept that the use of the term "co-whatsamols" was disparaging of other companies' products and neither was it a term which failed to recognise the professional standing of the recipients nor the special nature of medicines. The Appeal Board therefore ruled no breach of the Code. The appeal therefore failed.

6 Zydol quiz

The quiz appeared in the special front page attached to a daily newspaper. It was headed "£1000 of prizes in our Big Bridge quiz". Entrants had to answer six questions and complete a tie breaker. The top ten entries were to be awarded £100 in vouchers for medical equipment.

COMPLAINT

Sanofi Winthrop alleged that the number of prizes on offer and their value were out of proportion to the skill required. Further, asking doctors to complete the tie breaker was in effect eliciting promotional copy by asking doctors to be creative about the bridging qualities of Zydol. This failed to recognise the professional standing of the recipients. Breaches of Clauses 9.1 and 18.2 were alleged.

RESPONSE

Searle submitted that the quiz complied with the Code as it was relevant to the medical profession, it was a *bona fide* test of skill and it reflected the professional standing of the recipients. Searle advised that twenty responses were received of which only two were completely correct. One of the medical questions, question 5, generated the most incorrect responses. There were ten prizes offered, each of £100 of medical equipment. The number of prizes equated to one prize per two thousand potential entries. The company did not consider this number of prizes to be out of proportion to the number of potential entries and the prizes themselves did not benefit an individual doctor but rather the patients the doctors treated. However, in view of the response only two prizes were to be given to the correct entries. The medical equipment would be purchased by Searle on behalf of the doctors. Searle disagreed that a tie breaker was in effect eliciting promotional copy. None of the answers received would be used in this way.

PANEL RULING

The Panel examined the quiz and accepted that it did have some relevance to the practice of medicine or pharmacy. There were six questions, three related to medical matters and three did not. The Panel noted the supplementary information to Clause 18.2 that a competition was more likely to be considered acceptable if its subject matter was clearly related to the practice of medicine or pharmacy. The Panel did not accept that the subject matter was inappropriate for the promotion of a medicine. The Panel noted that the questions had been shown to be difficult as one of the medically related questions generated the most incorrect responses.

The Panel noted that the prizes were within the new recommendations that the maximum acceptable cost to the donor of a prize in a promotional competition was £100. The Panel considered that the number of prizes available was somewhat on the high side but noted that in view of the response only two prizes were to be awarded to correct entries. The Panel considered that the quiz was on the limits of acceptability as regard to the nature of the questions and the number of prizes on offer but decided that it did not breach the Code. The Panel therefore ruled that there was no breach of either Clause 9.1 or Clause 18.2 of the Code.

Complaint received **22 July 1994**

Case completed **8 November 1994**

CASES AUTH/185/7/94 & AUTH/212/9/94

DIRECTOR v SMITHKLINE BEECHAM

Breaches of undertakings

Two instances involving breaches of undertakings by SmithKline Beecham were drawn to the attention of the Code of Practice Authority. The items concerned were a letter on Famvir sent to a doctor by a representative (Case AUTH/185/7/94) and a Famvir journal advertisement (Case AUTH/212/9/94). Further breaches were ruled by the Panel in respect of the repeated use of claims previously ruled unacceptable and the company was also held to have breached Clause 2 in each case. The Panel also reported SmithKline Beecham to the Appeal Board.

SmithKline Beecham appealed against the rulings of breaches of Clause 2 on the basis that the breaches of undertakings had occurred because of human error. This was accepted by the Appeal Board in respect of the earlier case (Case AUTH/185/7/94) but it upheld a breach of Clause 2 in the second case (Case AUTH/212/9/94) as it was the second occasion within a short span of time in which an undertaking had failed to be fully implemented by the company. Both cases were reported to the ABPI Board of Management which noted the findings of the Appeal Board and welcomed the fact that SmithKline Beecham had already decided to have an audit of its procedures carried out by the Authority.

Case AUTH/185/7/94

CODE OF PRACTICE PANEL CONSIDERATION

The Wellcome Foundation Ltd complained that a letter sent by a SmithKline Beecham Pharmaceuticals' representative to a general practitioner promoting Famvir included claims which had previously been ruled to be in breach of the Code. In view of the fact that the complaint involved possible breaches of undertakings, the matter was taken up as a complaint by the Director of the Authority as the Authority itself was responsible for ensuring compliance with undertakings. This accorded with guidance previously given by the Appeal Board.

SmithKline Beecham Pharmaceuticals said that following receipt of the Authority's letter, it had undertaken a full review of its activities following breach rulings in Cases AUTH/105/1/94 and AUTH/140/3/94. The company outlined the actions which had been taken to ensure that all materials were withdrawn and provided copies of various internal documents. Unfortunately, a representative had continued to use a standard follow up letter which contained claims which the sales force had been briefed were in breach of the Code. Representatives had been reminded of their responsibilities and the letter formally withdrawn. The company believed this to be an isolated incident and it was now reviewing all its procedures and its current flow chart (which showed the materials withdrawal/recall process) so as to make them as failsafe as possible. The company accepted that it was its responsibility to ensure that the error did not occur but it did not represent SmithKline Beecham knowingly breaching the undertaking, simply a case of human error without intent.

The Panel ruled that the claims "Excellent penetration to the infection site", "More powerful and prolonged antiviral effect", "Requires less drug, less often for effective results" and "Faster relief from herpetic pain [compared with aciclovir] with early treatment started within 48 hours" were all in breach of Clause 7.2. These or similar claims had previously been ruled in breach in Cases AUTH/105/1/94 and AUTH/140/3/94.

The Panel ruled that there had been a breach of Clause 2 of the Code with regard to the failure by SmithKline Beecham to implement its undertakings. It was also decided to report the company to the Appeal Board in accordance with Paragraph 8.2 of the Constitution and Procedure.

APPEAL BY SMITHKLINE BEECHAM

SmithKline Beecham said that, as clearly indicated in its original response, it accepted that there had been a breach of undertaking in that the representative response letter was overlooked when material was withdrawn. The company maintained that this was an oversight which occurred in what was otherwise a sound company procedure. The company fulfilled all of its obligations in respect of ensuring appropriate personnel were briefed on the outcome of the cases and the rulings which were given. Indeed, a sales force meeting had been called to brief them on the issues and rulings.

The oversight occurred at a time of extraordinary pressure within the team responsible, occasioned by the strategy being exercised by Wellcome which was to complain about every piece of promotion in use by SmithKline Beecham. As the Panel was aware, Wellcome made five complaints alleging numerous breaches of the Code and an additional three complaints were authored by clinicians in hospital or general practice. This did not excuse a breach of undertaking but indicated that the company's procedures were being stressed beyond normal. The company believed that the action taken by it subsequent to the rulings of breach, which were documented in the materials already provided, indicated that the company had acted properly. The omission of the letter from an otherwise extensive list of materials being withdrawn strongly supported that this was an oversight. No intent to ignore the undertaking was suggested. Under the circumstances, SmithKline Beecham maintained that while a breach of undertaking had occurred, which was recognised by the company as extremely serious, it had not brought discredit upon the industry or reduced confidence in it. It should not be considered a breach of Clause 2 and further action by the Panel was unwarranted.

Case AUTH/212/9/94

CODE OF PRACTICE PANEL CONSIDERATION

The Wellcome Foundation Ltd complained that a journal advertisement for Famvir which appeared in Hospital Doctor of 8 September 1994 included claims which had previously been ruled in breach of the Code. The same advertisement subsequently also appeared in the issue of 22 September. In view of the fact that the complaint involved possible breaches of undertakings, the matter was taken up as a complaint by the Director of the Authority as the Authority itself was responsible for ensuring compliance with undertakings as referred to in Case AUTH/185/7/94 above.

SmithKline Beecham Pharmaceuticals confirmed that the advertisement in question contained claims ruled in breach. It appeared that as a result of its undertakings, all weekly, monthly and bi-monthly advertisements were cancelled/amended but this particular one on a quarterly schedule was overlooked. This was a simple case of human error with no intent to continue to use claims, but clearly in breach. The company argued, however, against a breach of Clause 2 of the Code.

The company advised that this, together with the recent case concerning the misuse of a representative follow up letter (Case AUTH/185/7/94 above), raised concerns about its internal withdrawal procedures and the company had conducted a thorough review and was instituting some amended standard operating procedures in this area. The company invited the Authority to audit the SmithKline Beecham procedures if it was considered that this would be a useful course of action.

The Panel ruled that the claims "'Famvir' is the first alternative antiviral to acyclovir..."(sic)"Requires less drug less often for effective results" and claims relating to Famvir's potency as an inhibitor of varicella zoster viral DNA replication and that it had a considerably more prolonged antiviral effect than aciclovir were all in breach of Clause 7.2. These or similar claims had previously been ruled in breach in Cases AUTH/105/1/94 and AUTH/140/3/94. A further claim which had been drawn to the Authority's attention by Wellcome was found to have previously been ruled not to be in breach.

The Panel ruled that there had been a breach of Clause 2 of the Code with regard to the failure by SmithKline Beecham to implement its undertakings. It was also decided to report the company to the Appeal Board in accordance with Paragraph 8.2 of the Constitution and Procedure.

APPEAL BY SMITHKLINE BEECHAM

SmithKline Beecham said that the fact that the journal advertisement appeared and was in breach of undertaking was clear. The issue that the company had was that Clause 2 (bringing the industry into disrepute) was inappropriate for what was essentially a case of human error.

SmithKline Beecham had taken clear and documented steps to implement the undertakings. Documentation was provided showing the company's withdrawal of the weekly, monthly and bi-monthly journals and the company again reiterated that this was a simple case of human error without intent. The company referred to its letter relating to Case AUTH/185/7/94 inviting the Authority to comment on its nearly completed procedures. The basis of the company's appeal was that Clause 2 was inappropriate and that there was clear precedent in Cases AUTH/31/4/94 and AUTH/124/3/94, that this particular clause, which the company regarded as clearly bringing the industry into disrepute, might not be appropriate.

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APPEAL BOARD RULINGS

In Case AUTH/185/7/94, noting the fact that the breach of undertaking had arisen as a result of human error, albeit by both the representative and by the company's head office, the Appeal Board ruled there had been no breach of Clause 2. The appeal therefore succeeded. Breaches of Clause 7.2 remained as these had not been appealed. In Case AUTH/212/9/94, the Appeal Board noted that again the breach of undertaking had arisen as a result of human error. It was, however, the second occasion within a short span of time in which an undertaking had failed to be fully implemented and, in view of this, the Appeal Board affirmed that there had been a breach of Clause 2 of the Code. The appeal therefore failed. Breaches of Clause 7.2 also remained as these had not been appealed.

REPORTS FROM THE PANEL TO THE APPEAL BOARD

The Appeal Board considered the reports made by the Panel in relation to both cases under Paragraph 8.2 of the Constitution and Procedure. The Appeal Board decided that both cases should be reported on to the ABPI Board of Management in accordance with Paragraph 11.1 of the Constitution and Procedure.

REPORTS TO THE ABPI BOARD OF MANAGEMENT

When the reports came before the ABPI Board of Management, a representative of the company explained what had happened and outlined the steps which had been taken to try to avoid a recurrence. The company had invited the Authority to audit its newly amended procedures.

The ABPI Board noted the findings of the Code of Practice Appeal Board and welcomed the company's plans to have an audit carried out by the Authority.

Proceedings commenced

Case AUTH/185/7/94	**22 July 1994**
Case AUTH/212/9/94	**16 September 1994**
Cases completed	**11 November 1994**

CASE AUTH/186/7/94

GENERAL PRACTITIONER v MEMBER COMPANY

Calls by representatives

A general practitioner complained about the practice of pharmaceutical companies setting up subsidiary companies to promote well established products. He had been approached by representatives under two different company names who had turned out to be promoting the same product.

The Panel considered that there was nothing in the Code which addressed the question of duplication of the promotion of particular products by representatives from the same or different companies. The Code limited the number of calls by a particular representative which in this case, was not excessive and no breach was ruled.

COMPLAINT

A general practitioner complained about the growing practice in the pharmaceutical industry of the setting up of subsidiary companies to promote well established products. He was concerned that the only reason for the establishment of these was that so that they could increase the promotion of their products contrary to the guidelines of the ABPI. For instance, he had been approached at least twice this year by a company regarding one of its products. On the day of his letter, he had agreed to see a lady from another company who had turned out to be selling nothing other than the same product. The complainant alleged that this was unacceptable and contravened the Code.

RESPONSE

The company concerned said that the second representative was one of a team of representatives employed under contract and operating under a name different to that of the principal company itself. No attempt had been made to disguise the fact that the same product would be promoted but the two teams of representatives were discussing entirely different indications. All of the representatives were given training on the Code and all were aware of the requirements of Clause 15.4 regarding the frequency of contact by each representative on each doctor.

The company submitted that the Code did not state that it was unacceptable for two companies to be promoting the same product. Furthermore, in this case, two companies were promoting different indications and different strengths of a product which had different product licence numbers. The company's own representative appeared to have approached the complainant twice in a period of seven months, which approximated to one call per tertial. The other representative had contacted the complainant once in the same period. Bearing in mind the supplementary information to Clause 15.4 of the Code, which allowed for an average of three calls on a doctor by a representative in a year, in addition to those responding to doctor requests for a visit, conduct of audio-visual presentations etc, the company did not believe that there had been a breach of the Code.

PANEL RULING

The Panel noted the supplementary information to Clause 15.4 of the Code which said that companies should arrange that intervals between visits did not cause inconvenience and that the number of calls made on a doctor by a representative each year should not normally exceed three on average. This did not include attendance at group meetings including audio-visual presentations and the like or a visit which was requested by a doctor or made in response to a specific enquiry or a visit to follow up a report of an adverse reaction.

The Panel considered that there was nothing in the Code which addressed the question of duplication of the promotion of particular products or related products by representatives from the same or different companies. In this case, the number of calls by each representative was not excessive. In consequence, the Panel ruled that there had been no breach of the Code.

Complaint received **25 July 1994**

Case completed **30 August 1994**

CASES AUTH/190/7/94 & AUTH/194/8/94

BOEHRINGER INGELHEIM/ETHICAL PHARMACEUTICALS v NAPP LABORATORIES

Disparaging references & misleading side effect claims in MST Continus mailing

Boehringer Ingelheim and Ethical Pharmaceuticals complained separately about a mailing consisting of a brochure on MST Continus tablets and suspensions issued by Napp Laboratories. The use of the term "imitator" in reference to Boehringer Ingelheim's product in the mailing was ruled by the Panel to be disparaging as was a statement, also in reference to the Boehringer Ingelheim product, that "MST CONTINUS Tablets have never been marketed in the UK under a different name, unlike another product currently available". A claim referring to increased side effects and vomiting based on a pharmacokinetic study was also ruled by the Panel to be misleading, as it was not made clear that it was referring to data not in patients. It was queried whether it was valid to present data on side effects from the study but this had not been raised in the complaint.

The Panel ruled no breach with regard to a phrase "Is imitation the sincerest form of flattery?" appearing on the outside of the envelope containing the mailing which was also alleged to be disparaging. Nor was any breach ruled with regard to two other allegations concerning a claim for Napp's support and educational services and a concluding statement at the end of the brochure.

Boehringer Ingelheim Limited (Case AUTH/190/7/94) and Ethical Pharmaceuticals Limited (Case AUTH 194/8/94) complained separately about a mailing consisting of a brochure (ref MS 064 OM) on MST Continus tablets and suspensions issued by Napp Laboratories Limited. Reference was also made in the brochure to Napp's product Sevredol tablets. Napp, although not a member of the ABPI, had nevertheless agreed to comply with the Code.

The background to the complaint was that there were currently two modified release morphine preparations in the UK, one being MST Continus tablets and the other Oramorph SR tablets marketed by Boehringer Ingelheim. The latter formulation was developed by Ethical Pharmaceuticals and until the early part of 1994 was marketed by another pharmaceutical company under a different brand name.

Case AUTH/190/7/94

1 Reference to competitor as imitator

COMPLAINT

Boehringer Ingelheim alleged that the mailing was disparaging of its product in breach of Clause 8.1 of the Code, citing three instances. These were: the phrase "Is imitation the sincerest form of flattery?" appearing on the outside of the envelope and the statements in the brochure "This imitator, in tablet form...." and "MST CONTINUS tablets have never been marketed in the UK under a different name, unlike another product currently available".

RESPONSE

Napp Laboratories submitted that the meaning of the word "imitator" was not that Boehringer Ingelheim had wholly or directly copied MST Continus tablets but that it had used them as a model. A photograph was submitted comparing the colours, sizes and shapes of MST Continus tablets and Oramorph SR tablets which showed they were almost identical in colour, size and shape. Various promotional items for Oramorph issued by Boehringer Ingelheim were also submitted which included the statements that "Oramorph SR tablets have been designed to provide a pattern of morphine relief similar to currently available sustained release morphine tablets" (added emphasis) and "Oramorph SR tablets have been designed to have a pharmacokinetic profile which closely resembles that of the other morphine sulphate slow release tablet currently available" (added emphasis). Napp also pointed out there were numerous references in the material for Oramorph SR to "the current sustained release morphine sulphate tablets" which were clearly identified as the Napp product and that the material stressed that the *in vitro* dissolution, bioavailability and blood level patterns were similar in both Oramorph SR and MST Continus tablets. The company submitted that it was clear from Boehringer Ingelheim's own literature that they were promoting Oramorph SR tablets to a great extent on the basis of their similarity to MST Continus tablets. Further, it was understood that the licence for Oramorph SR tablets was obtained by using data confirming the pharmacokinetic similarity of that product to MST Continus tablets and on that basis no clinical data was supplied or required.

Finally, with regard to the statement "MST CONTINUS tablets have never been marketed in the UK under a different name, unlike another product currently available", Napp submitted this was a statement of fact in response to Boehringer Ingelheim's marketing of Oramorph SR tablets as new. Napp had been concerned by reports from its representatives of confusion amongst health professionals over whether Oramorph SR tablets were a new product and it was therefore seeking to clarify the position.

RULING

The Panel did not accept that the question "Is imitation the sincerest form of flattery?" was disparaging and ruled there was no breach in relation to that allegation. The Panel considered that to a certain extent Boehringer Ingelheim had invited references to its product as being an "imitator" given the thrust of its promotion of Oramorph SR tablets as being designed to closely resemble MST Continus tablets. Nevertheless, the Panel considered that the use of the word "imitator" was inappropriate as it had connotations of inferiority and

that, furthermore, the phrasing used in the brochure "The success of MST CONTINUS Tablets and Suspensions has attracted acclaim as well as an imitator. This imitator, in tablet form, exhibits...", was inappropriate. The Panel considered that it was disparaging and ruled there was a breach of Clause 8.1. The Panel also considered that the statement "MST CONTINUS Tablets have never been marketed in the UK under a different name, unlike another product currently available." was unacceptable in that it was disparaging of the competitor product and ruled there was a further breach of Clause 8.1.

2. Claim on increased side effect of vomiting based on pharmacokinetic study

COMPLAINT

Boehringer Ingelheim alleged that the claim that Oramorph SR tablets exhibited an increased incidence of vomiting in the brochure was not supported by any data from patient studies. It was based solely on a pharmacokinetics study carried out in twenty seven healthy volunteers given a single dose of 30mg and there was no data relevant to the chronic treatment of terminally sick patients. Breaches of Clause 7.2, 7.3 and 7.7 were alleged.

RESPONSE

Napp pointed out that the reference to vomiting occurred in a paragraph clearly relating to pharmacokinetic matters and was alongside a graph in the brochure presenting pharmacokinetic information. There was no intention to make a clinical claim in the section on pharmacokinetics and it did not believe that a health professional would interpret the reference to vomiting as anything other than an effect exhibited in the referenced pharmacokinetic study.

Napp advised that nevertheless, following discussions with Boehringer Ingelheim, it had reached an understanding with that company to instruct Napp representatives to be careful not to make clinical claims on the basis of the study.

RULING

The Panel noted that the actual study by Houston *et al*, referenced to the disputed claim in the brochure, comprised a comparison between MST Continus tablets and Morstel SR tablets and that no explanation had been provided as to whether Morstel SR tablets were Oramorph SR tablets or not. The Panel also queried whether it was valid to present data on side effects from a study in which this data appeared somewhat incidental to its primary purpose of comparing the pharmacokinetics of the two products. Furthermore, the study was limited in terms of the numbers of subjects involved and its duration. These criticisms had not, however, been specifically raised by Boehringer Ingelheim.

The Panel considered that it was an established principle under the Code that any claim in advertising was automatically read as referring to data in patients and that if this was not the case, the position had to be made clear in the advertisement. With regard to the wording in the brochure, the Panel considered that the claim was a clinical claim for the product. It was not a statement about the pharmacokinetics but a statement about side effects which was clearly related to clinical usage. The Panel considered that it was misleading and ruled it was in breach of Clause 7.2 of the Code.

3 Support and educational services

COMPLAINT

Boehringer Ingelheim alleged that the final section in the brochure headed "Unrivalled service and commitment" was inaccurate and misleading in breach of Clauses 7.2, 7.3 and 7.8 as it suggested that only Napp provided support and educational services to professionals involved in palliative care. The company submitted that it had a major presence in the field of palliative care for many years and during that time it had provided support and educational services for palliative care professionals, patients and their families.

RESPONSE

Napp Laboratories provided information on a number of palliative care initiatives sponsored by the company and various literature produced for health professionals on palliative care. It was pointed out that Boehringer Ingelheim had not provided any evidence of its support and educational services in palliative care.

RULING

The Panel noted the evidence submitted by Napp and the lack of any evidence provided by Boehringer Ingelheim on its activities and decided on the information before it there was no breach of the Code.

4 Concluding statement in brochure

COMPLAINT

Boehringer Ingelheim alleged that the final sentence in the brochure "In conclusion; for palliative care that looks after your hospital's needs as much as those of its patients, you need to start with MST CONTINUS and stay with MST CONTINUS." was inaccurate, all embracing and did not reflect current practice in the use of analgesia in palliative care in breach of Clauses 7.2, 7.3 and 7.7. It implied that only Napp could "look after your hospital needs as much as those of its patients" and that it was necessary to start therapy with MST Continus and to remain on it.

RESPONSE

Napp submitted that the statement was intended to sum up the two principal messages of the mailing; the extent and reputation of both its morphine presentations and its range of support and educational services for health professionals.

RULING

The Panel considered that the disputed sentence was simply a wrap up statement for the promotional item. The

Panel did not accept the allegations and ruled there was no breach.

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Finally, Boehringer Ingelheim alleged a breach of Clause 9.1 in that it considered health professionals would object to the type of copy employed in the brochure particularly given that it was dealing with products for the care of terminally ill patients. The company also asserted that there was a case for requesting that steps be taken to recover the item and that a corrective statement should be issued by Napp.

Neither of these points were accepted by the Panel.

Case AUTH/194/8/94

COMPLAINT

Ethical Pharmaceuticals made the following allegations.

1 It was disparaging for Napp to imply that Ethical's product was an imitator and to refer to the fact that the product had previously been marketed in the UK through another licensee as this was of no consequence to the current marketing situation. For Napp to refer to this was not only disparaging but it might have had safety implications by way of an intention to confuse prescribers and other professionals concerned with the administration of a controlled drug.

2 That the use of the word "imitator" or the implication of imitation of Napp's controlled release system was unjustifiable since the release control systems employed were fully distinguishable. Reference was made to legal actions relating to this issue in the UK and Australia.

3 There was no support in any patient studies for Napp's assertion that Oramorph SR tablets caused a higher incidence of vomiting than Napp's product. Such data that did exist was taken from volunteer studies and it was to be expected that morphine-naive subjects would suffer a higher degree of side effects than patients undergoing a normal treatment regimen.

4 The claim for "Unrivalled service" was disputed.

RESPONSE

Napp reaffirmed its submission on the allegations made by Boehringer Ingelheim and commented on the legal proceedings between the two companies. Napp submitted that the decisions on those actions could not be used as evidence whether Oramorph SR tablets did or did not imitate its products. With regard to the reference to "morphine-naive" subjects in the study referenced in the brochure, it was pointed out that the study was a randomised cross-over study so that all patients received both treatments at different times. The study was also blinded. Any factor of "morphine naivety" would have been equally applicable to both treatments.

RULING

The Panel considered that the allegations made by Ethical Pharmaceuticals were subsumed by those made by Boehringer Ingelheim. The Panel's rulings in Case AUTH/190/7/94 therefore applied to the allegations made in this case.

Complaints received	**28 July 1994 & 9 August 1994**
Cases completed	**12 September 1994 & 15 September 1994**

CASE AUTH/191/7/94

GENERAL PRACTITIONER v MEMBER COMPANY

Conduct of market researcher

A general practitioner complained about the conduct of a market researcher. The Panel noted that there was a conflict of evidence over whether the researcher said she was a personal caller as alleged but it was considered that this might have been the result of a misunderstanding. The Code's requirements only related to disguised promotion and neither the researcher's conduct nor the survey was considered to constitute disguised promotion. No breach was ruled.

COMPLAINT

A general practitioner submitted a complaint about a market research survey on a particular product carried out on behalf of a member company.

The complainant explained that during a extremely busy day's work he was told by one of the reception staff that he had a personal telephone call from a named caller, whom the complainant could not recall ever having spoken to, met or written to. Despite being extremely busy he had asked for the call to be put through as it was a personal call. He was therefore surprised to discover that the caller was speaking on behalf of the member company, enquiring as to how often he prescribed the product as she was doing a study on this. She enquired as to whether the complainant could spare approximately half an hour to complete a questionnaire. The complainant informed the caller that unfortunately he would not be able to spare this amount of time. She then enquired whether the complainant could spare the time the following week. Again, the complainant informed her that he didn't have the amount of time to spare. He was then very surprised to hear the caller enquire whether a payment of £30 would entice him to change his mind. Naturally, again he informed her that he did not have the time to spare.

The complainant drew attention to two points. Firstly, he objected to pharmaceutical representatives, particularly those whom he had never met, informing his reception staff that they were personal callers in an attempt to bypass the reception staff to be put through immediately to himself. Secondly, without wishing to imply in any way that the caller was offering any illegal payment, he found it professionally and morally insulting after having twice informed her that he had no spare time to be offered a cash payment in order to persuade him to find time to complete her questionnaire.

RESPONSE

The company concerned explained that the case related to a piece of market research conducted on its behalf by a market research organisation. The company submitted that it was conducted in accordance with the market research guidelines and was in no way intended to be disguised promotion. It was perfectly normal for payment to be made for the time the doctors devoted to such activities.

The researcher concerned was very experienced. Her initial approach was via the receptionist who gave her a specific time to call back. When she called at the appointed time, the receptionist explained that the doctor was still busy and she was to try again in fifteen minutes. This she duly did and was asked by the receptionist to try again later. On the fourth occasion she was put through to the complainant. The company pointed out that the receptionist knew that the call related to a market research exercise since screening questions about the doctor's use of certain medicines had been asked in order to establish that there was indeed any point in speaking to the complainant.

The company submitted that following the initial invitation to take part in the research, the standard offer of £30 remuneration as a token for the time taken in participating in the market research had been made. The complainant responded that the money was not relevant but he simply did not have the time. The conversation was terminated at that point.

The company submitted that it did not believe that the market research survey was in any way promotional and enclosed a copy of the questionnaire and a copy of the introduction given to the interviewers. The company submitted that the survey was totally within market research guidelines and it was regrettable that the complainant felt sufficiently upset to write both to the Code of Practice Authority and the company. A copy of the caller's *curriculuum vitae* which gave an idea of the breadth of experience she had acquired during her career, a copy of the market research company's own in house instructions for GP interviewing, to which the caller insisted that she had adhered, and copies of the guidelines for market research to which the agency conformed were provided.

RULING

The Panel examined the documentation and noted that there was some conflict of evidence as the company submitted that the receptionist would know that the call was related to a market research exercise since screening questions had been asked. There had, however, been four telephone calls from the caller and some misunderstanding might have arisen. The Panel considered that it was unacceptable for anyone to describe themselves as a personal caller when in fact they were not.

The Panel noted the requirements of Clause 10.2 of the Code, that market research activities must not be disguised promotion and considered that if a market research survey was not disguised promotion then it did not come within the Code even if the activities themselves were not beyond criticism.

The Panel did not accept that the questionnaire was promotional. It noted that the complainant had been told that the survey related to the use of the product. The Panel noted that participants could be paid an appropriate fee for participation in a market research survey. It considered that the £30 was not unreasonable.

The Panel did not consider that the market research activities were disguised promotion and therefore ruled no breach of Clause 10.2 of the Code.

Complaint received **29 July 1994**

Case completed **5 September 1994**

CASE AUTH/193/8/94

ALCON LABORATORIES v ALLERGAN

Betagan booklet & loose sheets - failure to include prescribing information

Alcon alleged that loose sheets contained in a booklet for Betagan by Allergan should have included prescribing information. The booklet was also alleged to be in breach of Clause 4.6 as it was more than four pages in length without a reference as to where the prescribing information could be found. These allegations were accepted by the Panel and breaches of Clauses 4.1 and 4.6 were ruled.

COMPLAINT

Alcon Laboratories (UK) Limited, a company not in membership of the ABPI, submitted a complaint about a booklet entitled "Betagan (levobunolol) Ocular Blood Flow and Glaucoma" issued by Allergan Limited.

The booklet consisted of a number of stapled pages and a flap containing three loose sheets. The prescribing information was given on the back page of the booklet.

Alcon alleged that the loose sheets were promotional in nature as they indicated favourable results obtained using levobunolol when treating glaucoma and were in breach of Clause 4.1 of the Code as they did not include prescribing information. A breach of Clause 4.6 of the Code was also alleged as the booklet was more than four pages long and there was no reference as to where the prescribing information could be found.

RESPONSE

Allergan Limited submitted that the loose sheets included in the booklet were summaries of published clinical studies. They made no reference to branded products and they were not regarded as promotional. The company submitted that excluding the loose sheets the booklet was only four pages long. The Code did not specify whether a page was a leaf or a side and on this basis Allergan considered the material to be in compliance.

RULING

The Panel examined the loose sheets enclosed in the folder at the back of the booklet.

The Panel did not accept the submission that because the sheets did not refer to the branded products they were not promotional. It considered that the loose sheets were promotional as they featured clinical studies involving levobunolol and as they were included in a promotional booklet. In order to comply with the requirement that each promotional item must be able to stand alone (supplementary information to Clause 4.1), each sheet required prescribing information. The Panel therefore ruled a breach of Clause 4.1 of the Code.

The Panel also ruled a breach of Clause 4.6 of the Code as the brochure consisted of more than four pages and there was no reference as to where the prescribing information could be found. The word "page" bore the usual meaning of a single side, as with page numbering in books, journals and other such publications.

Complaint received 2 August 1994

Case completed 6 September 1994

CASE AUTH/196/8/94

GENERAL PRACTITIONER v MEMBER COMPANY

Newspaper article

A general practitioner complained that a Sunday newspaper magazine article which referred to the benefits available from a named prescription medicine was in breach of Clause 20.2 because it encouraged patients to ask for it by name.

The Panel considered that neither the conduct of the company nor the content of its press releases were unacceptable and no breach was ruled.

COMPLAINT

A general practitioner complained that a patient had brought in a copy of a Sunday newspaper magazine which contained an article on a particular condition and which referred to the benefit available from a named prescription medicine.

The complainant expressed the view that the article was in breach of Clause 20.2 of the Code in that it encouraged patients to request a particular product by name.

RESPONSE

The member company said that it had issued a number of press releases to the lay press since the launch of the product and copies of these were provided. Both the company and its agency logged all contacts with the medical and lay press. There was just one record of contact with the author of the item involved. A copy of the document sent to the author was provided. The company emphasised that it had no direct contact with the newspaper and its direct contact with the author had been restricted to this one occasion on which its agency provided widely available publically distributed information which the company believed was not promotional. As a practising general practitioner, the author had been detailed on the product by one of the company's representatives, but only in that context and not as a medical correspondent.

RULING

The Panel noted that the article consisted of a personal account by a particular sufferer from the condition and that a footnote gave information about the condition and its treatment.

The Panel examined the various news releases which had been provided by the company but did not consider that any of these were such as to be unacceptable and in breach of the Code.

The author of the footnote had been sent information and had been detailed on the product in the normal way as a general practitioner. The Panel considered that nothing had been done by the company, or its agent, to which exception could be taken and ruled that there had been no breach of the Code.

Complaint received 11 August 1994

Case completed 19 September 1994

CASES AUTH/199/8/94, AUTH/211/9/94, AUTH/220/10/94, AUTH/259/12/94 & AUTH/260/12/94

GENERAL PRACTITIONERS & SECRETARY TO LOCAL MEDICAL COMMITTEE v MEMBER COMPANY

Prescription reminder letter sent to patients

Three general practitioners complained that a prescription reminder letter sent by a member company to patients on a particular product constituted advertising to the public. The Panel ruled that there had been no breach and two of the complainants appealed. The Appeal Board had some reservations about the content of the letter but considered that it was not in breach of the Code.

Complaints

Three general practitioners complained about a letter sent by a member company to patients who were taking one of the company's products. The letter asked patients to make an appointment with the doctor and stated that the doctor was likely to give another prescription for the product. The complainants alleged that the letter was a form of promotion of the medicine to the public. One of the complainants alleged that the letter was highly unethical and undesirable particularly as it had been sent without consent and as he had decided to stop the patient's treatment with the product.

RESPONSE

The company explained that as stated in the data sheet, the recommended duration of treatment with the product was up to three years. It was recognised and accepted by physicians that treatment of the condition with the product was of a long term nature. Published data reinforced the need for patients to be compliant from one cycle to the next and to remain on therapy for the recommended duration.

The company submitted that the letter formed part of a patient prescription reminder service which had been reviewed and approved by the Medicines Control Agency as part of the patient information leaflet enclosed in the pack. The company therefore considered the service as part of its labelling. The reference to the patient reminder service appeared in a section of the patient information leaflet. The patient was being offered a service to facilitate remembering the need to make follow up appointments with their doctor after having finished their current cycle of therapy in order to discuss the continuation of the treatment. Patients were reminded that participating in this service was entirely voluntary. A reminder letter was issued to the patient shortly before the expected expiry of the current cycle. The reminder letter reiterated the text of the patient information leaflet and did not contain any product claims. It was presented in a factual and balanced way and was only sent in response to direct requests by patients for whom therapy had already been initiated by the doctor.

PANEL RULING

The Panel noted that the prescription reminder letter would be sent only to patients on the product who had returned the card included in the patient information leaflet. The service had been reviewed and approved by the Medicines Control Agency as part of the patient pack information leaflet.

The Panel considered that it was not unacceptable in principle for pharmaceutical companies to provide a service to remind patients on long term therapy to return to their doctor as their medication was running out. Whether such a service would comply with the Code would depend on how it was carried out and the contents of any material used in the service. The Panel did not accept that the content of the reminder letter in question constituted an advertisement to the public as the recipient would have been prescribed the product by their doctor and no product claims were made beyond a reference to the disease area. The Panel therefore ruled no breach of Clause 20 of the Code.

APPEAL BY TWO COMPLAINANTS

The complainant in Case AUTH/199/8/94 appealed because he considered that the reminder letter was contrary to the spirit of Clause 20.2 of the Code and he objected to the wording of the letter which could not be described as balanced. When it stated that the doctor would most likely prescribe, this was a prejudgement on the prescribing process which altered patients' expectations and fundamentally interfered with the doctor patient relationship. The suggestion that patients make an appointment might for various reasons be inappropriate and even cause unnecessary anxiety.

The complainant in Case AUTH/220/10/94 thought it was both unethical and undesirable to send such letters to patients. In the case of the patient about whom the complainant had written, the complainant had decided not to continue the therapy after consultation with a specialist. Sending such a letter to the patient, particularly without the complainant's permission or consent placed him in an awkward situation. The patient was now left wondering whether the complainant's decision to stop the therapy was in fact a correct decision or not. The complainant alleged that this doubt had obviously been raised in the patient's mind by receiving the letter to which he was objecting.

RESPONSE

The company stated that the patient would only request the reminder letter as a result of reading the patient information leaflet. The reminder service had a number of features in common with the patient information leaflet such as advising the patient to make an appointment with the doctor and the likelihood of a further prescription. The patient information leaflet also stated that the therapy was recommended for three years and patients should continue on the product for as long as the doctor

prescribed it. The company did not accept that the letter was encouraging the public to ask the doctor to prescribe a specific medicine as the course of treatment had already been prescribed. The service was compliance orientated and did not interfere with the role of the doctor. In long term therapy compliance issues were crucial if any benefit were to be obtained.

The company accepted some patients might be prompted by the leaflet or the reminder letter to enquire in more detail why a long term therapy had been terminated but that itself was not objectionable. It submitted that proper counselling would ensure no confusion. The company submitted that appointments for reassessment were a natural part of long term therapy and the recommendation in the reminder letter and the leaflet was unlikely to cause anxiety.

The company submitted that doctors had not been told about the reminder service as such. It was mentioned, however, by representatives during discussions with doctors but not all doctors would know about the service. The reminder service only operated for a limited number of cycles as the company did not want to be reminding patients who had completed the recommended course of treatment.

APPEAL BOARD RULING

The Appeal Board considered that it was somewhat unusual for a product to have a statement in the data sheet that the recommended duration of therapy was up to three years. The Appeal Board accepted that pharmaceutical companies could provide a service to remind patients on long term therapy to return to their doctor as their medication was running out. The Appeal Board had some reservations about the content of the letter and considered that it could have been better worded. The reminder letter was only sent to patients who had been prescribed the product and was not considered to promote the product. It noted that the reminder letter had a number of features in common with the patient information leaflet which had perhaps not been seen by doctors as it was not included in the ABPI Compendium of Patient Information Leaflets.

The Appeal Board upheld the Panel's ruling that there was no breach of Clause 20 of the Code.

The appeals therefore failed.

Complaints received	**Case AUTH/199/8/94**	**18 August 1994**
	Case AUTH/211/9/94	**14 September 1994**
	Case AUTH/220/10/94	**10 October 1994**
Cases completed	**Case AUTH/199/8/94**	**16 November 1994**
	Case AUTH/211/9/94	**30 September 1994**
	Case AUTH/220/10/94	**16 November 1994**

Following completion of these cases two further complaints were received, one from a general practitioner and one from a Secretary to a Local Medical Committee. (Cases AUTH/259/12/94 & AUTH/260/12/94). It was decided that these complaints were covered by the Appeal Board's ruling of no breach and no further action was taken.

CASE AUTH/200/8/94

HOSPITAL CHIEF PHARMACIST v ASTA MEDICA

Unacceptable letter on ferrocontin folic written by a representative

A letter written by a representative from Asta Medica about Ferrocontin Folic which described it as "the best" and "beyond comparison" and referred to its low cost "so even the administrators would be happy" was complained about by a hospital chief pharmacist. The letter had been left in a hospital for a consultant obstetrician together with a pack of Ferrocontin Folic tablets. The Panel ruled that the representative had failed both to maintain a high standard of ethical conduct and to comply with all the relevant requirements of the Code due to the content of the letter, the omission of prescribing information, the failure to comply with sample requirements and the failure to have the letter certified. Further, the tone and wording failed to recognise the professional standing of the recipient.

COMPLAINT

A hospital chief pharmacist complained about a letter on Ferrocontin Folic left by a representative from Asta Medica Limited for a consultant obstetrician. The letter was accompanied by a product data sheet and a pack of thirty Ferrocontin Folic tablets all of which were joined by a series of stickers referencing the product, which could not be removed without damage to the data sheet.

The complainant alleged that in addition to the apparent light-heartedness of the letter to the consultant who reputedly never saw representatives, the letter breached Clause 7.8 by describing Ferrocontin Folic as "the best" and there were further breaches of Clauses 7.8, 7.2 and 7.3 with the claim that the product "was beyond comparison". Finally, the complainant alleged that the final paragraph in the letter which referred to the low cost of Ferrocontin Folic tablets and stated "so even the administrators would be happy" was in bad taste.

RESPONSE

Asta Medica Limited, although not a member of the ABPI, had nonetheless agreed to comply with the Code. The company advised that having had the opportunity to study the information and discuss the circumstances with the appropriate sales manager, it unfortunately agreed that the representative had acted in breach of the Code. It was clearly stated company policy that all representatives operate within the limitations of the Medicines Act, the data sheet of the product, approved promotional material

and the Code. The representative in question had been properly trained and had passed the appropriate ABPI examination. The representative therefore should have recognised that he was in breach of the Code and the company advised that he had been formally and severely disciplined. The company pointed out to the best of its knowledge, this was the first occasion in which any complaint had been made about the activities of a representative from its company.

RULING

The Panel considered that the representative in question had clearly failed to maintain a high standard of ethical conduct in the discharge of his duties and to comply with all relevant provisions of the Code as required under Clause 15.2. The use of the superlative "the best" and the exaggerated claim "beyond comparison" was not in accordance with Clause 7.8, neither did the tone of the letter and the concluding paragraph in it recognise the professional standing of the recipient as required under Clause 9.1. Further, the letter had not been certified as required under Clause 14, prescribing information for the product had not been included as required under Clause 4.1 and it was apparent that no signed request form had been obtained for the provision of the sample of Ferrocontin Folic tablets as required under Clause 17. The Panel therefore ruled there was a breach of Clause 15.2.

Complaint received 19 August 1994

Case completed 30 September 1994

CASE AUTH/201/8/94

HOSPITAL PHARMACY BUSINESS SERVICES MANAGER V BOEHRINGER INGELHEIM

Inadequate labelling of air freshener promotional aid for Bonefos

A hospital pharmacy business services manager complained that a Bonefos promotional aid air freshener disributed by Boehringer Ingelheim had the potential to cause clinical problems or confusion to staff. A breach of Clause 9.1 was ruled by the Panel as the item failed to recognise the special nature of medicines as it had not been adequately labelled.

COMPLAINT

A hospital pharmacy business services manager complained about a promotional aid for Bonefos distributed by Boehringer Ingelheim Limited. The complainant had also written directly to Boehringer Ingelheim about the matter.

The item in question was a plastic tablet container with a solid fresh air deodorant inside. The only writing on the tablet container was Bonefos, together with an indication that the name was a trade mark.

The complainant alleged that the promotional aid had the potential to cause clinical problems to patients or at least confusion to staff and raised a number of concerns. Firstly, staff who had never administered the product before could potentially apply the air freshener as an ointment. Secondly, those staff who had administered the product before might assume that the wrong product had been sent to the ward and this could delay treatment. Thirdly, the air freshener might not be compatible with hospital disinfectant policies.

RESPONSE

Boehringer Ingelheim Limited explained that the air freshener was a product reminder offered by sales representatives to hospital professional staff at the time of detailing Bonefos. On offering the item, a representative fully described what it was and how and where it should be used.

The company submitted that the use of the name Bonefos on the air freshener did not mislead as the product was supplied in capsules or ampules. The prescription for Bonefos would clearly indicate which of these was intended to be given to the patient and no confusion could arise with the solid nature of the air freshener. Were the air freshener to be a medicinal product, the labelling on what could be regarded as a medicinal pack would be inadequate as it did not include most of the information required for a medicine. The air freshener was handed to staff who would know what it was and would use it appropriately and would not store it with medicines for the ward.

The company submitted that the use of the air freshener as a promotional aid recognised the special nature of medicines and the professional standing of the recipients. Bonefos was a potent medicine used in seriously ill patients. Some of the procedures on these patients and the conditions from which they suffered gave rise to very unpleasant smells. The offer of an air freshener associated by name with Bonefos brought together the benefit of improving the environment with the reminder of the product name. The company pointed out that the air freshener was not a medicinal product that would be required to be handled by the pharmacy nor was it any form of disinfectant that would be directly subject to the hospital's infection control policy. The manufacturer of the air freshener had advised that the gel had not been shown to support growth of micro-organisms and had been widely supplied for use in hospitals and nursing homes.

The company advised that following the complaint, it had decided to provide representatives with self adhesive labels to be applied to the lid of any air fresheners remaining in their possession. The label clearly indicated that the contents were an air freshener. This action was taken in order to try to address the complainant's concerns rather than as an acceptance of the need for the

label on what was so obviously not the medicine Bonefos.

RULING

The Panel noted the supplementary information to Clause 18.2 of the Code that the names of medicines should not be used on promotional aids when it would be inappropriate to do so, for example, when it might mislead as to the nature of the item.

The Panel considered that the air freshener should have been labelled as air freshener so as to avoid any confusion. It was inadequate to provide the air freshener in a tablet container labelled only with the name of the product. It noted that the representative would provide an explanation when handing out the promotional aid but considered that this was not sufficient as the promotional aid would be seen and used by people who had not had the benefit of the explanation from the representative. In any event, promotional items had to be able to stand alone.

The Panel did not accept all the points raised by the complainant but decided there had been a failure to freshener had not been adequately labelled to avoid any likelihood of confusion. The Panel therefore ruled there was a breach of Clause 9.1 of the Code.

Complaint received **24 August 1994**

Case completed **29 September 1994**

CASE AUTH/202/9/94

DIRECTOR v MEMBER COMPANY

Criticisms of a journal advertisement in letter in medical journal

A letter in a medical journal critical of a journal advertisement for a medicine was taken up as a complaint.

The Panel considered that the overall impression of the advertisement had been to mislead as to the scope of the product's indications and ruled a breach of Clause 7.2. This view was not accepted by the Appeal Board which allowed the appeal and ruled that there had been no breach.

COMPLAINT

A letter in a medical journal was critical of a journal advertisement for a medicine issued by a member company. In accordance with established procedure, this was taken up as a complaint under the Code.

The author of the letter said that the wording of the advertisement implied that the product could be used for the treatment and prevention of two conditions whereas, while it was licensed for the treatment of both, it was licensed for the prevention of one only.

RESPONSE

The company concerned said that the advertisement did not imply that the product could be used for the prevention of both conditions. It was made clear what the indications were and these were entirely consistent with the product licence.

PANEL RULING

The Panel considered that the overall impression of the advertisement, despite the limited clarification in the secondary text, was that the product could prevent both conditions. It was licensed for the prevention of only one of them and it was accordingly ruled that there had been a breach of Clause 7.2 of the Code.

APPEAL BY RESPONDENT COMPANY

The company explained that great care had been taken in the design of the advertisement to ensure that the licensed indications were made clear. The company considered that far from providing "limited clarification", the text explicitly described the two licensed indications.

APPEAL BOARD RULING

The Appeal Board did not accept the Panel's view that the overall impression of the advertisement was that the product was indicated for the prevention of both conditions. The Appeal Board ruled no breach of the Code and the appeal succeeded.

Proceedings commenced **24 August 1994**

Case completed **16 November 1994**

CASES AUTH/203/8/94

PHARMACEUTICAL SERVICES NEGOTIATING COMMITTEE v MEMBER COMPANY

Use of a PSNC letter by a representative

The PSNC complained about the use by a representative of a letter sent by the PSNC to a third party. The Panel considered that there were no grounds to show a breach on the available information and no breach was ruled.

COMPLAINT

The Pharmaceutical Services Negotiating Committee (PSNC) complained about a representative of a member company using a letter from the PSNC to a third party to promote sales of its branded product. The letter discussed the availability of certain products on NHS prescription. The PSNC had been told about the use of the letter by the pharmaceutical adviser to a family health services authority (FHSA).

The PSNC had objected in the past to the third party recipient of the letter using it without consent and maintained that the member company would be aware of those objections. The PSNC similarly objected to the member company now using the letter without consent.

The PSNC acknowledged that its information on how the letter was being used was second or third hand but stated it had no reason to believe that it was inaccurate.

The PSNC sent a subsequent letter to the Authority from the pharmaceutical advisor to a family health service authority (FHSA) which stated that she had discussed the letter sent to the Authority by the PSNC with the medical director who had discussed the issue initially with the representative from the member company. The letter further stated that it had no evidence that correspondence between the PSNC, health professionals and the third party was being presented to general practitioners by the member company.

The PSNC sent a subsequent letter to the Authority from the pharmaceutical advisor to a FHSA which stated that she had discussed the letter sent to the Authority by the PSNC with the medical director who had discussed the issue initially with the representative from the member company. The letter further stated that it had no evidence that correspondence between the PSNC, health professionals and the third party was being presented to general practitioners by the member company.

RESPONSE

The company submitted that it was difficult to respond to the complaint in view of the lack of detail provided. The company confirmed that it had not issued the letter to its field force and agreed that it would be improper to do so. As the letter related to generic prescribing, it had no promotional value to the company and therefore, it was at a loss to understand the substance to the complaint, if indeed there was any substance given that the PSNC commented that the information was second or third hand.

RULING

The Panel decided that in order to progress this matter, it would write directly to the medical director of the FHSA to ask for details of the discussions he had had with the representative, whether the representative had given him any relevant papers and whether he would be prepared for his name to be given to the member company in order that it could investigate the matter further.

The medical director advised the Authority that he did not wish to be identified to the member company and he did not wish to be involved in taking the matter any further.

The Panel noted that it was not possible for the company to investigate the matter further. It considered there were no grounds to show any breach of the Code and accordingly ruled that there was no breach of the Code.

Complaint received **26 August 1994**

Case completed **26 October 1994**

CASE AUTH/205/8/94

SMITHKLINE BEECHAM PHARMACEUTICALS v WELLCOME FOUNDATION

Material from medical information department on Zovirax used by representatives

SmithKline Beecham Pharmaceuticals complained that an item issued by The Wellcome Foundation Limited's medical department on Zovirax was continuing to be used by a representative contrary to previous advice from the company. The item comprised a booklet consisting of copies of a number of clinical papers with a "Dear Doctor" letter forming the front cover. The item was originally intended as a response to enquiries on the subject. Wellcome had instructed its field force to destroy the item previously following discussions with SmithKline Beecham.

A breach of Clause 4.1 was ruled by the Panel as the item did not include prescribing information and a breach of Clause 15.2 was also ruled in that the representative had failed to observe all relevant requirements of the Code.

It was observed in the consideration of this case that the exemption from the Code for replies made in response to individual enquiries from members of the health professions was a limited exemption for a specific response to unsolicited enquiries and that there appeared to be a general misunderstanding in companies regarding the scope of the exemption. (Note: Advice on this issue was provided in the PMCPA Quarterly Review October 1994)

COMPLAINT

SmithKline Beecham Pharmaceuticals Limited complained about certain material issued by The Wellcome Foundation Limited which dealt with the effects of Zovirax in herpes zoster. The material in question was a booklet consisting of copies of a number of clinical papers with a "Dear Doctor" letter signed by a doctor from Wellcome's medical department forming the front cover of the item.

SmithKline Beecham stated that Wellcome maintained that the item was a specific medical response to an enquiry from the medical profession. SmithKline Beecham alleged that it was being widely distributed by representatives from Wellcome at meetings and this had been taken up with the company. Wellcome had responded by indicating that the piece was outdated and had been superseded by more up to date information. It had also indicated that it was only sent to doctors in response to specific enquiries and that steps had been taken with the representatives involved and the sales force in general concerning the matter.

SmithKline Beecham had subsequently discovered that the item was still being distributed and had been made freely available to doctors attending a recent meeting sponsored by Wellcome.

A breach of Clause 4.1 was alleged as the item did not include prescribing information and it was also alleged that the representative involved was in breach of Clause 15.2.

RESPONSE

The Wellcome Foundation Limited explained that it had now had the opportunity to investigate the complaint fully and had determined which representative was involved. It appeared that despite previous instructions to the field force concerning the provision of this information, the representative in question had failed to destroy the material. The representative had now been severely reprimanded and new instructions had been sent out to the field force clearly stating that they were not to provide the information again in the future. They were also advised to destroy any copies that they still had in their possession immediately.

The company apologised for the breaches of Clauses 4.1 and 15.2 of the Code.

RULING

The Panel ruled that there was a breach of Clause 4.1 of the Code due to the failure to include prescribing information on the item and a breach of Clause 15.2 in that the representative had failed to observe all relevant requirements of the Code.

In considering the matter, the Panel noted that the exemption from the Code for replies made in response to individual enquiries from members of the health professions was a limited exemption for specific responses to unsolicited enquiries. The document in this case was a promotional item subject to the Code and would have been even if it were supplied by the medical department as opposed to the sales force. The Panel noted that there appeared to be general misunderstanding in companies regarding the scope of the exemption for replies made in response to enquiries.

Complaint received **30 August 1994**

Case completed **4 October 1994**

Note:
The following advice on responses to unsolicited enquiries was given in the Quarterly Review for October 1994:

> "Responses to Enquiries
>
> Clause 1.2 of the Code states, *inter alia*, that the term "promotion" does not include replies made in response to individual enquiries from members of the health professions and they are thus exempt from the requirements of the Code.
>
> This exception applies only to a particular answer to a particular question. It is not an opportunity to provide wide ranging promotional information which is free from the requirements of the Code of Practice.
>
> Responses to enquiries must be genuine personalised answers to the questions raised to be exempt from the Code under Clause 1.2. If it is intended to supply

information above and beyond that, then it must be treated as promotional material, comply fully with the Code and be certified. It must not be assumed that merely because information is sent out by the medical information department rather than by the marketing department, then it is not promotional in nature.

Any information or material routinely made available to representatives to give to health professionals in answer to enquiries must comply with the Code.

Enquiries about matters not covered by the licence must be handled with care and it is advisable that they are only dealt with by the company's medical or medical information departments."

CASE AUTH/207/8/94

DIRECTOR v BOEHRINGER INGELHEIM

Implied claim for unique characteristics in Motens journal advertisement

An article in the Drug and Therapeutics Bulletin on Boehringer Ingelheim's product Motens concluded that it "saw no evidence of a specific `cushioning effect' with lacidipine" as claimed in promotion. This was taken up as a complaint and a Motens journal advertisement was ruled by the Panel to be misleading as implying that cushioning effects with Motens were unique to that product.

COMPLAINT

An article on lacidipine (Motens) in the Drug and Therapeutics Bulletin of 18 August 1994 referred to claims made by Boehringer Ingelheim Limited for Motens that its gradual onset of action "cushions the fall in blood pressure" and "cushions against side effects". The article concluded that it "saw no evidence of a specific `cushioning effect' with lacidipine". In accordance with established practice, this criticism was taken up with Boehringer Ingelheim as a complaint under the Code.

RESPONSE

Boehringer Ingelheim submitted that the two claims "cushions the fall in blood pressure" and "cushions against side effects" had been the primary basis for the promotion of Motens since its introduction. They were non quantitative, non comparative statements and described a quality of the product that was considered to be important to prescribers. That quality was the slow onset of pharmacodynamic effect which avoided a sudden drop in blood pressure and resulted in a low incidence of vasodilator side effects. Supporting evidence for these claims were submitted. The company queried how the Drug and Therapeutics Bulletin could see no evidence of a cushioning effect with lacidipine when the report confirmed that lacidipine had "a more gradual effect than nifedipine", that "the speed of onset avoids an abrupt fall in blood pressure" and that unwanted effects "are usually mild".

Copies of various promotional items for Motens were submitted as requested by the Panel.

RULING

The Panel considered the information before it and noted the wording in a Motens journal advertisement that:

> "Suppose you could choose an anti-hypertensive with a gradual onset of action which cushions the fall in blood pressure.
> Furthermore, suppose it could also cushion against side effects.
> New Motens can."

The Panel considered that the implication of this wording was that you could now choose an antihypertensive offering these qualities of gradual onset of action and cushioning against side effects whereas you could not do so beforehand. Although these qualities were features of Motens, they were not specific or unique to that product. The Panel therefore considered that the advertisement was misleading in implying that these characteristics were unique to Motens and ruled that there was a breach of Clause 7.2 of the Code.

Proceedings commenced	**31 August 1994**
Case completed	**15 November 1994**

CASE AUTH/213/9/94

GENERAL PRACTITIONER v NON MEMBER COMPANY

Failure to advise in a letter whether product prescribable on NHS

A general practitioner complained that a "Dear Doctor" letter did not state whether or not the product was prescribable on FP10 or on private prescription only and nor did it give the cost of the product. The Panel considered that, although it might have been helpful, in the particular circumstances it was not a breach of the Code to omit information about the reimbursement of the product. The cost was given in the prescribing information. No breach of the Code was ruled.

COMPLAINT

A general practitioner copied a letter to the Authority that he had sent to a company concerning the promotion of one of its products. The company concerned, although not a member of the ABPI, had nevertheless agreed to comply with the Code.

The complainant pointed out that nowhere did the material indicate whether or not the product was prescribable on an FP10 or on private prescription only. The complainant's view was that by stating only its legal category as prescription only medicine, the inference likely to be drawn was that it was prescribable. The complainant had to assume that this lack of information was designed to deliberately trap the unwary into prescribing the product on the NHS. This could result in the GP concerned having to pay the cost himself. The complainant also alleged that there was no mention anywhere of the cost of the preparation and queried how doctors could advise patients without knowing the cost.

RESPONSE

The company explained that the item in question was a "Dear Doctor" letter announcing the introduction of the product, which had not been blacklisted. Legally, therefore, doctors could prescribe the product on an FP10, although family health services authorities (FHSAs) and health boards might independently make a policy decision not to allow reimbursement of the product within their designated areas. The company's current advice to all general practitioners was that they should check with their local FHSA or health board prior to writing prescriptions on FP10s. The company pointed out that the price was given on the reverse side of the letter in the prescribing information.

RULING

The Panel noted that the "Dear Doctor" letter did not contain any statement relating to the reimbursement status of the product. It appeared to the Panel to be an unusual situation in that the reimbursement of prescriptions was left to family health services authorities and health boards to make local policy decisions.

The Panel considered that if the product were not prescribable at all on the NHS, then the "Dear Doctor" letter should have stated this clearly. The Panel considered that whilst it might have been helpful to give information about NHS reimbursement of the product, it was not a breach of the Code to omit this information. The Panel therefore ruled no breach of the Code.

The Panel noted that Clause 4.2 of the Code requires the cost of the medicine to be included in promotional material and this had been given in the prescribing information which appeared on the back of the letter. The Panel therefore ruled no breach of the Code.

Complaint received 20 September 1994

Case completed 17 October 1994

CASE AUTH/214/9/94

Stiefel Laboratories v Dermal Laboratories

Misleading graph & misleading use of references in Emulsiderm mailing

Four allegations made by Stiefel about a mailing by Dermal on Emulsiderm were considered by the Panel. A graph comparing Emulsiderm's antibacterial effectiveness with a proprietary emollient based on a study which compared Emulsiderm with the complainant's product, Oilatum, was ruled to be misleading as it was not made clear that the basis of the comparison was between one product containing an antibacterial agent (Emulsiderm) and the other which did not (Oilatum). The use of a reference to an editorial in the British Medical Journal in relation to the statement "Regular treatment with Emulsiderm can help to reduce the patient's reliance on topical steroids" was also ruled to be misleading as the BMJ editorial was only referring to the regular use of emollients in general terms and not specifically Emulsiderm. A similar allegation regarding the use of another reference to a claim was rejected along with an allegation concerning data cited in support of claims regarding Emulsiderm's antibacterial effectiveness in high dilution.

Stiefel Laboratories (UK) Limited complained about a mailing on Emulsiderm consisting of a brochure (ref EMU068/JUN94) issued by Dermal Laboratories Limited. Neither company was a member of the ABPI but each had agreed to comply with the Code.

1 Antibacterial Effectiveness - Comparative Study

COMPLAINT

The first allegation related to figure 1 in the brochure which consisted of a graph comparing the *in vivo* antibacterial effectiveness of Emulsiderm emollient with a proprietary emollient, referenced to data on file. Stiefel pointed out that the data on file was a study comparing Emulsiderm emollient with its own product Oilatum which, in contrast to its product Oilatum Plus, contained no antibacterial agent and for which it made no claim of antibacterial activity. The study therefore failed to compare like with like. Furthermore, in the study Oilatum was applied undiluted directly to the toe webs which was not in accordance with the instructions for use in the product data sheet. A breach of Clause 7.2 was alleged as the supporting evidence was neither balanced nor fair and as the promotional claim itself was misleading. A breach of Clause 8.1 was also alleged as Stiefel considered that it unfairly denigrated its product as the brand name Oilatum was used in the study and was provided as supporting material to the claim on request.

RESPONSE

Dermal submitted a copy of the protocol and study in question in addition to the in house report provided to Stiefel in support of various claims in the brochure. Dermal submitted that it was commonplace for combination products to be compared with their plain counterparts and cited the current promotion of Oilatum Plus with Oilatum by Stiefel as such an example.

RULING

The Panel considered that although it might be acceptable to compare a combination product with its plain counterpart, as submitted by Dermal, it should have been made clear in the promotional material that the basis of the comparison was between one product which contained an antibacterial agent and another which did not. The Panel therefore considered that the graph was misleading and ruled it was in breach of Clause 7.2 of the Code. The Panel did not accept that it was disparaging of the competitor product as alleged and ruled there was no breach of Clause 8.1. With regard to the actual use of the competitor brand name in the data, this was not unacceptable in relation to Clause 7.10 as the study itself was not promotional material.

2 "Regular treatment with Emulsiderm will help to reduce the patient's reliance on topical steroids."

3 "As well as rehydrating the skin of eczema patients by replacing lost lipids, Emulsiderm helps combat micro-organisms such as *Staphylococcus aureus* which have been shown to aggravate the condition."

COMPLAINT

Stiefel alleged that the above statements in the brochure referenced to the British Medical Journal and The Archive of Dermatology respectively were misleading and in breach of Clause 7.2 of the Code as neither publication referred to Emulsiderm.

RESPONSE

Dermal submitted that the two references were offered by way of footnotes merely as supportive evidence of substantiation to indicate examples of publications which respectively highlighted the role of *S aureus* in eczema and endorsed the usefulness of emollients like Emulsiderm in reducing patients' reliance on steroids.

RULING

The Panel considered that the clear inference of the reference given to the British Medical Journal in relation to the statement "Regular treatment with Emulsiderm can help to reduce the patient's reliance on topical steroids." was that the British Medical Journal cited Emulsiderm as helping to reduce the patient's reliance on topical steroids. The Panel therefore ruled that it was misleading and breached Clause 7.2 as the British Medical Journal editorial was only referring to the regular use of emollients in general terms and not specifically Emulsiderm.

With regard to the claim "As well as rehydrating the skin of eczema patients ....., Emulsiderm helps combat micro-

organisms such as *Staphylococus aureus* which have been shown to aggravate the condition" referenced to The Archive of Dermatology, the Panel considered that it did not necessarily imply that The Archive of Dermatology was specifically discussing the role of Emulsiderm in combating micro-organisms only that *Staphylococcus aureus* had been shown to aggravate eczema. The Panel therefore did not accept that it was misleading and ruled that there was no breach.

4 **"Recent studies have demonstrated that Emulsiderm, ... is effective against *Staphylococcus aureus* even in high dilution."**

COMPLAINT

Stiefel alleged that the *in vitro* work cited as the reference to the above claim for Emulsiderm's effectiveness even in high dilution did not support the efficacy of the product at its recommended bathwater dilutions. The dilution of 1/1000 with three thirty minute exposures employed in the *in vitro* study was not in keeping with the data sheet instructions for Emulsiderm. A breach of Clause 7.2 was alleged.

RESPONSE

Dermal submitted details of the investigators and methodology used which demonstrated a high level of effectiveness against *S aureus* in just ten minutes with one exposure to Emulsiderm at a dilution of 1/1000. Further data which demonstrated significant activity even at 1/5000 dilution, provided additional evidence that Emulsiderm was effective against *S aureus* even in high dilution.

RULING

The Panel considered that the rate of dilution used in the *in vitro* data cited in the brochure was broadly in line with the instructions for use of the product in the bath given in the prescribing information and the data sheet. These instructions which were for 30ml Emulsiderm emollient to a 6 - 8 inch bath with 15ml for infants, were general in nature without precise details as to the exact rate of dilution required for the product. No account was taken of the size of a bath for example. The Panel therefore did not accept the allegation and ruled there was no breach of the Code.

Finally, the Panel did not accept there was a breach of Clause 2 as alleged by Stiefel.

Complaint received 21 September 1994

Case completed 28 October 1994

CASE AUTH/217/10/94

CONSULTANT IN PHARMACEUTICAL MEDICINE v MEMBER COMPANY

Implication in journal advertisement that patients could take medicine and drive

A consultant in pharmaceutical medicine complained that statements in a journal advertisement implied that patients who suffered from a particular condition could receive the advertised product and drive a motor vehicle and this was untrue. The allegation was not accepted by the Panel which ruled no breach.

COMPLAINT

A consultant in pharmaceutical medicine complained about a journal advertisement issued by a member company for one of its products. The complainant drew attention to two statements in the advertisement and alleged that the statements implied both directly and indirectly that patients who suffered from a particular condition could receive the product and drive a motor vehicle. The complainant alleged that this was untrue and drew attention to certain statements in the product's data sheet. A breach of Clause 7.2 of the Code was alleged.

RESPONSE

The company concerned submitted that patients suffering from the condition should be assessed by a responsible physician or psychiatrist and a recommendation upon ability to drive made on an individual patient basis. If a patient were deemed to be fit to drive, then the data sheet for the product was quite clear. The company submitted that the advertisement did not recommend driving regardless of physical and mental state. It merely sought to advise that patients who were otherwise capable of driving would not be further impaired by treatment with the product.

RULING

The Panel considered that doctors would be aware that patients presenting with the condition should be assessed and a recommendation upon ability to drive made as appropriate. The Panel did not consider that the advertisement recommended that every patient who was to be treated with the product would immediately be capable of driving. It considered therefore that the advertisement was not unacceptable and ruled no breach of the Code.

Complaint received 4 October 1994

Case completed 8 November 1994

CASE AUTH/218/10/94

HOSPITAL PHARMACIST v MEMBER COMPANY

Conduct of a representative

A hospital pharmacist complained that a representative who had telephoned to enquire about a change of therapy which had been instituted had misled by failing to make it clear that he was from a pharmaceutical company.

There had clearly been a misunderstanding between the parties and this had been contributed to by the representative failing to make his identity clear from the beginning. There was however insufficient evidence upon which a ruling could be based and the Panel ruled no breach.

COMPLAINT

A hospital pharmacist complained about the activities of a medical representative from a member company. The hospital had recently made a policy decision to change from one product to another. The complainant appreciated that this would not be welcomed by the company whose product was being discontinued and had expected a local representative to want to discuss the reasons for the change. However, the complainant objected to the representative ringing to elucidate information and presenting himself in such a way that it was assumed that he was a member of the medical staff. He was twice given the opportunity to announce who he worked for but he only identified himself when directly challenged after the conversation had progressed for some time. The complainant was not happy with time being wasted in this way nor with the use of such an underhand method of finding out information.

RESPONSE

The company concerned said that it considered that there had been a misunderstanding and there had certainly been no intention to mislead. The company submitted that it was perfectly proper for an approach to be made to a department such as pharmacy to try to ascertain treatment policies and to attempt to arrange a meeting to discuss such policies as had occurred in this instance. A simple telephone call with this objective could not be considered an inconvenience. The company therefore considered that its representative's approach was proper and did not breach the Code by intent or deed.

RULING

The Panel reviewed a memorandum prepared by the representative to set out his remembrance of the conversation with the complainant. The representative and the complainant were not entirely at one in relation to what had transpired. The Panel noted, however, that it was accepted by the company that its representative had not, in the first instance, said where he was from.

The Panel considered that there was not sufficient evidence upon which a ruling of a breach of the Code could be based. The recollections of the parties differed in certain respects and it was not possible to determine with certainty exactly what had happened. There had clearly been a misunderstanding between the parties and the Panel considered that this had been contributed to by the fact that the representative had not made it clear at the beginning of the conversation that he was speaking on behalf of his pharmaceutical company. Failure to provide such information was not in itself a breach of the Code but could clearly contribute to one.

In the circumstances, and having noted all that had been said by both parties, the Panel ruled that there had been no breach of the Code.

Complaint received **10 October 1994**

Case completed **21 November 1994**

CODE OF PRACTICE REVIEW - FEBRUARY 1995

CASES

AUTH/163/6/94	Director v Bayer	Criticisms of Ciproxin promotion in BMJ letter	Breach 7.2	Appeal by respondent
AUTH/165/6/94 AUTH/166/6/94	Astra Pharmaceuticals v Lederle Laboratories/SmithKline Beecham	Promotion of Zoton – various claims & medical information brochure	Breach 3.2, 7.2 & 7.8	Appeal by respondents
AUTH/172/6/94	GP v member company	Claim in promotional material	No breach	Appeal by respondent
AUTH/173/7/94 AUTH/174/7/94 AUTH/175/7/94 AUTH/181/7/94 AUTH/195/8/94	GPs v member company	Company sponsored disease management survey in a journal	No breach	No appeal
AUTH/178/7/94	Pharmaceutical services director v member company	Letter sent to chief executive of NHS trust regarding hospital manufacture of medicines & conduct of representatives	No breach	No appeal
AUTH/180/7/94	Proctor & Gamble v non-member company	Telephone helpline for the public	No breach	No appeal
AUTH/184/7/94	Sanofi Winthrop v Searle	Promotion of Zydol – various promotional items	Breach 3.2, 9.1 & 10.1	Appeal by complainant & respondent
AUTH/185/7/94 AUTH/212/9/94	Director v SmithKline Beecham Pharmaceuticals	Breaches of undertakings	Breach 2 & 7.2 Report to ABPI Board of Management	Appeal by respondent
AUTH/186/7/94	GP v member company	Calls by representatives	No breach	No appeal
AUTH/190/7/94 AUTH/194/8/94	Boehringer Ingelheim/Ethical Pharmaceuticals v Napp Laboratories	Disparaging references & misleading side effect claim in MST Continus mailing	Breach 7.2 & 8.1	No appeal
AUTH/191/7/94	GP v member company	Conduct of market researcher	No breach	No appeal
AUTH/193/8/94	Alcon Laboratories v Allergan	Betagan booklet & loose sheets – failure to include prescribing information	Breach 4.1 & 4.6	No appeal
AUTH/196/8/94	GP v member company	Newspaper article	No breach	No appeal
AUTH/199/8/94 AUTH/211/9/94 AUTH/220/10/94 AUTH/259/12/94 AUTH/260/12/94	GPs & Secretary to Local Medical Committee v member company	Prescription reminder letter sent to patients	No breach	Appeal by complainants
AUTH/200/8/94	Hospital chief pharmacist v Asta Medica	Unacceptable letter on Ferrocontin Folic written by representative	Breach 15.2	No appeal
AUTH/201/8/94	Hospital pharmacy business services manager v Boehringer Ingelheim	Inadequate labelling of air freshener promotional aid for Bonefos	Breach 9.1	No appeal
AUTH/202/9/94	Director v member company	Criticisms of a journal advertisement in letter in medical journal	No breach	Appeal by respondent
AUTH/203/8/94	PSNC v member company	Use of a PSNC letter by a representative	No breach	No appeal
AUTH/205/8/94	SmithKline Beecham Pharmaceuticals v The Wellcome Foundation	Material from medical information department on Zovirax used by representatives	Breach 4.1 & 15.2	No appeal
AUTH/207/8/94	Director v Boehringer Ingelheim	Implied claim for unique characteristics in Motens journal advertisement	Breach 7.2	No appeal
AUTH/213/9/94	GP v non-member company	Failure to advise in a letter whether a product prescribable on NHS	No breach	No appeal
AUTH/214/9/94	Stiefel Laboratories v Dermal Laboratories	Misleading graph & misleading use of references in Emulsiderm mailing	Breach 7.2	No appeal
AUTH/217/10/94	Consultant in pharmaceutical medicine v member company	Implication in journal advertisement that patients could take medicine and drive	No breach	No appeal
AUTH/218/10/94	Hospital pharmacist v member company	Conduct of a representative	No breach	No appeal