PRESCRIPTION MEDICINES
CODE OF PRACTICE AUTHORITY

QUARTERLY REVIEW JULY 1994

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Case Reports

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

New Edition of the Code of Practice for the Pharmaceutical Industry

At its Annual General Meeting on 14 April, The Association of the British Pharmaceutical Industry (ABPI) agreed new versions of the Code of Practice for the Pharmaceutical Industry and the Constitution and Procedure for the Prescription Medicines Code of Practice Authority. The new Code came into operation on 1 May 1994 but its new requirements will not apply until 1 September 1994.

Important changes made include:

- no payment of room rental to doctors by pharmaceutical companies for rooms to be used for meetings, etc
- number of samples limited to ten per product per doctor per year
- promotional aids to cost the donor company no more than £5 excluding VAT
- promotional prizes to cost no more than £100 excluding VAT

Copies of the typescript version of the new Code of Practice can be obtained from the PMCPA. A printed version will be available in due course and an order form will be circulated shortly.

Company reinstated to ABPI membership

Duphar Laboratories Limited, which was suspended from membership of the ABPI as a consequence of Case AUTH/93/11/93, reported in the April 1994 Quarterly Review, was reinstated to membership by the ABPI Board of Management at its meeting on 14 June following receipt of a satisfactory audit report on the company's procedures from the PMCPA.

Legibility of prescribing information

Much prescribing information remains difficult to read and the supplementary information to Clause 4.1 of the new Code of Practice sets out recommendations for improving clarity.

They are:

- *type size should be no smaller than 7 point*
- *lines should be no more than 100 characters in length, including spaces*

- *sufficient space should be allowed between lines to facilitate easy reading*
- *a clear style of type should be used*
- *there should be adequate contrast between the colour of the text and the background*
- *dark print on a light background is preferable*
- *emboldening headings and starting each section on a new line aids legibility*

Companies are reminded that as from 1 September 1994, when the new Code of Practice comes fully into operation, the prescribing information in their promotional material will be expected to be in line with the above recommendations.

Location of non-proprietary name

The 1993 edition of the Code of Practice states in Clause 4.2:

"In addition the non–proprietary name of the medicine or a list of the active ingredients using approved names where such exist must appear immediately below the most prominant display of the brand name in 10 point bold or in a type size which occupies a total area no less than that taken by the brand name".

The 1994 edition has a similar provision except that instead of "..... immediately below ....." it states ".... immediately adjacent to .....".

The purpose of this change was to allow greater flexibility so that, for example, the approved name could go after the brand name if the most prominent display of the brand name was in the text of a "Dear Doctor" letter and the approved name could not readily go beneath.

It is understood that some have interpreted "immediately adjacent to" as meaning "immediately after". That is not so and it is anticipated that most promotional material will continue to have the approved name immediately below the most prominent display of the brand name.

Attention is drawn to the supplementary information to Clause 4.2 which states that: "Immediately adjacent to ....." means immediately before, immediately after, immediately above or immediately below.

Regulations to implement the EC Directive on the advertising of medicinal products for human use

The EC Directive on the advertising of medicinal products for human use should have been implemented by 1 January 1993 but, as previously advised, regulations to that end are still awaited. Further information as to implementation will be circulated when available.

Letter to doctors on room rental

To assist medical representatives when advising doctors of the proscription of the payment of room rental, letters on PMCPA notepaper are available which they can give to doctors. Companies were offered these in Circular CODE/94/52 of 12 May 1994 and many requests have been received. Copies of the letter remain available on application to the PMCPA.

Guidelines on company procedures

Guidance as to the administrative procedures which companies are advised to have in place to ensure compliance with the Code of Practice was sent to companies in Circular CODE/94/51 of 12 May 1994.

A further point has since been added to those in Circular CODE/94/51 to say "Procedures should ensure that Clause 18 relating to gifts and inducements is complied with and that promotional gifts or prizes comply with Clauses 18.2 and 18.3"

The procedures will be included in the printed version of the new Code of Practice

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.

Seminars open to all take place at the Royal Society of Medicine on:

Wednesday, 6 July 1994 (fully booked)
Friday, 5 August 1994
Friday, 9 September 1994

Seminars can also be arranged for individual companies.

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

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CASE REPORTS
JULY 1994

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

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CASE AUTH/86/10/93

GENERAL PRACTITIONER V MEMBER COMPANY

Post Marketing Surveillance Study

Complaint A general practitioner, submitted a complaint regarding a post marketing surveillance (PMS) study carried out on behalf of a member company upon one of its products.

The complainant enclosed a copy of a letter from a research associate from an agent which was carrying out the study on behalf of the company and stated that his partnership would not be bribed into prescribing the medicine at great expense to the taxpayer. The complainant stated that it would be too easy to do a computer search and produce the numbers required. The complainant alleged that bribing doctors to prescribe the medicine was completely unreasonable.

The letter from the agent sent by the complainant stated that the study involved the collection and recording of data four times during the six month period each patient was surveyed. Payment was made per patient visit with an opportunity to earn a further bonus after collection of seven patient reports. The letter also stated that subject to the agreement of participating doctors, a practice manager involved in a study might earn up to £150 per participating doctor, to be paid in the form of vouchers redeemable at major high street stores. A schedule of payments was enclosed with the letter which stated that two assessments with the patient and an assessment not requiring a patient visit would each earn £7. There was a payment of £30 for participation in a survey on the effectiveness of the software following the completion of seven full case reports which involved an individual interview, or a payment of £120 for completion of a written questionnaire covering the operation of the reporting system following completion of 25 full patient reports. The schedule of payments also referred to payments available to the person responsible for the data entry, which were £5 per patient at the initial visit and £5 per patient at the final visit.

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Response The company submitted that the study had two objectives. Its primary objective was to monitor the safety of the product within an unselected general practice population during treatment. The study was designed so that patients were only entered once the doctor had made the decision to prescribe. A comparator group was considered necessary because it was foreseen that a large number of adverse events could be reported which were not related to the treatment of the condition. The secondary objective was to compare and contrast the quality of the data collected by the different methods and different companies. The involvement of pharmaceutical companies directly in PMS studies had led to accusations of using the studies for promotional purposes. It was decided therefore that the studies should be undertaken by one company taking a paper based study and three companies, using their computer based networks; one of these companies ceased trading before the launch of the study and therefore took no part in it.

Investigator payments throughout the study to date followed the British Medical Association guidelines. The protocol had been submitted to the Medicines Control Agency and to the ABPI as required by the guidelines. Patient recruitment had been far short of expectation and the recruitment figures were provided. Following discussions with the MCA recruitment had been extended for a further year.

The company pointed out that the complaint referred to the letter which had been sent by a research associate following a telephone conversation with the practice involved. The letter was part of the normal running of the study by the agent and had not been submitted to the company. The reference to a bonus after seven patients appeared to be an adaptation of the particular research associate and was not part of the standard letter, which was provided together with the study documentation.

The agent submitted that the software assessment exercise was designed to allow general practitioners to provide feedback to help the company improve its performance and simplicity of operation of the PMS software. The research was undertaken as quite a separate exercise from the completion of PMS reports and required the participant to undertake extra work and time over and above the completion of PMS reports.

Panel Ruling The Code of Practice Panel had examined the study documentation and had noted that the decision to enter a patient in the study was to be made after the physician had decided to prescribe. It had further noted from the study documentation that there were to be four assessments made during the six month assessment period, three scheduled patient visits and one general practice assessment of records. The number of patients to be entered by any one practitioner was limited.

The Panel had noted that the PMS guidelines drawn up by the ABPI, the British Medical Association, the Committee on Safety of Medicines and the Royal College of General Practitioners applied to this study although these guidelines were in the process of being revised.

The Panel did not accept that the payments to doctors for participating in the study at £7 per form were unacceptable as they were within the suggested scale of fees published by the British Medical Association.

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The Panel noted that the Code covered promotional practices only and that if a PMS study was not in effect a disguised form of promotion it did not come within the scope of the Code, even if particular aspects of it were not beyond criticism.

The Panel had considered that neither the study nor the documentation was promotional in nature and it therefore did not come within the scope of the Code. There had accordingly been no breach of it.

The Panel had been concerned, however, about the letter in question sent by the agent. It considered that the company should have exercised better control of its agent's activities on its behalf. The Panel had queried whether the payments to practice managers were acceptable under the PMS guidelines. The Panel had also been unhappy about the reference to bonus payments being available if a doctor had more than seven patients in the study. It was noted that the payment was in relation to a market research interview undertaken separately but considered that this had not been made clear in the letter in question, the wording of which was unfortunate. The Panel had requested that its concerns should be drawn to the attention of the company.

Appeal The complainant appealed against the Panel's ruling. The appeal was based simply on a matter of professional ethics. The complainant considered that he was responsible for the actions of his locums when he was on holiday, or on study leave, and indeed could be sued and penalised by the patient and the FHSA for any misdemeanours they committed. He therefore submitted that the company was 100% responsible for the actions of its agents and would further submit that it was using the agent as a cover for actions with which it would not wish to be directly associated.

The complainant pointed out that the costings of the British Medical Association and The Royal College of General Practitioners were that doctors' time was worth £107 per hour. This of course should include overheads which were largely reimbursed as a matter of GMS services. Payment to practice managers, were they to receive the money themselves and not the doctors, would have to be advised to the FHSA which were reimbursing 78% of practice managers' wages. There was no provision for this.

Appeal Response The company reiterated its belief that the post marketing surveillance study was an important, well structured study consistent with the PMS guidelines drawn up by the ABPI, the BMA, the CSM and the RCGP and, as such, involved no breach of the Code of Practice. The company had already indicated that it shared the concern at some of the wording and content of the letter sent out by its agent to a number of general practitioners but this was done completely outside of its contractual arrangement and without prior knowledge or approval. The company reiterated that it had informed the agent in the strongest terms that any activities that it undertook by way of evaluation of its own systems and software at its behest must be totally independent of the post marketing surveillance study and conducted as a completely separate exercise. Similarly, it had reiterated that all and any correspondence which in any way referred to the study had to be subject to scrutiny and prior approval.

Appeal Board Ruling The Appeal Board examined the study documentation. It was extremely concerned about the reference in the covering letter from the research associate to the fact that bonus payments were available if a doctor had more than seven patients in the study as it was not made at all clear in the letter that the payment was in relation to a market research interview.

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The Appeal Board considered that the member company was responsible for the letter in question as it referred to its PMS study and the company should have been aware of what the agent was doing on its behalf. The Appeal Board requested that these serious concerns be drawn to the attention of the company which ought to have exercised more control over the activities of its agents.

The Appeal Board noted that the company had introduced improved procedures to ensure that the activities complained of could not be repeated and that all correspondence referring in any way to the PMS study would be subject to scrutiny, as set out in the terms of its contract with the agent.

The Appeal Board noted that the Code covered promotional practices only and that if a PMS study was not in effect a disguised form of promotion it did not come within the scope of the Code, even if particular aspects were not beyond criticism.

Notwithstanding its concerns, the Appeal Board decided that on balance, neither the study nor the documentation was promotional and it therefore did not come within the scope of the Code. The appeal therefore failed.

Complaint received **18 October 1993**

Case completed **23 February 1994**

CASE AUTH/98/1/94

DOCTOR V LEO LABORATORIES LIMITED

Article in Woman's Own on Dovonex

Complaint A doctor complained that an article on Dovonex published in Woman's Own of 22 November 1993 was a blatant "plug" for the product. The article stated that Dovonex was one of the leading treatments for psoriasis and was now available as a cream and referred to patient preference for cream formulations. The complainant alleged that the article was by virtue of its content an advertisement for a prescription only medicine directed to the public.

Response Leo Laboratories submitted that the information released to the press was not promotional in nature. Some of the information supplied had been prepared in collaboration with with a patient association and the press briefing documents had been part of an information pack of material sent to medical journalists in the specialist and lay press.

Panel Ruling The Code of Practice Panel accepted that psoriasis aroused a good deal of interest among patients who were often dissatisfied with their current treatments. The Panel noted that the press release issued by Leo Laboratories stated that Dovonex was the "leading vitamin D analogue treatment for psoriasis", whereas the article in Woman's Own referred to it as "one of the

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leading treatments for psoriasis". A company issuing information had to be very careful that it was factual and presented in a balanced way so as to avoid the risks of raising unfounded hopes of successful treatment. The Panel decided that the article in Woman's Own was not an advertisement and that on balance the information provided by Leo Laboratories which had led to the article in Woman's Own was not unacceptable. The Panel therefore ruled no breach of the Code.

Appeal The complainant alleged that the item clearly promoted the product by brand name, therapeutic function, ease of application and name of manufacturer and concluded with the exhortation that patients ask their doctors for more details. Nothing could be more promotional and if not an advertisement it fell little short of being an advertisement. The complainant alleged that the whole tenor of the item in question was to encourage a move towards patient-led demand for Dovonex reinforced by the final exhortation in the article "Ask your doctor for more details".

Appeal Response Leo Laboratories submitted that the press information pack had been provided to medical editors of medical journals and the lay press. The pack included information on psoriasis and problems with treating it in addition to information on Dovonex. The company had not been in subsequent contact with Woman's Own. The only contact had been the provision of the press information pack. The motive behind sending the pack was the introduction of a new cream formulation of Dovonex. Woman's Own had misinterpreted the information supplied to it and the claim in the article that Dovonex was one of the leading treatments for psoriasis had not been made by the company.

Appeal Board Ruling The Appeal Board noted the requirements of Clause 20.2 of the Code that information about medicines which is made available to the general public either directly or indirectly must be factual and presented in a balanced way so as to avoid the risks of raising unfounded hopes of successful treatment or misleading with respect to the safety of the product. Statements must not be made for the purpose of encouraging members of the public to ask their doctors to prescribe a specific medicine. Clause 20 permitted the distribution of information to the general public. There was no restriction on who could receive such information but the restrictions related to the nature of the information.

The Appeal Board examined the press information pack supplied by Leo Laboratories and considered that the press release included in it was not balanced as required by the Code. The press release mentioned the brand name frequently and featured very positively on the benefits of Dovonex. The Appeal Board considered that the press release made the press information pack unacceptable. The press release had not been presented in a balanced manner and the Appeal Board therefore ruled a breach of Clause 20.2 of the Code. The Appeal therefore succeeded.

Complaint received **6 January 1994**

Case completed **11 March 1994**

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CASE AUTH/102/1/94

GENERAL PRACTITIONER V PROCTER & GAMBLE PHARMACEUTICALS UK LIMITED

Symposium newsletter

Complaint A general practitioner submitted a complaint regarding an advertisement enclosed with December 1993 "Video Horizons". The item in question was a newsletter headed "Rational Antibiotic Prescribing for Urinary Tract Infection". The newsletter stated that it reported on an important symposium on urinary tract infection and rational antibiotic prescribing.

The complainant objected to receiving it in the form presented. It appeared to be a review of antibiotic prescribing but, in practice, he considered it to be an eight page advertisement for Procter & Gamble. He did not believe that an impartial review could manage to name the product of one company and fail to mention the specific products of other companies. He was sure that there were many areas where the document was in breach of the Code.

Response Procter & Gamble Pharmaceuticals UK, Limited submitted that the newsletter did not contain misleading information, claims or comparisons. All authors of the articles featured in the newsletter were asked to review and comment upon both the article for which they held sole responsibility and the document as a whole, before it was made available for distribution/publication. Each contributor confirmed that the newsletter provided a representative, balanced account of the consensus meeting. Copies of the approval forms from the authors were provided.

Procter & Gamble invited authors to the meeting with the concurrence of the Chairman. Each author was selected due to their specific interest in urinary tract infection (UTI) and their stature within academic circles. The stated aim of the meeting was that these leading physicians reached consensus on how UTI should be treated, considering resistance problems, safety and cost.

The company acknowledged that the newsletter was used for promotional purposes.

The company pointed out that it was constrained by existing UK copyright laws, which prohibited any mention of trade marks other than their own. Where an anti-microbial agent other than MacroBID was recommended in the newsletter, a generic name was used.

Panel Ruling The Code of Practice Panel noted that the newsletter was headed "Rational Antibiotic Prescribing for Urinary Tract Infection" and was a report on a symposium attended by microbiologists, general practitioners and practice nurses, with speakers from the UK, Europe and North America. The newsletter was presented as a series of articles by the speakers at the symposium and included sections which had been highlighted. Many of the highlighted sections mentioned either nitrofurantoin or MacroBID.

The Panel noted that the newsletter had been produced by the company as a report on a company sponsored meeting. The product name, MacroBID, had been used and prescribing information was included. The Panel noted that the approval form signed by the authors stated that the newsletter was to be used by medical representatives when discussing urinary tract infection with doctors and would be posted to doctors. The Panel decided that the newsletter was promotional and therefore came within the scope of the Code.

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The Panel noted that Clause 7.10 of the Code prevented companies using the brand names of other companies' products without prior permission. The company could not therefore mention the specific products of other companies and there was no breach of the Code in that regard.

The Panel considered that the Newsletter was reasonably balanced and did not breach the Code in that regard. It was noted that the prescribing information for Macrobid appeared on the back of the Newsletter in a style similar to the rest of the text. It was not obvious by looking at the Newsletter that it was in fact promotional material. The Panel therefore ruled that the newsletter was a form of disguised promotion in breach of Clause 10.1 of the Code. The Panel noted that that being so, it was also in breach of Clause 4.6 of the Code as it consisted of more than four pages and a clear reference had not been given as to where the prescribing information could be found.

Complaint received **17 January 1994**

Case completed **18 March 1994**

CASE AUTH/103/1/93

CONSULTANT PAEDIATRICIAN V MEMBER COMPANY

A leavepiece

Complaint A consultant paediatrician alleged that the inclusion of a telephone card on a leavepiece issued by a member company amounted to offering an incentive to prescribe the product. The complainant was also concerned that the product was being promoted in such a way as to amount to encouraging poor medical practice.

Response The company submitted that the leavepiece followed a series of three mailings, each of which contained a reply paid card for the doctor to request a free telephone card. The use of the telephone card did not amount to an incentive to prescribe. It was inexpensive and relevant to the practice of medicine.

The company submitted that it was clear from the series of mailings, the leavepiece in question and the representatives' briefing material that the product was being presented in a suitable way.

Panel Ruling With regard to the telephone card, the Panel noted a previous case which concerned a £2 phonecard provided to requesting doctors in which it had been decided that a phonecard of modest value was an acceptable gift. This decision was reflected in the supplementary information to Clause 18.2 of the Code. The Panel noted that the telephone card in question was said to be only provided in response to requests although it appeared that the complainant might not have actually requested a phonecard but had nevertheless received one. The Panel decided, however, that the provision of the phonecard was acceptable as it was inexpensive and relevant to the practice of medicine. The Panel therefore ruled no breach of the Code.

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The Panel did not accept that the literature or the representatives' briefing material were encouraging poor medical practice as alleged. The Panel noted the particular therapeutic area at issue and considered that doctors would be aware of the treatment rationale of the condition. The Panel therefore ruled no breach of the Code.

Complaint received **21 January 1994**

Case completed **16 March 1994**

CASE AUTH/104/1/94

GENERAL PRACTITIONER V LOREX PHARMACEUTICALS LIMITED

Conduct of a representative

Complaint A general practitioner complained about the conduct of a representative from Lorex Pharmaceuticals Limited. The representative had left a photocopy of an article published in The Pharmaceutical Journal which appeared to have been superimposed on a second piece of paper bearing the Tildiem 90 logo. The article in The Pharmaceutical Journal consisted of advice on the prescribing and dispensing of modified release preparations of diltiazem, nifedipine and theophylline which had been given by the Council of the Royal Pharmaceutical Society of Great Britain. The complainant alleged that the document as a whole was obviously intended to give the impression that The Pharmaceutical Journal was specifically promoting Tildiem, which he was sure was without the journal's knowledge. The complainant had no idea as to what extent Lorex had been using the document as a promotional tool, whether the representative had been doing this on his own, or whether it had been sanctioned by Lorex.

Response Lorex, although not a member of the ABPI, had nevertheless agreed to comply with the Code. The company acknowledged that the basic document was a copy of the article which was actually used by its sales force. The company had obtained the appropriate authorisation to do so. The company submitted that the representative had acted on his own initiative and placed a sticker carrying the name of the product above the copy of the article to create the document that the complainant had received. The company submitted that it had not encouraged representatives to modify the original document in any way and had notified its sales force to make sure that it would not happen again.

Ruling The Code of Practice Panel noted that the allegation concerning the possible contravention of copyright laws was outside the scope of the Code. The Panel considered that by attaching the Tildiem 90 sticker to the Council advice published in The Pharmaceutical Journal, the created document became promotional material for that product. It therefore needed to include prescribing information. As there was no prescribing information on the document concerned the Panel ruled a breach of Clause 4.1 of the Code. It was not considered that the Code had otherwise been breached.

Complaint received **20 January 1994**

Case completed **14 March 1994**

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CASE AUTH/105/1/94

GENERAL PRACTITIONER v SMITHKLINE BEECHAM

Promotion of Famvir

Complaint A general practitioner, complained about the promotion of Famvir (famciclovir) by SmithKline Beecham Pharmaceuticals.

The complainant expressed his unease about some of the advertising claims associated with the product which he suspected were misleading and unsubstantiated. The complainant pointed out that it was stated that Famvir had the power to produce effective relief from pain, implying analgesic properties and a reduction in zoster related pain, for which no relevant evidence was quoted and, indeed, which remained unproven even in large well conducted trials. The only qualification given was that pain reduction occurred by inhibiting viral replications and reducing tissue damage, although this reference came from work done with aciclovir and referred only to the acute phase. Furthermore, it was difficult as most general practitioners, himself included, were not competent statisticians and found it difficult to evaluate the advertising claims drawn from referenced research. It was therefore disquieting to find such references (as in the Famvir promotional literature), coming from *in vitro* studies when used as the basis for claims for clinical performance.

The complainant pointed out that the journal advertising had been rapidly followed by a number of direct mailings concentrating on unfavourable comparisons with aciclovir. It was stated that Famvir was better absorbed, with higher plasma concentration and a considerably more prolonged anti-viral effect and thus required less drug less often. The complainant alleged that it was misleading to suggest compliance to be the limiting factor in therapeutic success, as it was rarely a problem in a such a distressing disease, and more so to imply that aciclovir was toxic. The important difference between the two compounds, as the complainant understood it, was that aciclovir was significantly more potent than famciclovir which was omitted from the material. The claims for absorption and tissue levels were also largely related to *in vitro* data.

The promotional materials supplied by SmithKline Beecham in response to this case were:-

A leaflet entitled "A powerful new alternative in the management of shingles" (ref 1293FM:MF/3/031), a "Dear Doctor" letter (ref 1293FM:LT/3/030), a news release for the medical press dated 13 January 1994, a document "For the attention of the accredited medical correspondent" which gave information about Famvir, a detail aid (ref 1093FM:DA/3/014), a fold out poster (ref 1293FM:PT/3/037), and two different journal advertisements (ref 0194FM:AD/4/058).

1. Claims for Pain Reduction

Panel Ruling The Code of Practice Panel accepted that SmithKline Beecham had not made claims that famciclovir was an analgesic. The Panel noted that the promotional material included claims that Famvir gave faster relief of herpetic pain with early treatment when compared with aciclovir and that such claims were referenced to Nye and data on file. The Nye study stated that "...pain resolution occurred at similar rates in all treatment groups". The data on file which appeared to be a sub group analysis of the Nye data showed a significant difference in favour of famciclovir for patients enrolled

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in to the study within 48 hours of onset of rash. The Panel accepted that there was some evidence in the data on file to support claims for famciclovir having a faster relief of herpetic pain with early treatment. It was not, however, sufficient to substantiate the strong claims for pain reduction in the promotional material. The Panel therefore ruled a breach of Clause 7.2. of the Code.

Appeal SmithKline Beecham Pharmaceuticals appealed against the Code of Practice Panel's ruling.

The company submitted the body of evidence from both registration studies indicated a shorter duration of zoster associated pain in patients treated with Famvir in comparison with both placebo and aciclovir. With regard to the claims in the material that Famvir had a faster relief of herpetic pain than aciclovir, this was based on the study by Nye and a sub group analysis of that data referenced as data on file in the promotional literature. This was the only comparative study of Famvir and aciclovir in chronic pain.

Detailed information on the data was presented to the Appeal Board.

Appeal Board ruling The Appeal Board accepted that the sub group analysis of the Nye study showed that famciclovir had a faster relief of herpetic pain with early treatment compared with the aciclovir group. The Appeal Board considered, however, that it was not sufficiently clear in the promotional literature that the faster relief of herpetic pain referred to a reduction in pain on a continuum and not immediate relief. Furthermore, the material did not in all places refer to the need for early treatment as being within 48 hours of onset. The Appeal Board considered that the data was insufficient to substantiate the unqualified claims for pain reduction in the promotional material and therefore upheld the ruling that there was a breach of Clause 7.2 of the Code. The appeal therefore failed.

2. Misleading information, claims and comparisons and the use of *in vitro* data

Panel Ruling The Panel noted the supplementary information to Clause 7.2 of the Code that care must be taken with the use of *in vitro* data so as not to mislead as to its significance and that the extrapolation of such data to the clinical situation should only be made where there was data to show that it was of direct relevance and significance.

The Panel accepted that SmithKline Beecham was not obliged to state that aciclovir was more potent than famciclovir. The Panel also noted that a medicine with a more favourable pharmacokinetic profile than another was not necessarily a better medicine. Superior bioavailability and more rapid and higher pharmacokinetic concentration did not necessarily mean that the medicine worked better in the clinical situation. The Panel recognised that *in vitro* data would form an important part of the supporting evidence for an antiviral agent. Such data had to be relevant to varicella zoster virus, as Famvir was only licensed for the treatment of shingles.

The Panel noted that the inside of the leaflet headed "A powerful alternative in the management of shingles presented data from *in vitro* studies and this was clearly stated. The Panel was however concerned that two stab points on the reverse of the leaflet "Excellent penetration to infection site" and "More powerful and prolonged antiviral effect", and similar claims in other material based on *in vitro* data gave the impression that famciclovir was superior to aciclovir. The Panel considered that there was some supporting evidence from *in vitro* data but that it was not sufficient to support the claims in the clinical situation. The Panel therefore ruled a breach of Clause 7.2 of the Code.

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Appeal SmithKline Beecham Pharmaceuticals appealed against the Code of Practice Panel's ruling.

SmithKline Beecham Pharmaceuticals submitted that *in vitro* studies were essential to demonstrate activity of an antiviral agent. They were critical to demonstrate the inhibition of viral replication and involved experiments modelled to correspond to the clinical situation. It was self evident that data on intracellular concentrations which formed the basis of the claims for excellent penetration to infection site would come from *in vitro* or *ex vivo* studies. Similarly it was also self evident that claims for more powerful and prolonged antiviral effect would also be based on *in vitro* data.

Detailed evidence was presented on the *in vitro* data on which the claims were based in the promotional literature.

The company submitted that the improved bioavailability of Famvir compared with aciclovir with *in vitro* evidence of higher intracellular concentrations of penciclovir, a longer intracellular half life and greater inhibition of viral DNA replication at similar concentrations compared with aciclovir provided a clear rationale for the claims and underpinned the clinical differences between Famvir and aciclovir. They were, therefore, clinically relevant by virtue of providing for a smaller dose and less frequent dosing regimen compared with aciclovir.

Appeal Board ruling The Appeal Board acknowledged that it was not possible to demonstrate the inhibition of varicella zoster viral DNA replication or prolonged antiviral effect other than by *in vitro* studies generally. The Appeal Board also accepted that the data might be of relevance to the clinical situation. The Appeal Board did not accept, however, that it would be self evident to those to whom the promotional material was directed that such claims as "Excellent penetration to infection site" and "More powerful and prolonged anti viral effect" were based on *in vitro* data.

Although it was indicated in the promotional material that the latter claims were based on *in vitro* data, by way of small footnotes, this was inadequate. It was a well established principle under the Code of Practice that one could not correct a misleading or inadequate statement by qualifying it in the small print. Furthermore, the Appeal Board did not accept that the claim "Excellent penetration to infection site" was substantiable by *in vitro* data alone.

The Appeal Board upheld the Panel's ruling that there was a breach of Clause 7.2. of the Code. The appeal therefore failed.

3. Compliance

Response SmithKline Beecham submitted that its promotional material referred to a simple three times daily regime with a patient friendly pack and small, easy to pick up, easy to swallow tablets. It believed that most doctors would regard compliance as important and it tried hard in the design of the product, the tablet and the packaging to help in this goal. Aciclovir had to be administered five times daily and the tablets were large, a factor that was generally accepted as being a difficulty for some patients, particularly the elderly. The only comparison made with the aciclovir was for dosing regimes. The company believed the benefits with famciclovir were self evident and did not suggest that compliance was the limiting factor in therapeutic success.

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Panel Ruling The Panel accepted that a more easily complied with treatment had advantages and did not consider that the promotional material overplayed this aspect. It therefore ruled that there had been no breach of the Code.

This was not appealed.

4. Disparaging references to aciclovir

Panel Ruling The Panel had considered that comparisons between famciclovir and aciclovir were to be expected, since they were currently the only two anti viral agents available for shingles. The Panel did not consider that the comparative claims for famciclovir disparaged aciclovir and therefore ruled that there had not been a breach of the Code in this regard.

Appeal The complainant appealed the Code of Practice Panel's ruling.

The complainant expressed his concern that a new drug seemed to be climbing on the safety profile established by another, when recent experiences with nucleoside analogues suggested that close chemical relatives exhibited different properties and may not be as well tolerated as might be expected. To imply patient tolerability now, before specific trials had confirmed it, must be misleading in the complainant's view.

Appeal Response SmithKline Beecham reiterated that all comparisons between Famvir and aciclovir were factual and based on *in vitro* differences, pharmacokinetic profiles and results of clinical trials. With regard to statements concerning the tolerability of Famvir, it was simply stated that clinical studies had shown that it was as well tolerated as aciclovir. In these studies no adverse events occurred that were not in keeping with the accepted adverse event profile for aciclovir. In order to be useful, any reference to the side-effect profile of a medicine should be placed in context by comparisons against other relevant members of its class. The company pointed out that the adverse events for Famvir were no different from those with placebo.

The data sheet itself stated:

> "Famciclovir has been well tolerated in human studies. Headache and nausea have been reported in clinical trials. These were generally mild or moderate in nature and occurred at a similar incidence in patients receiving placebo treatments".

Appeal Board ruling The Appeal Board considered that famciclovir had been shown in clinical trials to be well tolerated as claimed in the promotional literature. The Appeal Board did not accept the complainant's submission. The appeal therefore failed.

Complaint received: **26 January 1994**

Case completed: **18 May 1994**

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CASES AUTH/106/1/94
AUTH/107/1/94
AUTH/108/1/94
AUTH/109/1/94
AUTH/110/1/94
AUTH/114/2/94

VARIOUS COMPLAINANTS V LEDERLE LABORATORIES

Use of a device in a Mailing

Complaints about a mailing for Monocor issued by Lederle Laboratories were received from four general practitioners (AUTH/106/1/94, AUTH.109/1/94, AUTH/110/1/94 and AUTH/114/2/94), a consultant in the psychiatry of old age (AUTH/107/1/94) and a consultant physician (AUTH/108/1/94).

Complaint All of the complaints concerned the fact that the mailing included an electronic device which was intended, when the mailing was opened out, to make a noise similar to that of a human heart. In many cases the devices had, however, activated before they were opened, resulting in alarm calls to emergency services and the like. One complainant objected to the waste of resources which such a mailing represented.

Response Lederle Laboratories said that the mailing had been sent out during the last week of January to approximately 13,000 physicians in the UK, consisting of mainly general practitioners and hospital physicians specialising in cardiology. The mailing itself contained technical information relating to the role of beta-blockers in managing cardiovascular disease. In order to improve the memorability of the mailing, a device had been fitted, which upon opening of the piece, emitted the sound of a heartbeat.

Lederle had been advised that this particular device had been used in a number of commercial mailings and was quite commonly found in various greeting cards. It would appear that a small number of the mailings activated before opening which was clearly caused by defective devices. The total number of complaints received by Lederle was less than a hundred, all of whom were either contacted personally or received a written apology. The mailing house concerned had received approval from the Royal Mail to send out this type of mailing, basically on the logic that it had been done before and they saw little or no risk of the subsequent concerns raised. In hindsight, Lederle, as a company, accepted that the item caused some concern among practitioners but it felt that it had always acted with total consideration for its end customers.

Ruling The Code of Practice Panel noted that it had previously ruled that devices such as that used here were not per se unacceptable under the Code. It depended on what they did. In this case, it was considered that the use of the device in the mailing failed to recognise the professional standing of the recipients and it was ruled to be in breach of Clause 9.1 of the Code.

The fact that some of the devices had prematurely activated was not a factor in the ruling of a breach of Clause 9.1. It was not considered to warrant a further ruling of greater censure, by way of Clause

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2 of the Code, though it was considered that if the mailing had led to widespread disruption, such a ruling might have been appropriate.

Complaints received **26 January - 4 February 1994**

Cases completed **7 March 1994**

CASE AUTH/111/1/94

CONSULTANT PAEDIATRICIAN V MEMBER COMPANY

Mailing for a device

Complaint A consultant paediatrician submitted a complaint about a mailing sent to general practitioners and paediatricians by a member company. The mailing promoted a device that had been withdrawn, following fears that part of the device might be hazardous. The complainant was disappointed to see that promotion of the device was continuing.

Response The company stated that it had recalled the devices after consultation with the Medicines Control Agency. The company had notified general practitioners and paediatricians at the time. When it had reintroduced a modified design of the device the company had sent a further letter to all doctors which predated the mailing in question. The mailing in question was sent subsequent to the reintroduction of the new stock.

Ruling The Code of Practice Panel noted that at the time the mailing in question was sent new stock of the modified device was available. The Panel therefore ruled no breach of the Code.

Complaint received **31 January 1994**

Case completed **28 February 1994**

CASE AUTH/112/2/94

CONSULTANT PHYSICIAN V MEMBER COMPANY

Claims for safety in various promotional materials alleged to be unsubstantiated

Complaint A consultant physician submitted a complaint about claims made by a member company for one of its products. The complainant expressed his serious concern regarding some of

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the apparent claims being made by the company for one of its products and the quality and design of its clinical studies on the product. He believed the studies published to date were of somewhat dubious scientific value. Further, the apparent claims being made that the product was likely to be as safe or more safe than a competitor product were nonsense and misleading.

Response The company submitted that the safety profile of any medicine was a vital consideration and, in order to be useful, any reference to its side effect profile should be placed in context by comparisons with other relevant medicines. Two of the three studies were comparisons with the competitor product and the third was a comparison with placebo. The company submitted that the promotional material referred to tolerability and adverse events.

Ruling The Code of Practice Panel noted that the studies had compared the two products and that the claims in the promotional material were for tolerability rather than for safety and decided that there was enough evidence to support the company's claim that the product was well tolerated and that it was as well tolerated as the competitor product. The Panel therefore ruled that there was no breach of the Code.

Complaint received **2 February 1994**

Case completed **7 April 1994.**

CASE AUTH/113/2/94

MEDICAL PRESCRIBING ADVISER V MEMBER COMPANY

Survey summary and leaflet sponsored by a member company

Complaint A medical prescribing adviser in primary care services complained about a leaflet on a disease and a survey summary on that disease which had been sponsored by a member company for another organisation. The complainant alleged that the distribution of the two items together specifically promoted one of the member company's products. The complainant was concerned that the telephone survey was a dubious form of research and alleged that a statement in the leaflet was unacceptable as the relevant studies were inconclusive.

Response The company concerned submitted that the market research was conducted independently using computer aided telephone interviews which were well known within market research to be an accurate and independent way of researching. The aim of the survey was to help produce the leaflet for doctors to give to their patients. It was suggested that those survey findings which were particularly related to, or would be of interest to, doctors should be enclosed with the leaflet. At no time was the enclosure of the survey summary with the leaflet intended to be promotional.

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With regard to the content of the leaflet, the company submitted that there was adequate evidence to support the disputed statement.

Ruling The Panel examined the survey summary and noted that it did mention a product. The Panel did not object to the use of the telephone interviews in the market research survey. It considered that the survey presented factual information and was not promotional. The Panel therefore ruled no breach of the Code.

The Panel noted that the leaflet discussed the disease area generally and that there was no mention of any products. With regard to the allegation concerning the content of the leaflet, the Panel considered that the leaflet was acceptable in this regard and therefore ruled no breach of the Code.

The Panel did not accept that distributing the leaflet with the survey summary promoted the product as alleged and therefore ruled no breach of the Code.

Complaint received **4 February 1994**

Case completed **25 March 1994**

CASE AUTH/115/2/94

GENERAL PRACTITIONER V MEMBER COMPANY

Product Help Line

Complaint A general practitioner complained that one of his patients had telephoned a product help line about the treatment of her child. She had been told that the child's symptoms fitted a particular condition and that the child should have been prescribed the product in question at the first consultation. The mother had been told to contact her doctor again and tell him of the conversation. The patient had subsequently complained to the FHSA about the matter and had left the complainant's list.

Response The member company in question denied that it either had, or sponsored, such a help line.

Ruling Following its initial consideration of the matter the Code of Practice Panel decided to ask the complainant for further information. It proved impossible, however, to obtain

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further information as to whom had been telephoned and where the telephone number had been obtained from and, in view of the conflict of evidence and its insufficiency, the Panel ruled that there had been no breach of the Code.

Complaint received **9 February 1994**

Case completed **19 April 1994**

CASE AUTH/118/2/94

GENERAL PRACTITIONER V MEMBER COMPANY

Payment of participants at a round table meeting

Complaint A general practitioner submitted a complaint about an invitation he had received to attend a meeting organised by a member company. The complainant stated that he would have been very happy to attend the meeting to discuss the management of a particular condition and have dinner at this excellent hotel, but he was uneasy about accepting a fee for attending and wondered whether it was within the ABPI guidelines.

The invitation was from the clinical research director who had invited the complainant to attend a round table meeting on the management of a condition. The invitation stated that it was anticipated that about 10-12 physicians, mainly general practitioners with some consultants, would attend each meeting which was to be introduced by a general practitioner. There would be a brief introduction followed by an expert comment from a consultant. This was to be followed by an open discussion to which it was hoped that everybody would contribute. The invitation stated that as the meetings were regarded as helpful input to the company's clinical research planning, the company was pleased to offer an advisory fee to all who attended and to meet travelling expenses. The invitation included an agenda for the meeting.

Response The company concerned submitted that the meetings were entirely non-promotional and were held for the purposes of medium term clinical research planning. The company submitted that it was made clear in the letter of invitation that attendees would be expected to contribute to the discussion for which the advisory fee was to be paid. The meetings were attended only by senior managers with planning responsibility. Members of the sales force had no involvement in the selection of doctors or their invitation or in the meeting itself. There was no promotion or disguised promotional content.

The company submitted that the cost of the meal and beverages was £25 per head and this was secondary to the nature of the meeting and not out of proportion to the occasion. Reasonable travelling expenses were reimbursed but no locum reimbursements or overnight accommodation were offered. Participants received an advisory fee of £50 which was within the rate recommended by the British Medical Association. The company submitted that it was accepted that if a company requested a qualified professional to provide his or her time and advise on a matter in which they have expertise, then an advisory fee could be paid.

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Ruling The Panel considered that the meeting was small enough to ensure that all the participants could make a contribution to the proceedings. The Panel noted that the company's products were not mentioned. The Panel accepted that the payments and the hospitality offered were reasonable. The Panel noted that the field force had no involvement in the selection of doctors, their invitations or in the meeting itself. It had been organised by the clinical research department.

The Panel did not consider that the meeting was promotional. The payment of the fee was considered to be a genuine payment for advice. The Panel therefore ruled no breach of the Code.

Complaint received **21 February 1994**

Case completed **19 April 1994**

CASE AUTH/119/2/94

FHSA CLINICAL DIRECTOR V MEMBER COMPANY

Journal advertisement alleged to be inappropriate and misleading

Complaint The clinical director to a family health services authority, complained about a journal advertisement issued by a member company for two of its products. The complainant suggested that the photograph in the advertisement was entirely inappropriate and misleading. The apparent age of the model would not be appropriate for a patient needing the medicines advertised. The complainant queried whether taking the particular medicines would make patients look like the photograph.

Response The company said that the advertisement was intended to compare the long lasting quality and properties of its products by drawing an analogy with a particular item shown in the photograph. The model was only used to bring "life" to the analogy and the model's presence presence was wholly incidental to the message being conveyed. To interpret the photograph as the complainant had done was inconsistent with the headline. The company did not believe that the professional audience to which the advertisement was aimed could place the same interpretation on the photograph as the complainant. This was borne out by market research carried out before publication. Taste was a subjective concept at the best of times and the company submitted that the photograph did not breach any standard of good taste and in no way failed to recognise the special nature of medicines or the audience to whom the advertisement was addressed.

Ruling The Code of Practice Panel considered that there was no claim made or implied that patients taking the products would look like the model in the photograph. Whilst noting the complainant's interpretation of the advertisement, the Panel did not think that it would generally be considered to be misleading and did not consider that it failed to recognise the special nature of

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medicines or of the audience to whom the advertisement was addressed. It was accordingly ruled that there had been no breach of the Code.

Complaint received **23 February 1994**

Case completed **5 April 1994**

CASE AUTH/121/2/94

GENERAL PRACTITIONER V RHONE-POULENC RORER LIMITED

Prescribing Information in a sponsored publication

Complaint A general practitioner submitted a complaint regarding an advertisement for Celectol which appeared in a bulletin sponsored by Rhône-Poulenc Rorer Limited. The complainant alleged that the advertisement did not include the generic name.

The bulletin was a special symposium edition and the final page of the document included the prescribing information for Celectol.

Response Rhône-Poulenc Rorer Limited submitted that there was no advertisement for Celectol in the document. The prescribing information appeared on the back cover to comply with the Code requirements as the bulletin contained references to celiprolol and was sponsored by the company. Rhône-Poulenc Rorer Limited submitted that this was in keeping with the policy of the publishers and previous adjudication on this type of publication. The company submitted that there was therefore no case to answer.

Panel Ruling The Code of Practice Panel examined the bulletin and considered that the inclusion of prescribing information for Celectol was an advertisement in its own right and as such needed to comply with the Code. The Panel noted that the generic name celiprolol was present in the prescribing information but did not appear immediately below the most prominent display of the brand name as required by the Code. The Panel therefore ruled a breach of Clause 4.1 of the Code.

Complaint received **28 February 1994**

Case completed **22 March 1994**

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CASE AUTH/122/3/94

GENERAL PRACTITIONER V 3M HEALTH CARE LIMITED

Conduct of a Representative

Complaint A general practitioner complained that a representative from 3M Health Care Limited booked an appointment with him but failed to either turn up or apologise in advance for the fact that he would be unable to keep the appointment.

Response 3M Health Care Limited said that an internal investigation had confirmed that one of its representatives did breach Clause 15.4 of the Code in the manner described. The company had apologised to the doctor concerned both verbally and in writing and all representatives had been reminded of their obligation to respect the time of doctors.

Ruling The Code of Practice Panel, noting that no mitigating circumstances had been put forward, ruled that there had been a breach of Clause 15.4 of the Code.

Complaint received 3 March 1994

Case completed 28 March 1994

CASES AUTH/123/3/94 AND AUTH/130/3/94

LEO LABORATORIES LIMITED AND UNIVERSITY LECTURER IN DERMATOLOGY V DERMAL LABORATORIES LIMITED

Leaflet on Dithrocream

Leo Laboratories Limited submitted a complaint about a leaflet on Dithrocream (Ref DIT031) sent by Dermal Laboratories Limited to general practitioners (AUTH/123/3/94). Dermal was not a member of the ABPI, but had nevertheless agreed to comply with the Code. Subsequently a complaint was received from a University Lecturer in Dermatology (AUTH/130/3/94) which was similar to one of the allegations made by Leo.

There were four heads of complaint and these were dealt with as follows.

Cost comparison Leo Laboratories submitted that a question on the front of the leaflet: "What price success in the treatment of psoriasis?", which appeared above information concerning the cost of one month's treatment with Dithrocream and calcipotriol, implied that the relative costs of Dithrocream and calcipotriol took into account clinical efficacy which was not so. No data were

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presented which compared efficacy or the cost of achieving such efficacy with the two preparations. The typical cost of one month's treatment with Dithrocream 0.25% was stated to be £4.97 compared with calcipotriol at £26.74.

The costs given on the front page were followed by an asterisk. The explanation for the asterisk was on page two of the leaflet. This stated that "Typical patient-cost assumes two grams of cream (or ointment) per application, over a 30 day period. Recommended dosage for Dithrocream is once daily, calcipotriol is twice daily. No comparison of effectiveness or use is intended (other than stated). Prices correct at time of going to press". Leo Laboratories was not aware of any data to support that that was the typical dose. The claim was therefore misleading.

Leo Laboratories pointed out that a 30 day treatment period at 2g Dithrocream per day resulted in a total dose of 60g. The cost of Dithrocream 0.25% was stated to be £4.14 for 50g. In order for a patient to receive 60g of Dithrocream it was necessary to prescribe two 50g tubes at a total cost of £8.28, so it was misleading to suggest that 60g treatment could be purchased for £4.97.

Dermal Laboratories submitted that the proposition underlying the question "What price success in the treatment of psoriasis?" was a frank acceptance of the clinical value and success of calcipotriol. This was amplified on page 2 of the leaflet under the same heading which stated "... calcipotriol significantly extends the prescribers' choice with a novel treatment successfully compared with dithranol.....". The item contained a statement on page 2 which said "No comparison of effectiveness or use is intended (other than stated)". It was naive to imagine that doctors did not consider cost when deciding which product to prescribe. Provided that the clinical perspective was fairly presented, there was no reason why cost comparisons should not be made. The "typical" cost was clearly explained in the text of the item. Dermal had chosen 2g on the basis of knowledge, experience and common sense in relation to the types of products and the conditions for which they were used. It was intended as a reasonable figure for the sole purpose of cost comparison. An amount of 2g was chosen because, to the nearest gramme, it was the most reasonable expectation of average use on which to base a calculation of such a nature. Both products were used for chronic treatment, the calculation was valid for any given period of 30 days, so the respective pack size, relative to the period chosen, was immaterial. In any case, citing the cost of two tubes of Dithrocream ignored the corresponding higher cost of £30.03 for two tubes of Dovonex, one of 100g and one of 30g.

The Code of Practice Panel noted the wording on the front page of the leaflet: "What price success in the treatment of psoriasis?" and that the typical cost of one month's treatment was given as £26.74 for calcipotriol and £4.97 for Dithrocream 0.25%. It also noted the statement on page 2 which said "..... no comparison of effectiveness or use is intended (other than stated)".

The Panel considered that the word "success" implied more than just a price comparison and that whatever the interpretation given to the success of a treatment, cost was not the only factor involved. The use of the word "success" and the disclaimer that no comparison of effectiveness or use was intended was a contradiction in terms and therefore misleading. The Panel ruled a breach of Clause 7.2 of the Code.

Cost-effectiveness Leo Laboratories alleged that the heading to page 3 of the promotional item: "Cost effective Dithrocream" was misleading as it implied that Dithrocream was cost-effective. No data had been supplied, nor was the company aware of any data to support the claim for cost-effectiveness.

The university lecturer said that the leaflet suggested that Dithrocream was more effective than

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calcipotriol (Dovonex) in the treatment of chronic plaque psoriasis. He was not aware of any cost effective analysis of Dithrocream nor could he see any reference to this in the leaflet. The leaflet was therefore making a false claim for the product Dithrocream by suggesting it was cost effective when no such health economic analysis had been performed. This type of promotion gave a bad name to true health economic evaluations of dermatological and other treatments.

Dermal Laboratories stated that the cost-effectiveness of Dithrocream was self evident. The company did not claim that Dithrocream was more cost-effective than any competitor product, but the established data on its efficacy and reputation, coupled with its low price, allowed the company to assert its cost-effectiveness. Page 3 of the item containing the cost- effectiveness statement was quite distinct from page 2, which dealt with cost comparisons. Page 3 dealt exclusively with Dithrocream.

The Panel noted the supplementary information to Clause 7.2 of the Code which stated that care must be taken that any claim involving the economic evaluation of a medicine is borne out by the data available and does not exaggerate its significance.

The Panel considered that no product could be cost-effective in isolation as there was always an element of comparison involved even if no other product was mentioned. Claims for cost-effectiveness had to be related to the cost of treatment in general. The information provided on page 3 of the leaflet had not dealt with the economic evaluation of the effectiveness of Dithrocream and no data had been provided to substantiate the claim. The Panel ruled that the claim was misleading and in breach of Clause 7.2 of the Code.

Specific Limitation on Dosage Leo Laboratories complained that the statement on page 3 of the promotional item: "Dithrocream and the period of short-term therapy can be adjusted to suit the patient's response and tolerance, with no specific limitation on dosage" was in contravention of the product licence. The prescribing information included on the item stated that: "Dithrocream should be applied once every 24 hours" and "Dithrocream should be used sparingly". The company alleged that both statements were specific limitations on dosage.

Dermal Laboratories submitted that the statement "No specific limitation on dosage" was accurate. "Short contact therapy" was itself a once daily regime and "sparingly" was not a specific limitation. The essence of Dithrocream dosage was to allow the experienced practitioner the discretion to adjust the strength used, the period of contact with the skin and the amount applied in accordance with the needs of each patient. There was a specific maximum dosage for Dovonex.

The Panel did not consider that the statements in the prescribing information that "Dithrocream should be applied once every 24 hours" and "Dithrocream should be used sparingly" were specific limitations on the use of Dithrocream and therefore ruled that there had been no breach of Clause 3.2 of the Code.

Date of preparation It was alleged by Leo Laboratories that no indication had been given as to when the promotional item had been drawn up or revised, in breach of Clause 4.2 of the Code.

Dermal acknowledged that the omission of the date of preparation was a regrettable error.

In view of the confusion which existed over this requirement and the fact that the matter would not be clarified until the Code was revised, the Panel decided not to make a ruling on this particular

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matter but was pleased to note that Dermal Laboratories had undertaken to include a date in future material.

Complaints received **4 March 1994 (AUTH/123/3/94)**
11 March 1994 (AUTH/130/3/94)

Cases completed **6 April 1994 (AUTH/123/3/94)**
25 March 1994 (AUTH/130/3/94)

CASE AUTH/124/3/94

DIRECTOR V CIBA PHARMACEUTICALS

Conduct of a representative

Complaint On 20 February 1994, the News of the World included an article concerning doctors and medical representatives. The article stated that "An undercover reporter posing as a pharmaceutical salesman went `on the road' calling on surgeries". It referred to alleged requests made by the doctors concerned and alleged provision by representatives of unacceptable hospitality, etc. Ciba Pharmaceuticals found out that it was one of its representatives who had obtained access to the doctors for the News of the World reporter. The company informed the Authority and prepared a standby press release on the matter which stated that the Prescription Medicines Code of Practice Authority had been informed. The matter was reported in GP magazine on 11 March 1994. In accordance with the usual procedure the matter was taken up as a complaint under the Code of Practice.

Response Ciba outlined the circumstances whereby it became aware of the fact that one of its representatives was involved and the enquiries that it had subsequently made. It had been determined that at the time the calls had been made the representative was in fact off sick from work. In a letter to the company the representative said that "It is true to say that I visited surgeries of Ciba customers in North London together with a gentleman who was not an employee of the company. At no time in the past have I been advised that such activity was contrary to company policy. At no time have I ever offered financial inducements to doctors. At no time have I contravened the ABPI Code of Practice".
The representative had been dismissed for gross misconduct. Ciba submitted a number of internal documents relating to the Code of Practice, including a mail message to Region 8 teams issued prior to the event in question which stated "Do not agree to take non Ciba-Geigy employees out with you for the day without company approval". The company asserted that representatives had been instructed to adhere to the Code of Practice and that this had been reinforced at meetings earlier in the year.

Panel Ruling The Code of Practice Panel had noted that it was an established principle under the Code of Practice that companies had to take responsibility for the conduct of their representatives if they were acting within the scope of their employment, even if they were acting

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contrary to their instructions. In this case, it had been considered that the action of the representative had been within the scope of her employment as access to the doctors had been obtained by her by virtue of her role as a representative.

The Panel considered that the representative had not behaved in an ethical manner and it had been ruled that there had been a breach of Clause 15.2 of the Code. The Panel noted from the article in the News of the World that the doctors had been deceived into believing that the accompanying newspaper reporter was actually another medical representative. Facilitating such a deception was conduct such as to bring the industry into disrepute and it was ruled that there had also been a breach of Clause 2.

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

Appeal Ciba Pharmaceuticals appealed against the Code of Practice Panel's ruling of a breach of Clause 2 but accepted that it had been in breach of Clause 15.2.

Ciba accepted that its representative should not have allowed a newspaper reporter to accompany her during visits to doctors. It did, however, appeal against the ruling of a breach of Clause 2. The company believed that over many years it had created a culture in its organisation wherein adherence to the Code was paramount. To reinforce this point, Ciba enclosed copies of a number of internal memos to its field forces.

In the case under consideration, it took immediate action to investigate the article in the News of the World and then took immediate disciplinary action. Of its own volition it submitted its findings to the Code of Practice Authority. There was, the company suggested, a difference between the responsibility of a company and the responsibility of an individual employed by a company. A company might be found to be in breach of the Code if an individual member of staff or a group of staff were involved in, for example, erroneous detailing, lavish entertaining or providing financial incentives to prescribe the company's products, etc. Under these examples the company should have had a control mechanism to identify and prevent such events. In the case of its representative in this instance, the company submitted that it was and is impossible to have a control mechanism to prevent such an event.

A breach of Clause 2 now appeared to be a sign of particular censure and the company did not consider this censure to be appropriate to the present case as it was an isolated incident and the company took immediate disciplinary action. The company accepted that it was in breach of Clause 15.2 and, in so doing, it submitted that it had accepted responsibility for its representative.

Appeal Board ruling The Appeal Board noted that a company had to take responsibility for the actions of its representatives if they were acting in the course of their employment, even if they were not acting in accordance with their instructions. The Appeal Board noted that the company had accepted that it was in breach of Clause 15.2. Although the representative had gained access for the

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newspaper reporter by going in as a representative of Ciba Pharmaceuticals, it was not clear that this would be regarded as a method of promotion as covered by Clause 2 of the Code. The circumstances were considered to be so out of the ordinary that there was no way in which a company could protect itself against such behaviour. In view of these factors, the Appeal Board ruled that the company had not been in breach of Clause 2 of the Code and the appeal therefore succeeded.

Proceedings commenced **7 March 1994**

Case completed **10 May 1994**

CASE AUTH/125/3/94

MEDICAL PRESCRIBING ADVISER V MEMBER COMPANY

Journal Advertisement alleged to be inaccurate

Complaint A medical prescribing adviser submitted a complaint about a journal advertisement issued by a member company for one of its products. The advertisement was aimed at pharmacists.

The complainant alleged that the advertisement was misleading as it quoted an agreement about dispensing which did not apply in Scotland. The complainant alleged that, in the interest of accuracy, it should be made clear in the advertisement that the agreement did not relate to Scotland and had never done so.

Response The company submitted that it was most unlikely that a pharmacist in Scotland would be misled by the advertisement. The company had not received any such comment from Scottish community pharmacists despite having run the advertisement several times.

Ruling The Code of Practice Panel considered that it might have been helpful if the advertisement had referred to pharmacists in England and Wales but, in the context of the advertisement, did not accept that the absence of such a reference was misleading. The Panel therefore ruled no breach of the Code.

Complaint received **7 March 1994**

Case completed **13 April 1994**

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CASE AUTH/126/3/94

INDEPENDENT MEDICAL ADVISER V MEMBER COMPANY

Cost comparison chart

Complaint An independent medical adviser to a family health services authority submitted a complaint about cost comparison chart issued by a member company for one of its products.

The complainant drew attention to the price of a competitor product given in the bar chart and the statement printed immediately below which indicated that the price was based on one day's treatment with branded product. The complainant alleged that the information was correct but the impression was totally misleading.

Response The company pointed out that the statement was easy to read and appeared so close to the relevant data that it could not be missed or misunderstood. The company had, however, decided to withdraw the material.

Panel Ruling The Panel noted that Clause 7.10 of the Code prevented the brand names of other companies' products being used unless the prior consent of the proprietors had been obtained. Companies were therefore usually obliged to refer to competitors' branded products by non-proprietary names.

The Panel noted that the chart was a comparison of the cost of one day's treatment with branded products. The Panel did not consider that the chart was misleading as alleged and therefore ruled no breach of the Code.

Complaint received **8 March 1994**

Case completed **25 April 1994**

CASE AUTH/127/3/94

INDEPENDENT MEDICAL ADVISER V MEMBER COMPANY

Journal advertisement alleged to be misleading

Complaint An independent medical adviser to a family health service authority complained about a journal advertisement issue by a member company.

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The complainant stated that the advertisement was one of a series which suggested that a general practitioner would be less than kind if he did not treat a particular condition with the product named. The complainant pointed out that the prescribing information in the advertisement did not give the condition as an indication for the product.

Response The company submitted that the wording of the advertisement had been carefully chosen in relation to the use of the product. The company pointed out that the prescribing information given in the advertisement clearly stated that one should "Refer to the data sheet before prescribing" and the data sheet stated quite clearly that the product was licensed for treating the particular condition.

Ruling The Code of Practice Panel noted that the data sheet for the product did state that it was indicated for the particular condition. The Panel also noted that the prescribing information advised consulting the data sheet before prescribing and gave a general indication for use. The Panel noted that Clause 4.2 of the Code required that the prescribing information include at least one indication for use consistent with the data sheet.

The Panel did not consider that the allegation which had been made was justified and therefore ruled no breach of the Code.

Complaint received **8 March 1994**

Case completed **11 April 1994**

CASE AUTH/128/3/94

NYCOMED (UK) LIMITED V MALLINCKRODT MEDICAL (UK) LTD

Advertisement for Optiray

Complaint Nycomed (UK) Limited complained about a journal advertisement for Optiray issued by Mallinckrodt Medical (UK) Ltd which appeared in the 20 January 1994 issue of Radmagazine. Neither company was in membership of the ABPI. Nycomed alleged that the advertisement exceeded two pages and was therefore in breach of Clause 6.1 of the Code.

Response Mallinckrodt Medical (UK) Ltd submitted that it had met the requirements of The Medicines (Advertising to Medical and Dental Practitioners) Regulations 1978 (SI 1978 No. 1020) in respect to multi-page advertisements and the statutory instrument had to be the binding authority.

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Ruling The Code of Practice Panel noted that the advertisement consisted of four pages and appeared as the centre spread in the magazine. Although the advertisement did not contravene the Regulations, Clause 6.1 of the Code required that no single advertisement included in a journal might consist of more than two consecutive pages. This was an instance where the Code requirements went beyond the legal requirements. The Panel therefore ruled a breach of Clause 6.1 of the Code.

Complaint received **9 March 1994**

Case completed **13 April 1994**

CASE AUTH/129/3/94

SENIOR EXECUTIVE IN A REGIONAL HEALTH AUTHORITY V MEMBER COMPANY

Alleged promotion prior to the grant of a licence

Complaint A senior executive at a regional health authority submitted a complaint regarding the promotion of a product by a member company.

The complainant had been advised by a pharmaceutical officer at a hospital that one of the pharmacists in the pharmacy department had telephoned the medical information department of the company requesting information from a product's data sheet. The pharmacist was informed that there was no data sheet available and told to call back a few days later when somebody would be able to answer the query. The pharmacist subsequently received a literature search on the product in the post. The pharmacist also stated that on a day prior to Christmas, a clinical development manager called to see one of the hospital doctors about the product and the clinical development manager had told the pharmacist that the product had received its licence that afternoon. The pharmacist had telephoned the company in the morning and had been told that the licence was not through yet.

It was alleged that the activity appeared to be either promotion of an unlicensed product or failure to supply a data sheet for a licensed product.

Response The company stated that it had received a licence in November 1993. The company submitted that it was not promoting the product without a product licence. The product was launched in the UK in February 1994. The data sheet was available to pharmacists and clinicians on the day after launch. Unfortunately this was unknown to the member of the medical information department who received the call from the hospital.

The company had checked its record concerning contact with the hospital and the company had been asked by the doctor to discuss the product with the pharmacy. On two occasions a summary of product characteristics had been sent to members of the pharmacy department.

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Ruling The Panel noted that the product had received its licence in November 1993. The Panel noted that the pharmacist had telephoned the medical information department in February 1994 and had been informed that there was no data sheet available. The Panel was concerned that the medical information department had not adequately dealt with the query from the pharmacist. The Panel considered, however, that the company's activities in the period referred to in the complaint did not constitute promotion prior to the grant of a product licence and therefore ruled no breach of the Code in that regard.

The Panel considered that it was not clear whether the product had been promoted in the time between the company receiving the licence and launching the product. It noted that the Medicines Act 1968 required that data sheets be provided to doctors prior to promoting a product. The Panel noted that a summary of product characteristics had been supplied on two occasions to the pharmacy department but UK law still required that a data sheet was supplied. The Panel noted that there was some confusion regarding summaries of product characteristics but that at the present time products still required a data sheet irrespective of whether or not the product had a summary of product characteristics. In any case this was not a matter covered by the Code but requested that its concerns be drawn to the attention of the company.

Complaint received **11 March 1994**

Case completed **14 April 1994**

CASE AUTH/131/3/94

PHARMACY SERVICES MANAGER V MEMBER COMPANY

Supply of medicines on a named patient basis

Complaint A pharmacy services manager submitted a complaint regarding the supply of a product to the hospital by a member company.

The complainant drew attention to Clause 18.6 of the Code stating that it said that distribution of supplies in hospitals should comply with individual hospital regulations, if any, and pointed out that the hospital did have a policy and it was not unreasonable to expect the company to have sought details of it. The complainant pointed out that the product was apparently ordered verbally by a consultant and dispatched to the hospital addressed to the pharmacist. In retrospect, his staff should have returned the goods as unsolicited goods and in future would do so unless the medicines had been ordered via an auditable system. The complainant also pointed out that the hospital had a policy on the use of unlicensed medicines and the company's method of supply prevented it from complying with its policy. The complainant accepted that the hospital was at fault because a consultant had ordered the medicines with no authority to do so. The complainant alleged that the company was also at fault because it had not complied with the Code. In addition it was good practice not to dispatch medicines without a written order.

The company was advised that the reference to Clause 18.6 of the Code referred to the second

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revision of the Seventh Edition of the Code. The current edition, the Eighth Edition, dealt with samples in Clause 17 and the former Clause, 18.6 was now Clause 17.9.

It was pointed out to the complainant that the Clause to which he referred was now Clause 17.9 and related to the distribution of samples and not the distribution of supplies as stated in the letter of complaint.

Response The company pointed out that all supplies of the product were undertaken in accordance with the Statutory Instrument 1984 No. 673 The Medicines (Exemption from Licences) (Importation) Order 1984. The product was not licensed in the UK and was only made available to consultants and general practitioners on a named patient basis. The company submitted that Clause 17 of the Code which referred to samples did not therefore apply. The company had received a written and signed request for the product from the consultant who had completed the company's form. As a result the product was dispatched to the hospital pharmacy under the cover of an appropriate letter. The consultant was also sent written confirmation of its dispatch. Copies of the letters were provided.

The company submitted that the product was not a sample as Clause 17.4 of the Code stated that a sample of a medicine must be no larger than the smallest presentation of the medicine on the market. As the product was not on the market in the UK the company submitted that it could not be provided as a sample. The company stated that the Code only covered products that were licensed in the UK. The company submitted that since receiving the complaint it had decided to revise two aspects of its named patient supply forms to avoid the situation arising again.

Ruling The Code of Practice Panel first noted that the company was incorrect to assume that the Code only covered products that were licensed in the UK as, for example, it was a breach of the Code to promote an unlicensed product.

The Panel considered that it might be permissible in certain circumstances to provide samples of medicines available only on a named patient supply basis. The Panel considered, however, that in this instance the product had been supplied as free goods as the purpose had been for treatment rather than for a health professional to familiarise himself with the product and acquire experience in dealing with it. They did not therefore come within the definition of a sample as given in the supplementary information to Clause 17 of the Code. The Panel therefore ruled no breach of the Code.

Complaint received **16 March 1994**

Case completed **19 April 1994**

CASE AUTH/132/3/94

DOCTOR V MEMBER COMPANY

Magazine supplement on a product

Complaint A doctor submitted a complaint concerning an eight page supplement which had been included with an issue of a medical journal. The supplement was described as being

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supported through an educational grant from a member company. The complainant alleged that the supplement was almost entirely about the product and was a blatant example of disguised promotion. It pretended to be "educational" but was completely unbalanced

Response The company submitted that the item's front cover clearly demonstrated the product name and including prescribing information and a product profile within the document could not in any way be considered as disguising its promotional nature. It appeared appropriate to publish the current views of a specialist and a GP who had considerable experience of using the product, with the intention of updating readers. The company believed the supplement to be a well balanced piece promoting current thinking regarding the use of the product which was not disguised in any way.

Panel Ruling The Code of Practice Panel noted that the item had appeared as a loose insert in a journal. It noted that the company did not dispute that the item was promotional in nature. The Panel noted that the supplement was primarily a report of the experiences of two individuals. While it was not surprising that the articles were well disposed to the product they presented both positive and negative points. The Panel did not find that the supplement was completely unbalanced as alleged. The Panel therefore ruled that there had been no breach of the Code.

The Panel was concerned that the supplement stated that it was supported through an educational grant and considered that this was not accurate as the supplement was promotional. The Panel considered that the company could have made it clearer that the item was promotional but did not accept that the supplement was a form of disguised promotion. It therefore ruled no breach of Clause 10.1 of the Code.

Complaint received **16 March 1994**

Case completed **5 May 1994**

CASE AUTH/133/3/94

PFIZER LIMITED V LEDERLE LABORATORIES

Suprax cost comparison chart

Complaint Pfizer Limited submitted a complaint about a dosage card for Suprax (Ref SUP137) issued by Lederle Laboratories.

Pfizer drew attention to a bar chart headed "Cost effective prescribing" which compared daily costs of Suprax with a number of other antibiotics including Pfizer's product Zithromax (azithromycin). The cost of Suprax 200mg once a day was given as £1.37 and the cost of azithromycin 500mg daily was given as £4.48.

Pfizer pointed out that the data sheet recommended dose for Suprax was a 7-14 day course at 200 or

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400mg a day according to the severity of the infection. By comparison the only recommended dose of Zithromax for all licensed adult infections was 500mg daily for three days. Using the prices given a course of Suprax at 200mg would therefore cost between £9.59 and £19.18 whereas the recommended dose of Zithromax would cost £13.43. Furthermore, a course of Suprax at 400mg would cost between £19.18 and £38.36 again compared to £13.43 for the recommended dose of Zithromax. Pfizer alleged that by giving a daily cost with no indication of dose or duration of dosing, the material was misleading in breach of Clause 7.2 of the Code.

Response Lederle Laboratories stated that it intended to withdraw the material within the next two weeks. The medical departments of Lederle and Pfizer had been in recent correspondence about the matter. A letter from Pfizer to Lederle, asking that the matter be concluded arrived while the chief executive of Lederle was in America and the matter had been referred by Pfizer to the Authority before the chief executive had had an opportunity to respond.

Panel Ruling The Panel noted that subsequent to receiving the response from Lederle, which had been copied to Pfizer, Pfizer had informed the Authority that it would like to withdraw its complaint. Withdrawal at that late stage was not possible under the established procedure.

The Panel noted that the chart was headed "Cost effective prescribing" and listed the daily cost of a number of antibiotics. It noted that no account had been made of the different dosing schedules for the antibiotics. In this regard the Panel noted that the most expensive antibiotic listed on the chart was azythromicin at £4.48 per day. The Panel noted that a course of azythromycin lasted three days and was the same for all indications whereas the usual course of Suprax was for 7-14 days at 200mg per day or in severe or complicated infections at 400mg per day. It was thus misleading to compare daily costs as no account of the different indications or duration of dosing had been made.

The Panel considered that the chart was misleading as alleged and ruled a breach of Clause 7.2 of the Code.

Complaint received **17 March 1994**

Case completed **18 April 1994**

CASE AUTH/134/3/94

HOSPICE MEDICAL DIRECTOR V MEMBER COMPANY

Journal on care

Complaint A medical director of a hospice wrote to express his disquiet regarding a journal which he understood had been distributed widely to general practitioners. It appeared to

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have been produced by a pharmaceutical company and was supposedly a non-promotional journal on an area of medicine. He could find no evidence that it had an unbiased editorial board and found some of the content to be blatantly promotional.

Response The company concerned stated that it had commissioned the journal. The intention was to raise legitimately the profile of the company in the arena and provide specialists with a readable and up to date journal emphasising the "team work" nature in the particular area of medicine. The journal was produced by a third party from articles commissioned by them thought to be of interest in the area. All the articles were approved by the authors prior to publication. In order to assure itself, the company had requested that the journal was reviewed through its copy approval process to ensure that it was not promotional and therefore complied with the Code.

The journal was distributed to health care professionals in the area and was not distributed widely to general practice, only to 285 GPs known to have a specialist interest in the area. The company submitted that the articles were well balanced and represented a fair view.

The company submitted that as the item was not promotional, no prescribing information was included. There was no mention of a brand name in the journal.

Panel Ruling The Panel examined the journal and noted that the articles covered a selection of topics presented in a low key fashion. There was no mention of products by brand name although it did refer to products by generic name. It further noted that the journal did include a short section on future developments. The Panel did not consider that the journal was promotional and therefore decided that it did not come within the scope of the Code.

Complaint received **17 March 1994**

Case completed **5 May 1994**

CASE AUTH/135/3/94

GENERAL PRACTITIONER V MEMBER COMPANY

Use of a plain envelope

Complaint A general practitioner complained about a plain envelope used by a member company to send a mailing about one of its products. The complainant alleged that this was in breach of Clause 7.5 of the Code (First Revision of the Seventh Edition). The complainant was irritated to be approached in this manner.

The company concerned was advised that the appropriate clause in the Eighth Edition of the Code of 1 January 1993, was Clause 10.1, the equivalent provision to Clause 7.5 of the old Code.

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Response The company concerned denied any breach of the Code and pointed out that under the Eighth Edition, the use of plain envelopes was permitted, although it was not permitted to address envelopes in such a way as to disguise them as personal communication.

The mailing in question was a plain, standard envelope with the doctor's address on a computer generated label provided by a mailing company. The company submitted that it was certain that the mailing was not disguised as there was absolutely no attempt to pretend that it was a personal letter.

Ruling The Code of Practice Panel noted that under the previous edition of the Code there was reference in the supplementary information to Clause 7.5 on disguised promotional material to doctors resenting promotional material being sent in the guise of personal communication such as when advertisements were enclosed in plain envelopes or addressed in real or facsimile handwriting on letters or postcards. Under the Eighth Edition of the Code, while the prohibition on disguised promotional material remained, the supplementary information had been reworded to delete the reference to the use of plain envelopes. Thus it was now permitted to use a plain envelope to send promotional material, provided that it was not disguised as a personal communication.

The Panel did not consider that the mailing was disguised as a personal communication. It was sent in an envelope with a typewritten address with a second class stamp. The Panel did not consider that the envelope was disguised in any way and therefore ruled no breach of the Code.

Complaint received **21 March 1994**

Case completed **14 April 1994**

CASE AUTH/137/3/94

SYNTEX PHARMACEUTICALS LIMITED V NYCOMED (UK) LTD

Promotion of Nycopren

Syntex Pharmaceuticals Limited submitted a complaint about a detail aid and a dosage card for Nycopren issued by Nycomed (UK) Ltd.

Nycomed (UK) Limited, although not a member of the ABPI, had agreed to comply with the Code. There were four allegations which were considered as follows:

Juxtaposition of product name and date

Complaint Syntex pointed out that the detail aid's front page showed a Nycopren figure standing on a plinth on which were the dates 1973-1994. The company alleged that the juxtapositioning of the name Nycopren and the dates implied that the product had been available on the UK market for that period of time which was incorrect in breach of Clause 7.2 of the Code.

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Response Nycomed refuted the allegation that there had been any attempt to imply that Nycopren had been on the market since 1973. The whole purpose of the front page and the top half of page 2 of the detail aid was to reinforce the obvious benefits of naproxen, that it had truly stood the test of time. The company submitted that its reference made this clear. It had questioned its salesforce and was satisfied that no misrepresentation had been perpetrated by them and no misunderstandings had arisen with their discussions with medical practitioners. There was no advantage whatsoever to Nycomed to infer that Nycopren had been available for 21 years. There was reference to the true age of the product both in the detail aid and in a brochure entitled "20 things you didn't know about Nycomed". This document had also been supplied by the company.

Panel Ruling The Panel examined the front page of the detail aid which depicted the Nycopren figure standing on a plinth on which were the dates 1973-1994. The Panel did not consider that it was clear that the dates referred to naproxen rather than Nycopren. The qualification that "Naproxen has been available since 1973 and its satisfactory benefit to side-effect ratio has been repeatedly demonstrated" which also appeared on the page in question was not considered to be enough to explain that the dates referred to naproxen and not to Nycopren. The implication was that Nycopren had been available since 1973 which was misleading as the product was developed and registered in 1985. The Panel therefore ruled a breach of Clause 7.2 of the Code.

"Up to 47% less damage to the gastric mucosa than plain naproxen"

Complaint Syntex complained about the claim which appeared in the detail aid and on the dosage card referenced to a study in which enteric-coated naproxen was administered to twelve healthy subjects for seven days. The company alleged that this was not representative of normal clinical practice and, as the conditions of the study were not stated, the claim was misleading in breach of Clause 7.2 of the Code.

Response Nycomed submitted that it was quite normal in this type of study, using healthy volunteers, to have this number of patients and duration of therapy. The company enclosed another paper which endorsed the referenced study's findings. Two other references quoted in the detail aid supported the benefits of enteric coated over plain naproxen and so the company did not believe the reference in question was misleading.

Panel Ruling The Panel noted that the supplementary information to Clause 7.2 of the Code stated that when referring to studies in healthy volunteers care should be taken so as not to mislead as to the significance of such data. Further, the extrapolation of such data to the clinical situation should only be made where there was data to show that it is of direct relevance and significance.

The Panel noted that the referenced study was in twelve healthy subjects before and after seven days treatment and this had not been made clear. There was no clinical data to support the claim. The Panel decided that the claim was misleading and therefore ruled a breach of Clause 7.2 of the Code.

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"If you really want to spend, spend, spend, try the most widely prescribed naproxen ec"

Complaint Syntex alleged that the statement in the detail aid clearly referred to Naprosyn EC since it was the only other enteric coated naproxen on the UK market. Syntex alleged that the statement was disparaging in breach of Clause 8.1 of the Code.

Response Nycomed submitted that the statement was based on a factual price comparison and was not intended to be disparaging. In view of the current government efforts to exert downward pressure on costs, the company submitted that it was reflecting this in its literature.

Panel Ruling The Panel noted that the statement "If you really want to spend, spend, spend, try the most widely prescribed naproxen ec" appeared immediately underneath the headline "Nycopren. save, save, save!" The Panel noted that Nycopren cost less than the Syntex product and the facts did not appear to be in dispute. Although the Panel had reservations about how the point had been phrased, it did not consider that the statement was disparaging and therefore ruled that there had been no breach of the Code.

"Nycopren. Tops with patients"

Complaint Syntex alleged that "tops" used in the claim "Nycopren. Tops with patients" was a superlative which had not been qualified or substantiated. The company alleged breaches of Clauses 7.3 and 7.8 of the Code.

Response Nycomed submitted that the claim was intended as a play on words to promote the company's "Rheuma" containers which were designed as easy to open containers for rheumatic patients. The "tops" literally referred to the bottle top which was illustrated by the Nycopren character lifting his "top". There was no deeper meaning intended.

Panel Ruling The Panel did not accept that "tops" was a superlative as alleged and therefore ruled no breach of Clause 7.8 of the Code. The Panel considered that the claim "Nycopren. Tops with patients" was probably intended to be a play on words relating to the container. It considered however that the claim implied that patients preferred Nycopren and noted that Nycomed had not provided any substantiation regarding patient preference for the product. The Panel therefore ruled a breach of Clause 7.3 of the Code.

Complaint received **24 March 1994**

Case completed **5 May 1994**

CASE AUTH/139/3/94

CONSULTANT PHYSICIAN V BRISTOL MYERS SQUIBB

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Conduct of a Representative

Complaint A consultant physician submitted a complaint about a letter sent to him by a teaching hospital representative of Bristol-Myers Squibb Pharmaceuticals Limited. The complainant alleged that the letter was an implied criticism of medical practice in the hospital and also implied that patients might be better being referred to an alternative hospital.

The letter in question thanked the complainant for seeing her regarding the results of the SAVE study and stated that she was disappointed that the complainant was not prepared to revise post MI guidelines based on the findings of the trial. The letter went on to read:

> "I am sympathetic to your need to convince the Hospital authorities of the requirement for a Cardiologist. I am also sure they are appreciative of your diligence with the cardiological service up to now, including raising funds for an echo machine. To have gone so far, and then to stop at the brink of such positive evidence on significant reductions in mortality, recurrent myocardial infarction, hospitalisation for heart failure etc, leads me to request that you reconsider our discussion and your declared intention. I would also expect local GP's to understand your intended actions, but they may well be forced to send more of their cardiology patients to *(another hospital)* and I don't think that will be the best outcome for them, you or your patients."

The complainant stated that the hospital had a written protocol for the management of patients in its coronary care unit, which had been agreed by all the physicians in the hospital. Management of myocardial infarction both in the acute situation and post-infarction had been the subject of several audits and the hospital had a consensus and an agreed stance. Furthermore, the cardiac policies were well known to the purchasers and there had never been a hint of criticism of the management policies. None of the management policies were in any way radical or unusual, they conformed to consensus statements as detailed in the medical journals. The complainant was therefore surprised that the representative should state in writing her disapproval of the management policies with the implication that patients would be safer if treated elsewhere.

The complainant had no was of knowing what the particular representative had been saying to general practitioners whom she visited but would have grave concerns if he was to hear that she was expressing her reservations to general practice colleagues.

Response Bristol-Myers Squibb stated that the representative concerned was a senior representative within the company and had operated to a very high standard during the eleven years that she had been with the company. She was an enthusiastic and conscientious employee and the company submitted that it was her over-enthusiasm for the SAVE study that led her to write to the complainant. The representative had clipped a business card to a blank sheet of paper. The letter was not on office headed paper and it was understood that it had neither been seen nor approved by the regional manager. This was not in accordance with the standard procedures and was not representative of the company's view of the matter. The representative had subsequently been reprimanded.

The company accepted that the letter was totally inappropriate. It did not believe, however, that the representative meant to be contemptuous or disparaging to the complainant although the wording

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could be interpreted as such. Because of this potential inference, the company had written to the complainant to apologise and to assure him that this was certainly not the company's view. The representative had been clearly debriefed and the potential interpretation explained to her.

Ruling The Panel considered that the letter clearly disparaged the clinical and scientific opinions of the complainant. The Panel therefore ruled a breach of Clause 8.2 of the Code. The Panel did not accept that the representative had maintained a high standard of ethical conduct as the letter was clearly inappropriate. The Panel therefore ruled a breach of Clause 15.2 of the Code.

Complaint received **30 March 1994**

Case completed **10 May 1994**

CASE AUTH/143/4/94

B BRAUN MEDICAL LTD V ANTIGEN PHARMACEUTICALS (UK)

Journal advertisement for Lignocaine

Complaint B Braun Medical Ltd submitted a complaint about an advertisement for lignocaine issued by Antigen Pharmaceuticals (UK), published in Today's Anaesthetist (January/February and March/April Editions).

B Braun alleged that the surface area of the advertisement at 623.7 square centimetres was larger than the required size of 420 square centimetres allowed for abbreviated advertisements. The complainant alleged a breach of Clause 5.3 of the Code.

Response Antigen had not previously agreed to comply with the Code. The company acknowledged that the size of the advertisement was in breach of the Code.

The company explained that the advertisement was a stop-gap insertion within a space which it had been committed to fill and was an adaptation of a smaller advertisement which had previously appeared. In increasing the size for the space available, a change of requirement to full prescribing information was overlooked. The company had withdrawn the advertisement from further publication and undertook to ensure that this would not happen again.

Ruling The Panel noted that the advertisement was larger than the size of 420 square centimetres allowed for an abbreviated advertisement. The Panel therefore ruled a breach of Clause 5.3 of the Code.

Complaint received **8 April 1994**

Case completed **26 April 1994**

CODE OF PRACTICE FOR THE PHARMACEUTICAL INDUSTRY

NUMBER		SUBJECT	BREACH
86	General Practitioner v Member Company	PMS study	NoB (A)
98	Doctor v Leo	Article in lay media	20.2 (A)
102	General Practitioner v Procter & Gamble	Symposium newsletter	4.6, 10.1
103	Consultant Paediatrician v Member Company	Leavepiece and telephone card	NoB
104	General Practitioner v Lorex	Conduct of a representative	4.1
105	General Practitioner v SmithKline Beecham	Various promotional materials	7.2 (A) (A)
106 107 108 109 110 114	General Practitioner) Consultant Psychiatrist) Consultant Physician) v Lederle General Practitioner) General Practitioner) General Practitioner)	Use of a device in a mailing	9.1
111	Consultant Paediatrician v Member Company	Mailing	NoB
112	Consultant Physician v Member Company	Various promotional items	No B
113	Medical Prescribing Adviser v Member Company	Survey and leaflet	NoB

KEY

(A) = Appeal

(A) (A) = Appeals from both the complainant and the respondent

CODE OF PRACTICE FOR THE PHARMACEUTICAL INDUSTRY

115	General Practitioner v Member Company	Product helpline	NoB
118	General Practitioner v Member Company	Round table discussion	NoB
119	FHSA Clinical Director v Member Company	Journal Advertisement	NoB
121	General Practitioner v Rhône-Poulenc Rorer	Sponsored publication	4.1
122	General Practitioner v 3M Healthcare	Conduct of a representative	15.4
123 130	Leo) v Dermal University Lecturer)	Leaflet	7.2
124	Director v Ciba	Conduct of a representative	15.2 (A)
125	Medical Prescribing Adviser v Member Company	Journal advertisement	NoB
126	Independent Medical Adviser v Member Company	Cost comparison chart	NoB
127	Independent Medical Adviser v Member Company	Journal advertisement	NoB
128	Nycomed v Mallinckrodt	Journal advertisement	6.1
129	Pharmacist in a Regional Health Authority v Member Company	Alleged promotion prior to licence	NoB
131	Pharmacy Services Manager v Member Company	Supply of a product	NoB
132	Doctor v Member Company	Journal supplement	NoB
133	Pfizer v Lederle	Cost comparison chart	7.2

KEY

(A) = Appeal

134	Hospice Medical Director v Member Company	Journal on care	NoB
135	General Practitioner v Member Company	Use of a plain envelope	NoB
137	Syntex v Nycomed	Detail aid and dosage card	7.2, 7.3
139	Consultant Physician v Bristol-Myers Squibb	Conduct of a representative	8.2, 15.2
143	B Braun v Antigen	Journal advertisement	5.3