PRESCRIPTION MEDICINES
CODE OF PRACTICE AUTHORITY

QUARTERLY REVIEW JANUARY 1994

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CASE REPORTS
JANUARY 1994

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

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AUTH/36/4/93

DERMAL LABORATORIES LIMITED v LEDERLE LABORATORIES

Cost comparison chart in a mailing for Traxam Foam

Complaint Dermal Laboratories Limited, a company not in membership of the ABPI, complained about a cost comparison chart in a leaflet for Traxam Foam issued by Lederle Laboratories.

The chart appeared below a heading "The X-factor is economy" and was itself headed "Daily cost of commonly used NSAID therapies, taking into account all presentations. Manufacturers recommended dosage." The chart then listed seven NSAID products and, in addition, Traxam Foam appeared at the bottom of the chart. A range of the daily costs for each product were shown as a bar which was coloured in two shades of green. It was stated underneath the chart that "Usual daily doses are used, rather than maximum permitted doses" and "Data based on January 1993 MIMS". The range for Traxam Foam was 19.5p to 39p which was the cheapest of the products listed in comparing daily costs at the top end of the range and second cheapest to the cost of ibuprofen oral (18.2p) at the lowest end of the range.

Dermal Laboratories Limited alleged that the omission of its product, Ibugel, which accounted for substantially higher usage than one of the products listed in the chart, ketoprofen gel, meant that the chart did not provide a clear, balanced view of the matters with which it dealt. Dermal had pointed out in its correspondence with Lederle that the daily cost of Ibugel ranged from 6.7p to a maximum of 20p and the inclusion of Ibugel in the chart would undermine the representation of Traxam Foam as the most economical NSAID choice. By omitting Ibugel the chart gave a glaringly distorted picture of the available NSAID therapies and their respective costs. Data were submitted to support the allegation and Dermal queried the data used by Lederle as not being as accurate as its data.

Dermal was also concerned about the use of the two-tone green bars to present the cost information and pointed out that for some of the products listed the highest price appeared to refer to maximum doses although the footnote stated that "Usual daily doses are used, rather than maximum permitted doses". It was hard to know what inference was supposed to be drawn from the figures.

Breaches of Clauses 7.2 and 7.6 of the Code were alleged.

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Response Lederle Laboratories submitted that as there were no firm recommendations on dosage for Ibugel there was no reasonable way it could be included in a cost comparison chart. The use of gram comparisons was unreasonable as they did not take into account the dosage or usage of the products and would be misleading.

Lederle accepted that the meaning of the two-tone green bars might possibly be ambiguous and it was proposed that the chart be amended to aid interpretation.

In its correspondence with Dermal, Lederle stated that it did not accept that Ibugel accounted for higher usage than ketoprofen gel as this was not reflected in the audit figures. The company did not accept the daily cost of Ibugel stated by Dermal and considered that analysis of the published clinical data gave a daily dosage in the range of 3.5-11g which would give a daily cost range of 25p-74p.

Panel ruling The Code of Practice Panel noted that it was often difficult to make valid cost comparisons, particularly for topical products for which clearly defined doses did not exist. The Panel also noted previous decisions of the Code of Practice Committee which had established that it might be possible to compare topical products on a cost per weight/volume basis depending on how the information was presented and provided it was clearly stated that usage rates might vary. In any cost comparison the basis of selection of products must give a reasonable overview and must not be chosen solely to put a company's own product in the best possible light.

The Panel considered that the heading "Daily cost of commonly used NSAID therapies" gave the impression that all commonly used therapies were included in the chart. The Panel considered therefore that the chart was a misleading comparison as it omitted any reference to Ibugel which, on the basis of the information before it, was a commonly used NSAID. The selection of the products in the chart did not give a fair overview.

The Panel was also concerned about a number of other aspects of the chart. It was not clear what was meant by the term "usual daily dose", nor was it clear what was meant by the colouring of the bars.

The Panel decided the chart was a misleading comparison and did not give a clear, fair, balanced view of the matters with which it dealt. The Panel therefore ruled breaches of Clauses 7.2 and 7.6 of the Code.

Appeal Lederle acknowledged that the chart was in breach of Clause 7.6 of the Code in relation to the meaning of the two-tone bars and future editions of the chart would be amended. The company appealed the breach of Clause 7.2.

Lederle submitted that at the time of preparation of the chart, ketoprofen gel accounted for significantly more unit sales based on Moving Annual Total (MAT) data than Ibugel. Further, as the chart was based on data sheet recommended daily dosages it was not possible to include Ibugel as it has no specific dosage recommendations. The data sheet merely stated "Lightly apply a thin layer of the gel over the affected area". An extrapolation of the specified dosage of a comparable product, would give a daily cost of 20-67p for Ibugel. There was no published clinical data for Ibugel. It was acknowledged that if the chart was being prepared now Ibugel would come under the heading "commonly prescribed NSAIDs". The figures quoted by Dermal were not available when the chart was being produced.

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PRESCRIPTION MEDICINES CODE OF PRACTICE AUTHORITY

QUARTERLY REVIEW

JANUARY 1994

Case Reports

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

Allegations in The Sunday Times

For three consecutive weeks in November, allegations appeared in The Sunday Times concerning the activities of pharmaceutical companies. In accordance with the usual practice all of these matters were taken up for investigation as complaints under the Code of Practice for the Pharmaceutical Industry and reports of them will be published in due course.

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

The long awaited further consultation document on the implementation of the EC Directive on the advertising of medicinal products for human use was issued in October by the Medicines Control Agency. Comments were submitted by the Association of the British Pharmaceutical Industry (ABPI) and by the PMCPA. It had been expected that the implementing regulations would be made before Christmas but it is now anticipated that they will not be made until early in the New Year.

It may be helpful to you to know how the proposed regulations will affect the content of promotional material so that you can make appropriate changes.

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

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

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

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

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

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

Audio–Visual Advertisements The requirements as to the provision of prescribing information in relation to audio–visual material as set out in Clause 4.3 of the Eighth Edition of the Code of Practice for the Pharmaceutical Industry will remain unchanged.

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

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

The Code of Practice will be amended in the above respects in due course.

Dates on Data Sheets

The Medicines (Data Sheet) Regulations 1992 (SI 1972 No 2076) state that loose data sheets (ie. data sheets other than those in the ABPI Data Sheet Compendium) must carry the date of their preparation or last review.

It has been observed that some of the loose data sheets which have come in to this Authority in connection with matters before it did not in fact bear a date. Companies are reminded of the legal requirements in this regard.

Seminars

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

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

Thursday, 3 February 1994
Wednesday, 2 March 1994
Wednesday, 27 April 1994

Seminars can also be arranged for individual companies.

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

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Appeal Board Ruling The Appeal Board acknowledged that it was very difficult to produce fair cost comparison charts, especially for topical products. It considered that Lederle had made considerable efforts to ensure the chart was fair. The Appeal Board noted that in any future charts Lederle would need to take account of the fact that Ibugel would be likely to be considered a commonly prescribed NSAID. The Appeal Board considered the data produced by the company and decided that, at the time, it was not unfair to exclude Ibugel from the chart. The Appeal Board considered the appeal was justified and ruled there had been no breach of Clause 7.2 of the Code.

Complaint received **6 April 1993**

Case completed **31 August 1993**

AUTH/42/5/93

THE DIRECTOR v BOOTS PHARMACEUTICALS LIMITED

Article in the "Yorkshire Post", regarding claims for Junifen

Complaint An article in the "Yorkshire Post", 5 May 1993 criticising the promotion of Junifen by The Boots Company PLC was taken up as a complaint under the Code in accordance with usual practice. The newspaper article reported on criticisms in a Medical Lobby for Appropriate Marketing (MaLAM) newsletter, a "Drug and Therapeutics Bulletin" article and a letter in "The Lancet". The article also reported that Boots was unable to provide references for a claim that Junifen "provides additional therapeutic advantages over paracetamol".

The Boots Company PLC submitted that the "Yorkshire Post" article was very misleading, not least in the false suggestion that it was unable to provide supporting evidence. The specific claims for additional therapeutic advantages for Junifen over paracetamol were made in an advertisement which appeared in "MIMS Thailand" and the matter was not therefore within the remit of the ABPI Code. The company had not made specific claims for additional therapeutic advantages for Junifen over paracetamol in the UK but acknowledged that essentially similar claims were made in the UK. Copies of the advertisement published in "MIMS Thailand", promotional material for Junifen previously used in the UK and the current UK material on Junifen, a dosage reminder card, were provided.

The Code of Practice Panel decided that it would direct its attention solely to three claims appearing in the dosage reminder card "Junifen Sugar Free is more effective at relieving pain than paracetamol", "Junifen Sugar Free is more effective at reducing temperature than paracetamol" and "Junifen Sugar Free is just as well tolerated as paracetamol" as being representative of the UK material as a whole.

Panel Ruling With regard to the claims "Junifen Sugar Free is more effective at reducing temperature than paracetamol" and "Junifen Sugar Free is just as well tolerated as paracetamol", the Panel decided that overall there was sufficient evidence submitted by Boots to substantiate the claims and ruled there was no breach of the Code.

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With regard to the claim "Junifen Sugar Free is more effective at relieving pain than paracetamol", Boots provided the study to which the claim was referenced. The study design was a randomised parallel group including 56 patients. There were four main end points which were pain, tenderness, swelling and time to overall recovery. The company submitted that there was overall superiority of ibuprofen over paracetamol in all four end points and that patient numbers were sufficient to detect statistically significant treatment difference across all end points. Another study was also submitted.

The Panel accepted that the study to which the claim was referenced was on balance in favour of ibuprofen in relation to differences in the pain score which were statistically significant. Despite this, it noted that the study was an open study with a small number of patients. Importantly, the Panel was concerned that the frequency of dose of paracetamol, at three times daily, was not in line with the usual frequency of four times daily or occasionally every four hours, limited to a maximum of four doses per day.

The Panel made a number of criticisms in relation to the second study submitted in support of the claim as the dose of ibuprofen at 10mg/kg three times daily was higher than the daily dose given in the data sheet of 20mg/kg in divided doses. Further, the dosage of paracetamol used in the study was questionable as it stated that "a 50% higher dose (paracetamol) could have been given safely, and the potential efficacy of this drug may thus have been underestimated". In this study paracetamol had been given three times daily instead of the usual four times daily. The Panel considered that this study did not support the claim.

The Panel accepted that there was some evidence from the study to which the claim was referenced to show that Junifen Sugar Free might be more effective than paracetamol at relieving pain. The limitations of this evidence was not, however, reflected in the unqualified claim used in the dosage card that "Junifen Sugar Free is more effective at relieving pain than paracetamol". The claim was thus unsubstantiated and the Panel ruled there was a breach of Clause 7.3 of the Code.

Appeal The company submitted that the analgesic effect of ibuprofen that was demonstrated in adults was relevant to the effects that could be expected in children. For a medicine that could be used for the same purpose in both adults and children, for both ethical and practical reasons the majority of data would be generated in adults and only a small number of confirmatory studies would be generated in children. There was ample data to support the superior analgesic efficacy of ibuprofen over paracetamol in a variety of pain models in adults receiving ibuprofen appropriate (on a mg/kg basis) to doses employed in children. The company submitted that it was reasonable and proper for the data to be extrapolated to the paediatric use of ibuprofen and paracetamol. The company also submitted that the pharmacokinetics of ibuprofen in children were considered similar to those seen in adults. The company provided additional data from studies on adults and children.

The company accepted that there were difficulties in assessing pain in children and that valid criticisms could be made of the individual studies. The company however submitted that it was important to look at all the data as a whole, which was in favour of ibuprofen. None of the studies favoured paracetamol.

Appeal Board Ruling The Appeal Board noted that the frequency of dose of paracetamol, at three times daily, used in the study to which the claim was referenced was not in line with the usual frequency, as paracetamol could be given four times daily or occasionally every four hours, limited to a maximum of four doses per day.

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The Appeal Board noted that there was not one study comparing Junifen with paracetamol in line with the recommended doses in sufficient patients of the appropriate age group. It accepted that there was a problem in assessing pain in children but considered there was a large difference between adults and children with respect to pain.

Overall, the Appeal Board accepted that the company had some evidence to show that ibuprofen was more effective at relieving pain than paracetamol, but it considered that the limitations of the evidence were not reflected in the claim that "Junifen Sugar Free is more effective at relieving pain than paracetamol". The claim was thus unsubstantiated and the Appeal Board ruled a breach of Clause 7.3 of the Code. The appeal therefore failed.

Complaint received **7 May 1993**

Case completed **29 October 1993**

AUTH/46/5/93

SCHERING HEALTH CARE LIMITED v MALLINCKRODT MEDICAL (UK) LTD

Allegations concerning a brochure for Hexabrix 320

Schering Health Care Limited made a number of allegations about a brochure on Hexabrix 320 issued by Mallinckrodt Medical (UK) Ltd, a company not in membership of the ABPI.

Reference to Prescribing Information Schering Health Care Limited alleged that the brochure contained no reference to the position of the prescribing information as required by Clause 4.6 of the Code of Practice. This had been admitted by Mallinckrodt Medical (UK) Ltd and the Code of Practice Practice Panel ruled that there had been a breach of Clause 4.6.

Sodium at Physiological Levels and Distinct Anticoagulant Properties The brochure claimed that Hexabrix was the only low osmolar contrast medium (LOCM) that contained sodium at physiological levels and that it was the only LOCM with distinct anticoagulant properties. This constituted an implied benefit of the product over other contrast media. Schering claimed that there was no published consensus that these features were of clinical relevance and alleged that the implied claims were unsubstantiated and misleading in breach of Clauses 7.2 and 7.3 of the Code of Practice.

Mallinckrodt explained the role of sodium in cardiac arythmia, referred to experimental in vitro and in vivo data, commented on the relevance of the presence of sodium to human tolerance and submitted a number of papers in support of its claim for anticoagulant properties.

The Panel considered that the presence of sodium at physiological levels seemed on the evidence to be a theoretical rather than a practical advantage. There was no evidence to substantiate clinical benefit. The Panel ruled that there had been a breach of Clause 7.2 in the relation to the implied claim that sodium at physiological levels was a clinical benefit. The Panel considered that the claim that Hexabrix had distinct anticoagulant properties was supported by evidence and ruled that there had been no breach of the Code in that regard.

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Optimal Image Quality with less Iodine A two page spread headed "Optimal image quality with less iodine" contained the claim that Hexabrix provided better image quality than a comparator in coronary angiography. Schering alleged that the claim was based on one study which did not reflect the whole literature and it was contradicted within the detail aid. The company alleged that the claim breached Clauses 7.2 and 7.3 and the study quoted was incompletely referenced in breach of Clause 7.5.

Mallinckrodt stated that it did not consider that there was a contradiction as two papers referred to coronary angioplasty in general and another referred to "selective" coronary angiography. The company considered that the statement "Optimal image quality with less iodine" was substantiated by these papers.

The Panel noted that one of the papers was an abstract and did not describe the methodology, the numbers were small and it was considered that it was an inadequate base to justify a claim for better image quality. Another of the papers stated that both contrast media studied were comparable. The Panel ruled that the claim for better image quality was in breach of Clause 7.2 of the Code and that the paper quoted had been incompletely referenced in breach of Clause 7.5 of the Code.

Minimal Interference with Cardiac Function A two page spread contained a series of graphs from published studies on the effect of Hexabrix on cardiac function under the heading "Minimal interference with cardiac function". Schering alleged that the graphs were presented so as to imply an advantage for Hexabrix over other media in their effects on cardiovascular function. However, none of the studies quoted showed a statistically significant difference between the media and this was not made clear. These implied claims for Hexabrix were alleged to contravene Clauses 7.2 and 7.3 of the Code and the use of the graphs contravened Clause 7.6.

Mallinckrodt said that it believed that the data in the graphs reflected the figures in the papers and no statistical significance was claimed or shown. It did, however, show that Hexabrix had minimal interference with cardiac functions, which was supported by a number of papers.

The Panel considered that the impression given by the two page spread was of a trend that favoured Hexabrix but none of the cited references concluded that any statistically significant difference existed. Any data presented in graphical form carried the implication that it was based on results which were statistically significant as otherwise it exaggerated the significance of those results. It was accordingly ruled that there was a breach of Clause 7.2 of the Code.

Effects on Capillary and Renal Blood Flow A page compared Hexabrix with other agents in their effects on capillary and renal blood flow. The data presented were from in vitro or animal studies and Schering alleged that this was not made clear and the implication that the results were of clinical relevance was not supported by the literature. The animal studies quoted did not use doses equivalent to those used clinically. Schering alleged breaches of Clauses 7.2 and 7.6 of the Code.

Mallinckrodt said that it showed references specific to this argument and these clearly stated that work was in vitro. It was well accepted that work of this nature was carried out on animals. It was normal practice to inject high doses of contrast media into animals and experimental models. This allowed the extrapolation of results to critical clinical situations. All of the animals received the same dosage of 1600 mg of iodine/kg body weight whatever the contrast medium used and the medullary flow decreased in the iopamidol and iohexol group but not in the Hexabrix group.

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The Panel considered that the criticisms concerned the implication that the in vitro and animal studies demonstrated a clinical advantage. The fact that the procedures had been in vitro or in animals was apparent only from footnotes and evidence of their application in the clinical situation was lacking. The Panel ruled there had been a breach of Clause 7.2 of the Code.

In Vivo Data: The Proof A double page spread entitled "In vivo data: the proof" reproduced electron micrographs from a published study to indicate that Hexabrix caused less clotting on intravascular catheters than other media. Schering alleged that the study was, however, uncontrolled with different centres using different catheters and investigating protocols, and the authors stated that no such study had yet been performed. Schering alleged that this page was in breach of Clauses 7.2, 7.3 and 7.6. On the facing page a further illustration was used to indicate that Hexabrix caused less clotting than a comparator. Schering alleged, however, that the catheters featured were non-identical and the illustration was thus misleading in breach of Clause 7.2.

Mallinckrodt referred to conclusions in a paper that "Despite the diversity of centres and procedures, a clear tendency could be seen in this survey in favour of a reduced or non-existent actuation of haemostasis when a low osmolality ionic contrast medium was used, compared to the consistent marked activation seen in each centre when non-ionic contrast molecules were injected". The illustrations complained about were of guidewires and not catheters.

The Panel considered that Schering was justified to question the implied conclusion of the illustrations chosen. The study quoted could only be used to indicate a trend that might represent a clinical advantage. The illustrations compared guidewires not catheters. The study involved only ten patients and could not support a clinical conclusion. Although the factors dealt with might reasonably be a consideration in the selection of contrast media, the suggested trend was considered to be rather overstated. It could not be regarded as "proof". It was ruled there had been a breach of Clause 7.2 of the Code.

Clinical Implications: The Result Schering said that the final double page spread, headed "Clinical implications: the result" implied that the foregoing features resulted in a clinical benefit for the product. Illustrations of three coronary angiograms demonstrated coronary thromboses associated with LOCM. Schering alleged that the angiograms involved were from three very sick patients who could not be regarded as typical and the page was therefore misleading in breach of Clause 7.2. On the facing page, the incidence of thrombotic complications during PTCA (percutaneous transluminal coronary angiography) was quoted from a table. Schering alleged that the figures quoted did not appear in the publication referenced and that one of the other studies listed in the table was incorrectly referenced. Schering alleged that the page was thus in breach of Clauses 7.2 and 7.5. In addition, at the bottom of the page, Hexabrix was described as "a shield against thrombotic complications" which Schering alleged was an all-embracing claim in breach of Clause 7.8.

Mallinckrodt said that nowhere in the relevant paper was it stated that three very sick patients were involved. The paper referred to experience over several years and some eight thousand plus procedures. The cases referred to where thromboembolitic complications were reported were all associated with the use of non-ionic contrast media. The company accepted that the referencing was a typographical error and would be amended forthwith. The statement "a shield against thrombotic complications" was a general claim and would need to read "<u>the</u> shield against thrombotic complications" to be all-embracing.

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The Panel noted that the photographs were not of three patients but of one case during an thrombotic episode and were intended to be illustrative. The paper itself reported three cases which did not appear to involve excessive pre-investigation morbidity. The Panel therefore ruled that there was no breach of the Code. With regard to the studies reported in the charts, the Panel considered that these were consistent in demonstrating a trend in favour of fewer thrombotic complications and ruled there was no breach of the Code. The Panel noted, however, that one study had been incorrectly referenced and ruled there was a breach of Clause 7.5. The Panel considered that although there was data to suggest that Hexabrix might reduce thrombotic complications, the claim "a shield against thrombotic complications" overstated the position. The Panel therefore ruled that it was an exaggerated claim in breach of Clause 7.8 of the Code.

Date of Preparation or Revision It was alleged by Schering that no indication was given as to when the detail aid was drawn up or revised in breach of Clause 4.2 of the Code. In view of the confusion which existed over this requirement, and the fact that the matter would not be clarified until the EC Directive on the advertising of medicinal products for human use was implemented in the United Kingdom, the Code of Practice Panel decided not to make a ruling on this particular allegation.

Complaint received **19 May 1993**

Case completed **1 September 1993**

AUTH/49/5/93

GENERAL PRACTITIONERS v ROUSSEL LABORATORIES

Provision of hospitality

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

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

This case concerned an allegation that a representative from Roussel Laboratories Ltd had organised a meeting at an expensive local restaurant. In this instance, the receptionists were not invited but it was alleged that they had been to other meetings sponsored by representatives. The complainants enclosed a handwritten note from the representative to one of the doctors which gave details about the meeting.

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Response Roussel Laboratories Ltd denied that its representatives had ever offered hospitality to the receptionists in the practice. The company pointed out that the meeting referred to in the document provided by the complainant had been postponed. The meeting in question had been held on another date at the same named restaurant and four doctors had attended. This had been the only meeting organised by the company. The representative concerned had held the meeting for the purpose of promoting Roussel products and it had taken place in a secluded corner of the restaurant, out of sight and earshot of the general public. The products on which the presentations focused were Tarivid, Surgam and Molipaxin. The representative had informed doctors of the latest developments concerning these and other products. The company submitted that the relevant dosage cards and data sheets were distributed. Discussions had continued over dinner which cost £18 per head, giving a total cost of £90. The company submitted that this could not be described as lavish, out of proportion to the occasion or in excess of a level which the recipients would normally adopt when paying for themselves. Roussel denied that the main purpose of the meeting was the dinner at the restaurant. It was organised to take place at least expense, in this instance in a quiet restaurant where mid-week a secluded corner was as quiet as that offered by a private room at a higher cost. The company had not assisted in equipping the doctors' new premises

Ruling The Code of Practice Panel examined the material provided by Roussel and noted that the Code permitted companies to provide hospitality within certain parameters as set out in Clause 19 of the Code, which stated that "The level of hospitality offered must be appropriate and not out of proportion to the occasion and the costs involved must not exceed the level which the recipients would normally adopt when paying for themselves". The Panel also noted supplementary information to Clause 19 which set out certain basic principles for any meeting: the meeting must have a clear educational content, the hospitality associated with the meeting must be secondary to the nature of the meeting and must be appropriate and not out of proportion to the occasion. Further, the Panel noted that the supplementary information to Clause 19 also stated that "The impression that is created by the arrangements for any meeting must always be kept in mind".

The Panel accepted that the total cost of £90 would not be unreasonable in appropriate circumstances and considered that this was not in excess of what doctors might pay for themselves.

The Panel accepted that the meeting did have an educational content but could not accept that the nature of the meeting justified the associated hospitality. In the Panel's view, the meeting was inappropriate as it consisted of discussions round a dinner table in a public restaurant and the hospitality was not secondary to the main purpose of the meeting. The Panel therefore ruled a breach of Clause 19 of the Code.

Complaint received **25 May 1993**

Case completed **10 September 1993**

AUTH/53/6/93

GENERAL PRACTITIONER v MEMBER COMPANY

Claims in a journal advertisement.

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Complaint A general practitioner submitted a complaint about two claims in a journal advertisement issued by a member company for one of its products. The complainant alleged that one of the claims promoted the product outside its data sheet indications and the other was not substantiated by an abstract quoted in the advertisement. Further, the complainant alleged that the citation of the abstract given in the advertisement was not in accordance with international convention.

Response The company submitted that the disputed claims were in accordance with the product's data sheet and a number of studies to support the claims were provided. The company submitted that the claim which was referenced to the abstract was not a claim which required referencing under the Code. The company acknowledged that convention with regard to references may not have been strictly adhered to but health professionals requesting further information would have been provided with the published abstract.

Ruling The Code of Practice Panel noted that the Code requires companies to provide references only in limited circumstances, such as when promotional material referred to published studies or where information and claims about side effects were based on data not submitted or notified to the licensing authority. The Panel considered that the claim which was referenced to the abstract was not obliged to be referenced under the Code and although the citation of the abstract was unclear and could be improved upon this did not constitute a breach of the Code. The Code of Practice Panel accepted the company's submission regarding the two claims and ruled no breach of the Code.

Complaint received **5 June 1993**

Case completed **16 August 1993**

AUTH/54/6/93

GENERAL PRACTITIONER v MEMBER COMPANY

Letters on computer drug dictionary errors

Complaint A general practitioner submitted a complaint about a mailing sent by a member company to doctors and practice managers regarding one of its products. The letters advised that some practice computers were generating incorrect scripts for the product. The complainant alleged that this was advertising in a scurrilous way, and did not acknowledge doctors' freedom to prescribe what they considered to be the correct dosage for individual patients.

Response The company concerned submitted that it had become aware that a number of general practice computers were programmed with incorrect dosages for the product and it had therefore written directly to general practitioners and practice managers to highlight the problem. It had not suggested that doctors should not exercise their medical opinion and expertise in deciding on the correct dosage. The letters formed part of a survey that was intended to reveal the number of computers programmed with incorrect dosages.

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Ruling The Code of Practice Panel considered that it was not inappropriate for the company to write to doctors and practice managers pointing out a possible error in recommended dosage levels. It considered that the letters could have been couched in more felicitous terms in order to avoid any inference that it was wrong for doctors to depart from the recommended dosage. The Panel ruled that there had been no breach of the Code.

The complainant appealed the ruling of the Panel.

Appeal The company submitted a more detailed analysis of the survey. The information regarding the recommended dosage had been supplied to general practitioners to ensure that there was no potential misunderstanding regarding the recommended use of the product.

Appeal Board Ruling The Code of Practice Appeal Board noted that at the time the letter had been sent out, there had been only anecdotal evidence that some computer drug dictionaries were inaccurate. In the event, a small number of incorrect dosages had been revealed through the survey. The company could not recommend any dosage differing from the data sheet recommendations, although doctors were free to use their discretion when prescribing. The Appeal Board did not consider that the appeal was justified and ruled that there had been no breach of the Code.

Complaint received **9 June 1993**

Case completed **7 October 1993**

AUTH/57/6/93

MARION MERRELL DOW LIMITED v SCHERING-PLOUGH LTD

Use of sponsored publication on drug interactions and antihistamines

Complaint Marion Merrell Dow Limited complained about a bulletin on drug interactions and antihistamines sponsored by Schering-Plough Ltd. The bulletin in question consisted of an article written by an independent author, a doctor, which appeared to be based mainly on a Committee of Safety of Medicines (CSM) "Current Problems" article on the subject and included a chart on drug interactions with second generation antihistamines. The bulletin also included an advertisement for the "Clarity Line", a freephone line for obtaining daily reports on the pollen count sponsored by Schering-Plough which used similar symbols and colours to those used in advertisements for Schering-Plough's antihistamine Clarityn (loratadine).

Marion Merrell Dow alleged that the bulletin itself was a promotional item for Schering-Plough's product Clarityn and that the advertisement in it for the "Clarity Line" was an advertisement for Clarityn which was in breach of Clause 4.1, due to the absence of prescribing information. A breach of Clause 9.4 was also alleged in respect of the reference to the Committee on Safety of Medicines in the bulletin and there were a number of other allegations concerning various aspects of the bulletin which Marion Merrell Dow alleged were misleading and disparaging of its product Triludan (terfenadine) in breach of Clauses 7.2 and 8.1. A breach of Clause 2 was also alleged.

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Ruling The Code of Practice Panel considered that although the "Clarity Line" advertisement clearly involved an allusion to the product Clarityn, it did not constitute an advertisement for that product and therefore ruled there was no breach of Clause 4.1 of the Code as prescribing information was not required.

On the question of whether or not the bulletin was a promotional item in itself, the Panel noted that the whole area of company sponsored publications, such as the bulletin in question, and reports on symposia and such like, was not at all clear cut under the Code. Although the Authority received very many enquiries about sponsored publications, there was little in the way of precedent. In all instances involving company sponsored publications, the decision as to whether or not the item was promotional or not had been taken on the facts of the particular case.

The Panel considered that the fact that a company sponsored an item did not in itself necessarily make that item promotional for that company's products. It would, however, be desirable for the company's sponsorship to be made clear on any such sponsored item.

The Panel noted that issues of the bulletin were written by independent authors who were commissioned by the publishing company rather than by the sponsoring company, and that any editorial input on the part of the sponsoring company was restricted in that the company could comment upon the article but it was for the author to accept or reject those comments. The bulletins were intended to provide informative, balanced articles on topics of current interest.

Schering-Plough advised that it had distributed the bulletin in question by mailing it to a target list of approximately 7,500 doctors, which comprised a sub-set of UK general practitioners that Schering-Plough had selected according to a variety of criteria to receive mailings. Sales representatives were also each provided with one hundred copies to allow for coverage of doctors who did not receive the mailing.

The Panel decided that the bulletin in question did not constitute a promotional item for Schering Plough's product Clarityn by itself but, as the company had clearly used it for promotional purposes, its use therefore came within the scope of the Code.

The Panel did not accept there was a breach of Clause 9.4 of the Code by the reference to the Committee on Safety of Medicines in the bulletin, as the bulletin itself was not a promotional item.

The Panel reviewed the content of the bulletin in detail in relation to the specific criticisms of it made by Marion Merrell Dow. It was considered that in a number of respects the bulletin inappropriately addressed the significance and levels of interactions and failed to put them in context, for example by omitting qualifications made in the source material.

The Panel considered that overall the bulletin was unbalanced and misleading as to the respective positions of terfenadine and loratadine as regards interactions. The Panel ruled that its use for promotional purposes therefore constituted a breach of Clause 7.2 of the Code of Practice. The Panel did not accept that there was a breach of Clause 2 of the Code.

Complaint received **30 June 1993**

Case completed **19 August 1993**

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AUTH/58/7/93

PARKE DAVIS & CO LIMITED v MEMBER COMPANY

Allegations concerning a journal advertisement

Complaint Parke Davis & Co Limited complained that a journal advertisement for a member company's product was in breach of Clause 3.2 of the Code as it promoted the product outside the terms of its licence. Breaches of Clauses 7.2 and 7.3 were also alleged in relation to a claim referenced to a study on another product which the complainant considered was misleading.

Ruling The Code of Practice Panel accepted the submission from the company concerned that the statements in the advertisement did not constitute claims for which the product was not licensed nor that the use of the reference involving another product was misleading. The referenced claim was a statement about a certain condition rather than a statement about the advertised product.

The Panel therefore ruled there was no breach of the Code in respect of either allegation.

Complaint received **8 July 1993**

Case completed **10 August 1993**

AUTH/59/7/93

DIRECTOR v SCHERING HEALTH CARE LIMITED

Unsubstantiated claim

Complaint An article in Drug and Therapeutics Bulletin, 21 June 1993, criticised certain claims made by Schering Health Care Limited for its product Skinoren, namely that it had an anti-inflammatory action and that it had a "unique triple action". In accordance with the normal practice, these criticisms were taken up under the Code of Practice.

The Bulletin had stated that it could find no clinical evidence for a specific anti-inflammatory effect in patients with acne vulgaris and this action was not in the data sheet. The manufacturer's claim that azelaic acid (the active constituent of Skinoren) had "a unique triple action" seemed somewhat contrived.

Response Schering Health Care submitted a number of published studies in respect of the claim that Skinoren reduced inflammation by inhibiting the formation of anti-inflammatory agents. The company pointed out that the other elements of the "triple action" claim, namely anti-bacterial and anti-comedonal properties, had not been questioned.

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Ruling The Code of Practice Panel reviewed each of the studies submitted by Schering Health Care, appraising the company's comments as to the manner in which each supported the claim that the product had an anti-inflammatory action. The Panel noted that in vitro work by Akamatsu et al had shown that azelaic acid inhibited the generation of reactive oxygen species which were potent inflammatory mediators. A number of papers supported the efficacy of azelaic acid in inflamed acne but authors were cautious on the question of whether an anti-inflammatory action contributed to its effectiveness.

The Panel considered that there was some evidence that an anti-inflammatory action contributed to the effectiveness of azelaic acid in the treatment of acne vulgaris. It was considered, however, that the data was insufficient to substantiate claims such as "Anti-inflammatory - Reduces inflammation by inhibiting the formation of inflammatory agents" and "Unique triple action". It was ruled that there had been a breach of Clause 7.3 of the Code of Practice.

Case commenced **12 July 1993**

Case completed **24 August 1993**

AUTH/60/7/93

KABI PHARMACIA LTD v NON-MEMBER COMPANY

Claim alleged to be misleading and unsubstantiated

Complaint Kabi Pharmacia Ltd submitted a complaint about a claim made in a journal advertisement, alleging that it was misleading, unsubstantiated and was a safety claim not based on any available data. It was also alleged that the advertisement disparaged other products by implication. Both Kabi Pharmacia and the company which had issued the advertisement were companies which, while not in membership of the ABPI, had agreed to comply with the Code of Practice. Breaches of Clauses 7.2, 7.3, 7.7 and 8.1 of the Code were alleged.

Response The respondent submitted evidence supporting its claim which, it stated, was consistent with the product's data sheet. The company asserted that the advertisement mentioned no other products and was not disparaging.

Panel Ruling The Code of Practice Panel did not accept that the claim constituted a comparison between the product advertised and others. It was a statement about the product. The Panel considered the submissions made by both companies in relation to the question of substantiation and decided that the claim was a statement of fact based on the rationale for the product's usage. The Panel ruled that there had been no breach of the Code.

Appeal Kabi Pharmacia appealed against the rejection of its complaint, submitting further information in relation to the points made by the company concerned and by the Panel. In turn, the respondent company submitted its comments upon the further points made by the complainant.

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Appeal Board Ruling The Appeal Board noted that the science was complex and that experts in the area were not entirely in agreement. The Appeal Board noted that there was no conclusive clinical paper and queried the use of the reference quoted to support part of the claim. Taking the body of evidence as a whole, however, the Appeal Board decided that the claim was acceptable and not disparaging. The Appeal Board therefore ruled that there had been no breach of the Code. The appeal thus failed.

Complaint received **12 July 1993**

Case completed **7 October 1993**

AUTH/61/7/93

GENERAL PRACTITIONER v BOOTS PHARMACEUTICALS LIMITED

Conduct of a representative and content of a detail aid

Complaint A general practitioner complained that biased and possibly misleading information was being used by Boots Pharmaceuticals Limited in the promotion of Brufen Retard. The complainant alleged that during the course of an interview, a representative from the company had made the claims "Brufen Retard is more effective than Brufen", "Brufen Retard is more effective than diclofenac retard", "Brufen Retard is better tolerated than Voltarol" and "Brufen Retard is better tolerated than Brufen" and had referred to a detail aid (ref no 1682/1/93). The complainant said that as he was questioning the representative's claims he read that the heading in the detail aid, under which the data showing a favourable profile of Brufen Retard compared to Brufen appeared, stated that both presentations were equally well tolerated. The representative had admitted that there was a favourable tendency but only a slight one, not significant, and had apologised if she had given him a different impression. The complainant had accepted the apology. The representative had subsequently returned to the practice and had left the last two pages of a study used to reference the claim in the detail aid that "Brufen Retard offers superior pain relief to divided dose Brufen".

The complainant said that the material provided by the representative confirmed the later explanation given by the representative and pointed out that the discussion section of the study quoted other papers which had shown that Brufen Retard was at least of equivalent efficacy to Brufen and as good as sustained release Voltarol.

The complainant alleged that the above mentioned claims were unsubstantiated and took strong exception to the selective quoting of papers as evidence. The complainant also stated his objection to the use of bar charts in the detail aid which could be misleading unless a clear explanation of their meaning was given.

The latter allegation was understood by the Panel to refer to the bar chart appearing beneath the claim "Brufen Retard is as equally well tolerated as divided dose Brufen".

The complainant's allegations were considered as follows:-

"Brufen Retard is more effective than Brufen" Boots pointed out that the claim in the detail aid read "Brufen Retard offers superior pain relief to divided dose Brufen" and was referenced to a study which showed statistically significant differences in favour of Brufen Retard over divided dose Brufen A second study was also submitted.

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The Code of Practice Panel noted that the complainant alleged that the representative had claimed that "Brufen Retard was more effective than Brufen" whereas the detail aid stated that "Brufen Retard offers superior pain relief to divided dose Brufen". In the absence of any other evidence as to what the representative had said, the Panel decided that it would make its ruling on the claim in the detail aid.

The Panel accepted that the study to which the claim was referenced supported the claim. The Panel had some reservations about the second study but considered that the claim "Brufen Retard offers superior pain relief to divided dose Brufen" was not unacceptable and therefore ruled no breach of the Code.

"Brufen Retard is more effective than diclofenac retard" Boots pointed out that the claim in the detail aid was that Brufen Retard has been shown to be more effective than sustained-relief diclofenac sodium referenced to a study which had shown statistically significant differences in favour of Brufen Retard over sustained release diclofenac sodium. The company also submitted two further studies which compared Brufen Retard to sustained release diclofenac sodium. The company acknowledged that the results of neither of the studies were statistically significant. However, both studies showed trends in favour of Brufen Retard for the majority of efficacy parameters.

The Panel considered that in the context in which it was put, the claim "Brufen Retard has been shown to be more effective than sustained release diclofenac sodium" would generally be taken to mean that Brufen Retard was more effective than sustained release diclofenac and the claim must be capable of substantiation on that basis. The Panel had certain reservations about the study to which the claim was referenced as it was a single blind study. The Panel accepted however that the study provided some support for the claim in the detail aid but noted that although both the other two studies showed trends in favour of Brufen Retard, statistical significance was not achieved. The Panel also noted the study quoted by the complainant which had stated that comparative clinical trials had demonstrated that sustained release ibuprofen had "as good or sometimes better efficacy compared to sustained release diclofenac sodium".

The Panel considered that there was some evidence to show that Brufen Retard was more effective than sustained-release diclofenac sodium but it was not sufficient to substantiate the claim that Brufen Retard was more effective than sustained release diclofenac sodium. The Panel therefore ruled a breach of Clause 7.3 of the Code.

"Brufen Retard is better tolerated than Voltarol" Boots pointed out that the claim in the detail aid read "Brufen Retard is better tolerated than sustained-release diclofenac sodium" and was referenced to a study which referred to both the number and percentage of adverse events. The company submitted that the claim was further supported by another study which showed a highly statistically significant difference in tolerability in favour of Brufen Retard. The company also submitted a third study to support the claim.

The Panel had certain reservations about the study to which the claim was referenced, as it was a single blind study. It noted that the second study provided a statistically significant advantage for Brufen Retard in relation to tolerance despite small numbers. The Panel noted that the third study had been misquoted in the company's response and the study actually favoured sustained-release diclofenac sodium over Brufen Retard. The Panel considered that overall there was insufficient evidence to support the claim "Brufen Retard is better tolerated than sustained-release diclofenac sodium". The Panel therefore ruled a breach of Clause 7.3 of the Code. Boots appealed against the ruling.

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Upon appeal the company submitted that substantiation of the superior tolerability of sustained release ibuprofen over sustained release diclofenac sodium was provided by pooling data from the three available studies. The pooled data was in favour of Brufen Retard. The company acknowledged that only one of the studies was statistically significant and that the other two studies had shown no statistical significance with one favouring sustained release diclofenac sodium.

The Appeal Board did not accept that it was appropriate to pool the data from the three studies as submitted by Boots. In this regard it noted that they were separate studies with different protocols and gave different results. Only one study was statistically significant and one was in favour of sustained release diclofenac sodium. It further noted that one was a single blind study and the other two were double blind.

The Appeal Board decided that, given the criticisms of the supporting data, the claim "Brufen Retard is better tolerated than sustained-release diclofenac sodium" was not accurate, balanced, fair and objective. The Appeal Board ruled a breach of Clause 7.2 of the Code. The appeal therefore failed.

"Brufen Retard is better tolerated than Brufen" Boots acknowledged that the representative in question had made an error in stating that Brufen Retard was better tolerated than Brufen. The company pointed out than an apology had been made at the time which had been accepted by the complainant. The company submitted that the claim in the detail aid that "Brufen Retard is as .. equally well tolerated as divided dose Brufen" was based on a study which showed comparable tolerability between Brufen Retard and divided dose Brufen. The company submitted a copy of the briefing material for a representative which included the Brufen Retard training manual and the Brufen Retard cycle plan for April to September 1993.

The Panel considered that the representative had misled the complainant in claiming that Brufen Retard was better tolerated than Brufen and had therefore ruled a breach of Clause 15.2 of the Code. The Panel had been of the view, however, that the representative might have been misled by the briefing material.

The Panel considered that the claim in the detail aid was acceptable but noted that the bar chart which appeared immediately beneath the claim gave the visual impression there was a reduction in gastrointestinal events associated with Brufen Retard compared to those associated with divided dose Brufen. The graph therefore appeared to contradict the claim. The Panel considered that this was misleading and therefore ruled it was in breach of Clause 7.2 of the Code.

Boots appealed against the Panel's ruling that there has been breaches of Clauses 15.2 and 7.2 of the Code.

Upon appeal Boots pointed out that the representative in question had apologised for her mistake and this had been accepted by the complainant. It was submitted that the representative had maintained a high standard of ethical conduct and as such was not in breach of Clause 15.2.

With regard to the bar chart, the company submitted that the data presented were a true representation of the exact figures from the clinical study. The company had not used any suppressed zeros or unusual scales and, in addition, numerical values to provide additional clarity had been included. If the graph showed a visual difference this was only because there was a real difference in the trial. The claim for equality was included along with patients numbers in an attempt to minimise any visual difference.

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The Appeal Board examined the bar chart and accepted the comments from Boots. The Appeal Board considered that the bar chart was not misleading and the appeal was justified. The Appeal Board therefore ruled no breach of the Code in respect of the bar chart.

With regard to the conduct of the representative, the Appeal Board noted that the apology had been accepted by the complainant and that the Panel had ruled a breach of Clause 15.2 of the Code, based on the fact that the representative had not complied with all the relevant requirements of the Code, as required by that Clause. The Appeal Board noted that the cycle plan for Brufen Retard stated that among the objectives were to promote Brufen Retard as being better tolerated with fewer gastrointestinal side effects than other NSAIDs and to demonstrate how Brufen Retard had fewer gastrointestinal problems than divided dose Brufen. The Appeal Board considered that the Brufen Retard cycle plan was instructing representatives to demonstrate how Brufen Retard had fewer gastrointestinal problems than divided dose Brufen, which was not consistent with the claim in the detail aid that "Brufen Retard is as equally well tolerated as divided dose Brufen". The Appeal Board considered that the representative had acted in accordance with the cycle plan. It was the cycle plan briefing material that was misleading and which did not comply with the relevant requirements of the Code as set out in Clause 15.8. The Appeal Board therefore ruled a breach of Clause 15.8 of the Code.

Complaint received **13 July 1993**

Case completed **1 November 1993**

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AUTH/62/7/93

DRUG INFORMATION PHARMACIST v MEMBER COMPANY

Unsolicited supply of a product

Complaint A drug information pharmacist submitted a complaint regarding the supply of a particular product by a member company. The complainant stated that the product had arrived unsolicited through the mail addressed to the pharmacy and alleged this was in breach of the Code as it was a sample which had not been supplied against a signed request. The complainant also alleged that this was an unethical means of promoting a product.

Response The company concerned submitted that there had been a recent change in the licence for the product and a new pack had been produced in order that patients would be treated in line with the new licence at the earliest possible date. The company wrote to doctors and pharmacists to advise of the changes to the licence. The company also contacted pharmacists at hospitals which were high users of the product offering to send one new pack on a "sale or return" basis. This letter asked pharmacists to return a card which was provided if they did not want the supply of the medicine.

Ruling The Panel noted the circumstances in which the product had been supplied and decided that it was not a sample as defined in Clause 17 of the Code but goods supplied on a sale or return basis. The Panel noted the method of dispatch of the product and considered that the company was offering a service in order to facilitate the change in use of the product required by the amendment to the product's licence. The Panel decided these were exceptional circumstances and on the facts of this case ruled there was no breach of the Code.

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Complaint received **21 July 1993**

Case completed **23 August 1993**

AUTH/63/7/93

CONSULTANT PHYSICIAN v FISONS PHARMACEUTICALS

All embracing and exaggerated claims in a "Dear Doctor" letter

Complaint A consultant physician alleged that an advertisement for Aerocrom issued by Fisons Pharmaceuticals strongly implied that it would increase patient compliance but he could find no mention in the advertisement of any data to support the claim and knew of no such data in existence. Even if the product did encourage regular compliance it was not clear that this would have any advantage over the more effective anti-inflammatory agent of inhaled steroids. It therefore worried the complainant that patients would be removed from inhaled steroids and put on to this combination inhaler, for which there was no evidence of any advantage over their existing therapy. The advertisement might lead to inappropriate changes in treatment when there was no evidence of benefit.

Response Fisons Pharmaceuticals said that the items in question were a brochure (ref: WP/AER/08/93) and an accompanying letter to doctors which referred to compliance in asthma and which had been sent on the introduction of the product earlier in the year. They recognised that patient compliance with anti-inflammatory therapy was poor and posed the question as to how this could be overcome. They did not and were not intended to provide the answer by suggesting that Aerocrom would increase compliance. What they did do was reveal that Aerocrom might be a pragmatic approach to the problem for some patients. An important reason for poor compliance with anti-inflammatories was that patients did not perceive that they derived any benefit with preventive therapy. Conversely, bronchodilators were prescribed for regular use and were taken regularly due to the symptom relief that was obtained. The company submitted that a realistic approach to overcoming poor compliance with anti-inflammatory therapy in asthma was to ensure that patients received their preventive therapy at the same time as their regular bronchodilator. The company reminded the Code of Practice Authority that the Code of Practice Panel had already ruled the claim for Aerocrom "In a therapy they'll take" to be "not unreasonable" and not in breach of the Code (Case AUTH/43/5/93).

Ruling The Code of Practice Panel considered that the brochure was generally acceptable, making factual statements about problems of compliance. It was noted that the statement "The relief they want" was present and this had been ruled to be in breach of the Code in Case AUTH/43/5/93. The statement "In a therapy they'll take" was there but following it was the phrase "Immediate symptom relief encourages compliance". The Panel considered that this latter statement was unsatisfactory for the same reason that the statement "The relief they want" had been found wanting. This was because it implied that the product could be used in acute attacks. It was considered that the claim "Immediate symptom relief encourages compliance" came within the scope of the breach of Clause 7.8 of the Code previous ruled in Case AUTH/43/5/93.

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In relation to the letter, the Panel noted that this again bore the statement "The relief they want" which had already been ruled to be in breach of the Code. Furthermore it included the claim "Because patients feel the relief they want, you can be sure that Aerocrom is a therapy they'll take" which the Panel considered also came within the scope of the ruling in Case AUTH/43/5/93.

In addition, the Panel noted that the letter made the questionable statements "New Aerocrom - a major advance towards asthma compliance" and "Aerocrom is an important new approach to overcoming poor compliance, ensuring patients receive effective asthma treatment". It was considered that it was exaggerated to claim that Aerocrom was a major advance towards asthma compliance or that it was an important new product which could ensure patients receive effective asthma treatment. The Panel also considered that the statement "Aerocrom is a suitable choice for all asthmatics who need more than a bronchodilator alone and all those who may not comply with their anti-inflammatory therapy" was all-embracing as it indicated that the product was suitable for all asthmatics which was not so. The claim implied that patients could be transferred from inhaled steroids to the product which might not be appropriate.

The Panel therefore ruled that the letter was in breach of Clause 7.8 of the Code.

Complaint received **21 July 1993**

Case completed **19 August 1993**

AUTH/64/7/93

HOSPITAL CONSULTANT v UPJOHN LIMITED

Inappropriate arrangements for a meeting

Complaint A hospital consultant complained that an invitation he had received from a representative from Upjohn Limited to attend a meeting for hospital doctors who had an interest in lipids was in breach of the Code in that his wife was invited to the meeting although she was not medically qualified and had no interest in the subject, and as, in the complainant's view, the level of entertainment was excessive. A copy of the invitation and programme for the meeting was submitted.

The meeting consisted of an overnight stay in a hotel with a round table discussion on lipid management taking place for three quarters of an hour prior to dinner for delegates and their partners on the Friday evening, with a one hour video meeting to be held on the Saturday morning followed by free time, a buffet lunch, a suggested guided tour of a nearby hall followed by a traditional cream tea at the hotel. A separate fashion presentation for wives was arranged to be held during the video meeting on the Saturday morning.

Response Upjohn Limited explained that the representative who had issued the invitation had discussed the need to hold a meeting with lipid specialists with his regional business manager. Because of the problems of distance and time for holding such a meeting, it was suggested that it should be conducted over a Friday evening/Saturday morning and that overnight accommodation should be offered to those attending.

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Various hotels were approached for quotes and one was chosen which offered a delegate rate which included partners free of charge. The representative had therefore sent invitations based on this information. The invitation was copied to the regional business manager who, on receipt of it had telephoned the representative to explain that inviting partners to such a meeting was in contravention of the Code and that the meeting should be cancelled forthwith. As several doctors had already responded declining the invitation the representative telephoned all those doctors from whom he had not had a response advising them that the meeting was cancelled.

The company acknowledged that the representative had breached the Code by issuing an invitation to doctors and their partners but pointed out that its internal system for authorization of such meetings was able to prevent the meeting taking place. The representative involved had been counselled regarding his conduct and the requirements of the Code had been reviewed with him. All regional business managers had been apprised of the situation and would communicate to the representatives the need to follow the Code. The company offered its assurances that an incident like this would not be repeated.

Ruling The Code of Practice Panel noted the actions taken by the company and the fact that the company had become aware of the problem and taken steps to stop the meeting prior to the receipt of the complaint. The Panel nonetheless considered that there was a breach of Clause 19 of the Code in that partners of delegates had been invited to attend a meeting. Furthermore, the balance of scientific education to hospitality in the proposed programme for the meeting was inappropriate. The Panel therefore ruled there was a breach of Clause 19 of the Code.

Complaint received **21 July 1993**

Case completed **12 August 1993**

AUTH/65/7/93

GENERAL PRACTITIONER v MEMBER COMPANY

Alleged unsolicited sample

Complaint A general practitioner complained that he had received a sample of a medicine sent by a member company to his predecessor who had left the practice and clearly had not requested the sample. It was alleged that this mailing contravened Clause 18.3 of the Code of Practice. When writing to the company, attention was drawn to Clause 17.3, the equivalent provision in the Eighth Edition of the Code which was now in force.

Response The company concerned advised that a mailing which included a reply paid card allowing a sample to be requested had been sent to general practitioners and returned cards had been sent to a direct mailing house which had dispatched the samples. The actual card in question could not be located. The company described the procedures which had been in operation and contended that a sample could have been sent only in response to a returned card.

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Ruling The Code of Practice Panel noted that the card could not have been signed by the doctor to whom the sample had been addressed as he had left the practice before the mailing was sent out. The cards had borne the names and addresses of the recipients and it might well be that a sample would be sent out following receipt of a signed card regardless of the signature upon it. There was no real evidence as to what had happened but in view of the procedures adopted by the company and its mailing house, it seemed unlikely that a sample would have been sent out unless a signed card had been received. The Panel accordingly ruled in the circumstances that there had been no breach of the Code.

Complaint received **26 July 1993**

Case completed **17 September 1993**

AUTH/66/7/93

HOSPITAL CONSULTANT v CILAG LTD

Brochure on Evorel

Complaint A gynaecologist complained about a brochure (ref: 0093875) issued by the Ortho Division of Cilag Ltd in relation to its oestradiol patch preparation, Evorel. The complainant alleged that this made disparaging comparisons with oestradiol implants and reproduced a fictional and inaccurate graph of oestradiol levels as if it was based on hard data. The complainant alleged that Ortho recognised that this was inaccurate and dishonest. Further, the complainant believed that the comparison set out to deceive the general practitioner and the gynaecologist.

Response Cilag Ltd refuted the allegations that it had recognised the graph as inaccurate and dishonest and that it had set out to deceive the general practitioner and gynaecologist. The page in question in the brochure was headed "Avoids tachyphylaxis associated with implant therapy". Tachyphylaxis was defined in Webster's Medical Dictionary as "diminished response to later increments in a sequence of applications of a physiologically active substance". In this context, the term was used to describe the phenomenon characterised by women who had received oestrogen implants for menopausal symptoms returning, at decreasing intervals after implantation, complaining that their symptoms had recurred despite their having plasma oestradiol levels well within the normal premenopausal range. It was a phenomenon which may occur with other routes of oestrogen replacement administration but had been observed primarily with implant therapy. Repeated implantation based on symptom recurrence could eventually lead to increasing oestradiol plasma levels.

The company submitted that the prevalence of this phenomenon amongst women receiving implant therapy was not yet known and reports varied from three per cent to twenty-four per cent. It was, however, one that was suspected to be not uncommon and likely to have been encountered by a gynaecologist. The word "associated" used in the brochure could be defined as to link or to connect and the company believed its statement to mean that tachyphylaxis may be linked/connected with implant therapy.

As far as the graph was concerned, it had been made clear that this was a diagrammatic representation which illustrated what had been observed in practice and it had been reproduced from a book. The company submitted further evidence to support the graph.

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Ruling The Code of Practice Panel considered that it had been made clear that the graph was a diagrammatic representation only. It did not consider that Cilag had intended to deceive recipients as alleged. The page as a whole, however, including the graph was considered to be inadequately qualified in view of the fact that the existence and clinical significance of tachyphylaxis in this therapeutic area was the subject of debate. Where a clinical or scientific issue existed which had not been resolved in favour of one generally accepted viewpoint, particular care needed to be taken to ensure that the issue was treated in a balanced manner in promotional literature. The Panel considered that there was some evidence to indicate the occurrence of tachyphylaxis in relation to oestrogen implant therapy but the fact that there were doubts about its existence and significance had not been taken into account and the page was therefore unbalanced. It was ruled that there had been a breach of Clause 7.2 of the Code.

Complaint received **30 July 1993**

Case completed **2 September 1993**

AUTH/69/8/93

CONSULTANT PSYCHIATRIST v ROCHE PRODUCTS LIMITED

Manerix notelets

Complaint A consultant psychiatrist complained that his secretary had been given a box containing a large number of notelets by Roche Products Limited. The notelets were printed at the top with the brand name, Manerix, together with the generic name, moclobemide, and his name which appeared at the bottom of the notelet. The complainant was seriously concerned to find his name printed on each notelet which he alleged could be seen by others as a form of endorsement. The complainant had had no personal communication with the company or any representative regarding the product.

Response Roche Products Limited submitted that the notelets were a desk reminder piece and they had been distributed by its sales force since mid-June. Representatives had been instructed to offer the notelets during sales calls and in almost every instance the item was happily received. On the rare occasion the item was refused the notelets were destroyed.

The company submitted that people in office practice frequently needed to attach notelets to paperwork and these regularly carried brand names. Adding the individual's name was seen as being helpful as it identified whom the note was from. The company did not accept that the item contravened the requirements for suitability and taste as set out in Clause 9.1 of the Code but did concede that the representative's action was inappropriate. The company had written to the sales force to re-emphasise that the notelets should not be left with the physician unless requested.

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Ruling The Code of Practice Panel considered that the notelets were an acceptable promotional aid, they were not in bad taste nor did they fail to recognise the professional standing of the recipient. The Panel accepted, however, that the notelets might be seen as an endorsement of Manerix by the doctor named on them. The Panel considered that, as the doctor's name actually appeared on the notelet, the representative should have handed them to the doctor in person in order that the doctor was aware of the notelets and could make a personal decision as to whether to use them or not. The Panel noted that this view was in line with the company's instructions to representatives on the use of the notelets. The Panel considered that the representative concerned had not maintained a high standard of ethical conduct and therefore ruled a breach of Clause 15.2 of the Code.

Complaint received **13 August 1993**

Case completed **15 September 1993**

CASES AUTH/70/8/93 AND AUTH/76/9/93

CONSULTANT PSYCHIATRIST v DUPHAR LABORATORIES LIMITED AND UPJOHN LIMITED

Promotion of Faverin

Complaint A consultant psychiatrist, submitted a complaint regarding a brochure on Faverin (ref: FAV/HM3/6/93) issued by Duphar Laboratories Limited. The brochure included a reference to Upjohn Limited and the matter was also taken up with that company.

The complainant drew attention to a table in the brochure which listed adverse events with Faverin (fluvoxamine), paroxetine, sertraline and fluoxetine referenced to a review article. The complainant alleged that the table showed far fewer adverse events with Faverin than with the competitor products and its presentation gave the impression that it was a simple comparison between the four products. The complainant pointed out that in the review article the table was clearly marked as being a compilation of four quite separate sets of data. Further, the authors commented on the fluvoxamine results that it should be kept in mind that the majority of the patients were participating in open, uncontrolled studies. The complainant also pointed out that in the summary on adverse effects the authors commented that overall, the adverse effect profiles of the different SSRIs were comparable. The complainant alleged that the brochure did not reflect the authors' opinion and so used the table in a misleading way. The complainant alleged a breach of Clause 4.3 of the Code (First revision of the Seventh Edition, January 1991) and in a further letter alleged a breach of Clause 11.2 of the Code (Eighth Edition, January 1993).

In writing to the companies concerned attention was drawn to the provisions of Clause 7.2 of the Eighth Edition of the Code being the equivalent requirement to Clause 4.3 of the First revision of the Seventh Edition.

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Response Duphar Laboratories Limited stated that the brochure had been sent to psychiatrists and pharmacists. The table in question was taken from a recent independent review of the selective serotonin reuptake inhibitors (SSRIs). In view of the unavailability of direct comparative trial data, the authors had prepared the table from the largest available published compilations of data on adverse effects reported in clinical trials. The heading of the table in the review was "Summary of adverse-effect profiles of paroxetine, sertraline, fluvoxamine and fluoxetine" and the related text referred to the differences in adverse effect profiles between the SSRIs as a class and the tricyclic antidepressants. No distinction was made between the profiles of what were described as the "newer agents" (paroxetine, sertraline and fluvoxamine).

The company agreed with the authors' conclusion that "Overall the adverse effect profiles of the different SSRIs are comparable" and hence made no specific claims in the brochure relating to the data in the table other than to state in a prominent headline that "Faverin has " ... probably the largest aggregate of information regarding safety ever amassed and published for any antidepressant drug." The intention was to bring to the attention of the prescriber that Faverin had the largest published safety data base of any antidepressant, in particular, of any SSRI. The company considered that this would provide a measure of confidence since the safety profile, as established in the early clinical trials, had been confirmed. The company pointed out that no statistically based conclusions could be or were drawn from the data presented, the variation in population size and composition precluded a direct comparison. The data on the other SSRIs were taken from numerous studies of varying designs and were similarly non-homogeneous.

Upjohn Limited pointed out that the brochure had been written by Duphar Laboratories Limited and it had no further comments to add to those submitted by Duphar.

Ruling The Code of Practice Panel examined the table in the brochure and considered that it gave the impression that there were fewer adverse events with Faverin compared to the other products listed. The Panel noted that the table in the brochure had been reproduced from the table in the review article.

The Panel noted that the summary for the adverse event section in the review article stated that "Overall, the adverse-effect profiles of the different SSRIs are comparable. However, as previously mentioned, the incidences reported for fluvoxamine may be underestimated because of the open-label design of the studies included in the analysis". The Panel noted that the fluvoxamine data was on 24,624 patients and 23,500 of those patients were participating in open uncontrolled studies. Further, that the review article stated that when pooled data from several controlled studies involving 222 patients were used, the frequencies of the adverse effect reported with fluvoxamine treatment were much higher than the information given in the table in the brochure. The review article also stated that the discrepancies between the two data sets were likely to be caused in part by differences in numbers of patients and designs of the studies. There was no reference in the brochure to the qualifications in the review article.

The Panel considered that without qualification the table in the brochure did not fairly reflect the review article to which it was referenced, given the statements in that review article that it had noted. The Panel ruled a breach of Clause 7.2 of the Code.

Complaint received **16 August 1993**

Case completed **21 October 1993**

Cont/...

AUTH/73/9/93

GENERAL PRACTITIONER v NON-MEMBER COMPANY

Journal advertisement

Complaint A general practitioner alleged that a journal advertisement issued by a company which was not in membership of the ABPI, but had nevertheless agreed to comply with the Code, was racist and distasteful.

Response The company concerned pointed out that the advertisement had been used for more than two years and only complimentary comments concerning the visual aspects had previously been received. The company submitted that the design of the advertisement was relevant to the nature of the condition and the therapy.

Ruling The Code of Practice Panel examined the advertisement and noted the requirement of Clause 9.1 of the Code that good taste must be observed in respect of illustrations, texts and themes of promotional material. The Panel acknowledged that taste was a subjective matter but decided that the advertisement was not in breach of the Code.

Complaint received **8 September 1993**

Case completed **8 October 1993**

AUTH/74/9/93

PHARMACIST IN A REGIONAL HEALTH AUTHORITY v MEMBER COMPANY

Mailing to general practitioners

Complaint A pharmacist with a Regional Health Authority alleged that a mailing sent by a member company was in breach of Clause 9.1 of the Code in relation to a "pop up" figure and in breach of Clause 18.2 of the Code in relation to an offer of a phonecard.

Response The company concerned had sent the mailing to general practitioners and submitted it had taken great care to determine the mailing's suitability for use with a medical audience. The "pop up" figure had been used to make the item more interactive.

With regard to the provision of the phonecard, the company pointed out that they would be distributed in response to the return of request cards which had been sent out with the mailing. Only one card was offered per doctor and the card was of low value.

Ruling The Code of Practice Panel noted that the "pop up" figure appeared when a brochure included in the mailing was opened. The Panel considered that there might be circumstances when the use of such a figure would breach the Code. It acknowledged that this was a subjective matter but considered that on balance there was no breach of the Code in this instance.

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With regard to the telephone card, the Panel noted a previous case which concerned a £2 phonecard provided to requesting doctors (Case COP 845/8/89) in which it had been decided that a phonecard of modest value was an acceptable gift. The Panel further noted that the decision in this case was reflected in the supplementary information to Clause 18.2 of the Code.

The Panel decided that the provision of the phonecard in question was acceptable and therefore ruled no breach of the Code.

Complaint received **13 September 1993**

Case completed **11 October 1993**

AUTH/75/9/93

PHARMACIST WITH A REGIONAL HEALTH AUTHORITY v ALLERGAN LIMITED

Illegible prescribing information

Complaint A pharmacist with a Regional Health Authority, complained about a "Dear Pharmacist" letter (Ref ACA/108/93) on Betagan sent by Allergan Limited. He was concerned at the light type used for the prescribing information which was printed on the reverse of the letter and stated that the prescribing information was readable on the illumination. It was considered that this amounted to a complaint that the prescribing information was not adequately legible.

Response Allergan Limited acknowledged that there was an unfortunate combination of grey printing on a semi glossy, off-white paper and that the finished product was not as expected. The company had approved final copy but had not critically reviewed the final product on the paper selected by the agency and the printer. The company submitted that the prescribing information was at worst case legible in normal circumstances. The prescribing information complied with the seven stated requirements in the supplementary information to Clause 4.1, particularly with regard to type size, length of line, spacing between the lines and the style of print. The grey colour for prescribing information had been selected to avoid the risk of showing through to the front of the letter.

Ruling The Code of Practice Panel examined the prescribing information on the letter and noted that it ran across the full width of the A4 sheet. It considered that the prescribing information, which was very pale, did not adequately contrast with the background. Further, although double line spacing had been used, it was difficult to bring one's eye from the end of one line to the beginning of the next line. The spacing between the lines was helpful but the Panel decided that overall the prescribing information was not clear and legible and therefore ruled a breach of Clause 4.1 of the Code.

Complaint received **13 September 1993**

Case completed **19 October 1993**

Cont/...

AUTH/78/9/93

PHARMACIST WITH A REGIONAL HEALTH AUTHORITY v MEMBER COMPANY

Implied comparison with competitor products in a sample offer

Complaint A regional technical pharmacist complained about a form issued by a member company which invited physicians to request samples of one of its products. Although the phrase "the real thing" which was used on the form referred to actual samples, it could be taken to suggest that competitor products were not "the real thing".

Response The company said that the aim of the promotion was to introduce a new presentation. It made no claims for the product itself. Considerable care had been taken to ensure that there was no confusion between the sample provided in the mailing and the actual product. To further explain that the sample was not real, the statement "If you'd like a sample of the real thing ....." was included in the reply paid card. There was no reference to any pharmaceutical product on the request card and it was difficult to see how the promotional piece could be taken to be a comparison with any other product or disparaging to it since no claims were made about the product in comparison with any others and the mailing related purely to the presentation.

Ruling The Code of Practice Panel noted that the mailing consisted of two leaflets, one of which included the form in question. The Panel noted that the leaflet which had the form in question attached to it said that the sample was not for clinical use. Immediately adjacent to that statement, but on the tear-off form to be returned, was the statement "If you'd like a sample of the real thing, please complete the section below...". The Panel further noted that no other products were mentioned in the leaflet. The Panel considered that the reference to "the real thing" did not carry the implication that competitor products were not the real thing. It was ruled that there had been no breach of the Code.

Complaint received **20 September 1993**

Case completed **18 October 1993**

AUTH/79/9/93

NHS MANAGERS v MEMBER COMPANY

Journal advertisement alleged to be unsuitable

Complaint Two NHS Managers working in primary healthcare submitted a complaint about a journal advertisement issued by a member company for one of its products. The complainants alleged that the advertisement was inappropriate and highly unsuitable in the light of current wars and disasters.

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Response The company submitted that the objective of the advertising campaign was to convey the seriousness of the condition that the product was designed to treat. The campaign had been carefully appraised and market research covering the specific point of natural disasters had been carried out to assess the impact of the advertisement. The response from the majority of doctors gave the impression that the advertisement had been successful in conveying the seriousness of the condition concerned.

Ruling The Code of Practice Panel noted that in the market research, specific attention had been paid to whether the advertisement gave offence, given the recent spate of natural disasters and war. The Panel noted the requirements of Clause 9.1 of the Code that good taste must be observed. The Panel acknowledged that taste was a subjective matter but considered that the advertisement was not inappropriate as alleged and therefore ruled that there was no breach of the Code.

Complaint received **17 September 1993**

Case completed **29 October 1993**

AUTH/80/9/93

MEDICAL ADVISER v MEMBER COMPANY

Journal advertisement

Complaint A medical advisor to a health authority and a family health services authority submitted a copy of a letter he had sent to a member company complaining about a journal advertisement for one of its products.

The complainant referred to discussions which had resulted in the company undertaking to be responsible in marketing its product and to abstain from marketing it as a first line treatment. The complainant alleged that the advertisement was highly irresponsible in financial and clinical terms and that it implied that general practitioners had been withholding necessary treatment from their patients previously.

Response The company stated that there was no restriction on first line treatment with the product and denied that it had ever made any such undertaking to the complainant as mentioned in the letter of complaint. The company pointed out that the advertisement compared the price of the product with its competitors. There was no implication that general practitioners had been withholding treatment.

Ruling The Code of Practice Panel did not accept that the advertisement implied that general practitioners were withholding treatment from their patients as alleged. It noted that according to the product's data sheet it was licensed for first line treatment. The cost savings in the advertisement clearly related to a comparison of the product to treatment with the competitors. The Panel decided that there was no breach of the Code.

Complaint received **22 September 1993**

Case completed **27 October 1993**

Cont/...

AUTH/81/9/93

GENERAL PRACTITIONER v SERVIER LABORATORIES LTD

Conduct of medical representative

Complaint A general practitioner complained about the conduct of a medical representative from Servier Laboratories Ltd. The representative had been accompanied by someone whom he had assumed to be his trainer. Having agreed to see the representative at short notice and for five minutes before his surgery started, the general practitioner had had to cut short the interview after ten minutes. The representative had requested a further interview but this was refused. The representative had, however, subsequently attempted to arrange a further interview with the doctor through his receptionist. As he had previously declined to agree to a further interview, the doctor found the representative's behaviour shocking and surprising.

Response Servier Laboratories Ltd, although not in membership of the ABPI, had nevertheless agreed to comply with the Code. The company submitted that the general practitioner had not been visited by a representative throughout the past two years and that there was a certain amount of information to provide to the doctor. The interview was estimated to have lasted 10-15 minutes. The representative had been accompanied during the visit by a more experienced sales representative who had played no part in the matter. The doctor had expressed a high level of interest in the information supplied and the representative wanted the opportunity to have a further meeting with him. When the receptionist refused to arrange a further meeting, the representative had left the surgery, totally respecting the doctor's wishes. The company submitted that the representative was only trying to complete his presentation of scientific information on the company's products in an accurate and responsible manner.

Ruling The Panel noted that it was always difficult to deal with cases involving the activities of representatives. With this in mind and with a view to establishing the facts more clearly, Servier's response to the allegation had, with its permission, been sent to the complainant so that the Panel would have the benefit of his comments upon it.

Having reviewed all the available evidence, the Panel considered that, on the balance of probabilities, the doctor's account of events was to be accepted. The Panel decided that the representatives had not maintained a sufficiently high standard of ethical conduct in asking the receptionist for a further appointment when this had previously been refused by the complainant and therefore ruled a breach of Clause 15.2 of the Code.

Complaint received **27 September 1993**

Case completed **19 November 1993**

AUTH/82/10/93

GENERAL PRACTITIONER V PARKE DAVIS AND CO LIMITED

Style of promotion

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Complaint A general practitioner submitted a complaint concerning the promotion of Ponstan Forte by Parke Davis and Co Limited. The complainant enclosed a copy of a letter (ref QO38 UK Sep 93) which was from a patient "Alice" at the Great Wall of China. The complainant alleged that he was sick of receiving letters of this type. He seemed to have received one a month with a variety of advertising ploys including a battery powered microchip device which relayed a message advertising Ponstan Forte. The complainant alleged that the promotion of Ponstan was over the top. He was annoyed about the frequency of mailings, and that the letter pretended that it was from a patient and did not say anything significant. Furthermore, it was not apparent from the envelope that the mailing was from a pharmaceutical company. He was also offended by the battery powered microchip device.

Response Parke Davis and Co Limited stated that during the last twelve months there had been five mailings sent to the complainant between March and September 1993 and copies were provided. The company had now removed the complainant's name from its mailing list.

Three of the mailings "Jane in Australia", "Barbara in Colorado" and "Alice in China" were letters from patients on holiday who had taken Ponstan Forte. All of these letters were on purple notepaper, included a photograph of the patient, and thanked the doctor for prescribing Ponstan Forte. The envelopes matched the purple notepaper with the front bearing the name of the country concerned and a prepaid stamp. The company name and address appeared on the reverse of the envelopes. The two other mailings were sent in white envelopes with the company name and address on the reverse; one was on menstrual disorders the other on pain relief. The mailing on menstrual disorders referred to the letter from "Jane in Australia". The mailing on pain relief referred to the letter from "Barbara in Colorado" and included the battery powered microchip device, which, when pressed, gave the message "I'm on holiday and my low back pain relieved thanks to my doctor and Ponstan Forte".

The company pointed out that the envelope for the "Alice in China" mailing was clearly from a pharmaceutical company as the company name and address was printed on the back of the envelope. The company submitted that it was quite clear that the envelope was not from a patient as the address of the recipient was typed, a prepaid franked envelope was used and the country of origin graphic was obviously fake. It did not appear to be a personal communication.

With regard to the "Alice in China" letter complained about, the company submitted that it clearly was not a personal letter as it was printed with a photograph and paper clip at the top. It also had prescribing information on the back of the letter and was sent in an envelope printed with the company name. The "Alice in China" letter promoted Ponstan Forte for the relief of arthritic pain.

With regard to the battery powered microchip device, the company pointed out that the device had to be pressed in a particular area before the message, which lasted five seconds, could be heard. The company submitted that as the voice box was only activated when a doctor purposely pressed the specific contact point, the doctor did not have to hear the message. The company acknowledged that good taste was subjective. It believed, however, that the device recognised the professional standing of doctors and delivered a serious message in a novel way. The device was intended neither as a gift nor an inducement. It had no value to the recipient.

Ruling The Code of Practice Panel examined the envelopes and noted that the three envelopes for the mailings, "Jane in Australia", "Barbara in Colorado" and "Alice in China", were small purple envelopes with matching notepaper which it considered was more the type of stationery used for personal correspondence. The envelopes included the name and address of the company on the reverse and the address on the front was typewritten. The Panel had some reservations about the type of envelope which had been used but decided that, on balance, the mailings were not disguised and therefore ruled no breach of Clause 10.1 of the Code.

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With regard to the allegation that the letters appeared to have been sent by patients, the Panel noted that the letters were signed with the relevant name, Jane, Barbara or Alice, and the prescribing information was printed on the reverse of each letter. The Panel considered that in view of the style and personalised tone of the letters from what appeared to be grateful patients, and of the notepaper and envelopes used, which were of the type used for personal purposes, the three mailings did not recognise the professional standing of recipients. The Panel also considered that the message on the battery powered microchip device "I'm on holiday and my low back pain relieved thanks to my doctor and Ponstan Forte" and the references to the letters from Jane and Barbara in the mailings on menstrual disorders and pain relief similarly did not recognise the professional standing of the recipients. Although there was no objection to the use of a battery powered microchip device as such, the personalised message on this particular device meant that it did not recognise the professional standing of the recipients. The Panel ruled that the style of promotion which had been adopted in these respects was in breach of Clause 9.1 of the Code.

With regard to the frequency of mailings, the Panel noted that five mailings has been sent over a six month period. It noted the supplementary information to Clause 12.2 which stated that the style of mailings was relevant to their acceptability to doctors and that criticism of the frequency was most likely to arise where their informational content was limited. The Panel considered that this aspect was covered by its ruling of a breach of Clause 9.1 of the Code. The Panel accepted that the regular mailings might have been irritating to some recipients but did not consider that they were in breach of Clause of 12.2 of the Code. The Panel therefore ruled no breach of that Clause.

Complaint received **4 October 1993**

Case completed **16 November 1993**

AUTH/84/10/93

MEDICINES CONTROL AGENCY v SMITHKLINE BEECHAM PHARMACEUTICALS UK

Journal advertisement for Seroxat

Complaint The Medicines Control Agency (MCA) complained about an advertisement for Seroxat issued by SmithKline Beecham Pharmaceuticals UK published in "MIMS Magazine", 12 October 1993.

The advertisement was a two page advertisement consisting of a right-hand page followed by a left hand page. On the first page there was a photograph which formed a flap. When the flap was opened it was possible to see the copy of the advertisement. The prescribing information appeared on the next page. There was no reference on the first page as to where the prescribing information could be found.

The MCA referred the advertisement to the Authority for action as there was no safety issue but the advertisement was technically in breach of Regulation 10(C) of the Medicines (Advertising to Medical and Dental Practitioners) Regulations 1978, SI 1978/1020.

SmithKline Beecham Pharmaceuticals UK was advised that Regulation 10(C) corresponded with Clause 4.5 of the Code which required that in a journal advertisement with the prescribing information appearing overleaf, reference to where it could be found must appear on the outer edge of the initial page of the advertisement in at least 8 point type.

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Response SmithKline Beecham accepted that the advertisement was in breach of Clause 4.5 of the Code as there was no reference on the first page to the appearance of the prescribing information overleaf. The advertisement would be amended with immediate effect.

Ruling The Code of Practice Panel examined the advertisement and noted that there was no reference on the first page to the fact that the prescribing information could be found overleaf, on the second page. The Panel therefore ruled a breach of Clause 4.5 of the Code as acknowledged by the company.

The Panel noted that the maximum length of a journal advertisement was two consecutive pages as set out in Clause 6.1. The Panel considered that there might be circumstances whereby a page with such a flap could constitute more than one page of advertising. The Panel considered, however, that in this particular instance the first page of the advertisement was acceptable and that it was in total only a two page advertisement.

Complaint received **14 October 1993**

Case completed **2 November 1993**

AUTH/85/10/93

GENERAL PRACTITIONER v MEMBER COMPANY

Mailing alleged not to be supported by direct evidence

Complaint A general practitioner submitted a complaint about a mailing sent by a member company which consisted of a "Dear Doctor" letter and a brochure. The mailing referred to deaths associated with a disease and treatment with a product. The complainant alleged that the mailing implied that treatment with the particular product would reduce the number of deaths and there was no direct evidence to support this.

Response The company submitted that the mailing had two purposes. Firstly, to remind doctors that the disease was a serious condition and a major cause of death in comparison to diseases which might have a higher profile. Secondly, to show that treatment with a particular product could prevent associated complications of the disease. The company did not accept that any claim was made or implied that the product reduced the number of deaths.

Ruling The Code of Practice Panel examined the mailing and noted that there was no actual claim that treatment with the product would reduce the number of deaths. It considered, however, that the references in the mailing to the disease and the effects of the product did imply that if patients received the product this might lead to a reduction in the number of deaths. The Panel did not consider that this implication was unreasonable and decided on balance that there was no breach of the Code.

Complaint received **15 October 1993**

Case completed **30 November 1993**

CODE OF PRACTICE FOR THE PHARMACEUTICAL INDUSTRY

NUMBER		SUBJECT	BREACH
36	Dermal v Lederle	Cost comparison chart	7.6 (A)
42	Director v Boots	Article in press	7.3 (A)
46	Schering v Mallinckrodt	Brochure	4.6, 7.2, 7.5, 7.8
49	General Practitioner v Roussel	Hospitality	19
53	General Practitioner v Member Company	Journal advertisement	NoB
54	General Practitioner v Member Company	Computer errors	NoB (A)
57	Marion Merrell Dow v Schering-Plough	Sponsored publication	7.2
58	Parke-Davis v Member Company	Journal advertisement	NoB
59	Director v Schering Healthcare	Article in medical press	7.3
60	Kabi Pharmacia v Non member company	Journal advertisement	NoB (A)
61	General Practitioner v Boots	Conduct of a representative and detail aid	7.2, 7.3, 15.8 (A)
62	Drug Information Pharmacist v Member company	Unsolicited supply of a product	NoB
63	Consultant Physician v Fisons	"Dear Doctor" letter	7.8
64	Hospital Consultant v Upjohn	Arrangements for a meeting	19

KEY

(A) Appeal

CODE OF PRACTICE FOR THE PHARMACEUTICAL INDUSTRY

NUMBER		SUBJECT	BREACH
65	General Practitioner v Member Company	Provision of a sample	NoB
66	Hospital Consultant v Cilag	Brochure	7.2
69	Consultant Psychiatrist v Roche	Provision of notelets	15.2
70 & 76	Consultant Psychiatrist v Duphar & Upjohn	Brochure	7.2
73	General Practitioner v Non member company	Journal advertisement	NoB
74	Pharmacist v Member Company	Mailing and phonecard	NoB
75	Pharmacist v Allergan	"Dear Pharmacist" letter	4.1
78	Pharmacist v Member company	Sample offer	NoB
79	NHS Managers v Member Company	Journal advertisement	NoB
80	Medical Advisor v Member Company	Journal advertisement	NoB
81	General Practitioner v Servier Laboratories Ltd	Conduct of a representative	15.2
82	General Practitioner v Parke Davis	Mailings	9.1
84	Medicines Control Agency v SmithKline Beecham	Journal advertisement	4.5
85	General Practitioner v Member company	Mailing	NoB

KEY

(A) Appeal