PRESCRIPTION MEDICINES
CODE OF PRACTICE AUTHORITY

CODE OF PRACTICE REVIEW

NUMBER 10

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

Amendments to the Code of Practice and the Constitution and Procedure agreed

At the Half-Yearly General Meeting of The Association of the British Pharmaceutical Industry (ABPI) in October, changes were agreed to both the Code of Practice for the Pharmaceutical Industry and the Constitution and Procedure for the Prescription Medicines Code of Practice Authority.

The changes arise from a review carried out by a Working Party established by the ABPI Board of Management at the end of 1994 which was followed by consultation with ABPI member companies and those companies which while not members of the ABPI have nonetheless agreed to comply with the Code and accept the jurisdiction of the Authority. The British Medical Association, the Medicines Control Agency and the Royal Pharmaceutical Society of Great Britain were also consulted as were the Code of Practice Appeal Board and the Code of Practice Authority itself.

Details of the changes have been sent to companies and it is anticipated that copies of the revised Code will be available ahead of the changes coming into force on 1 January 1996.

Data sheets and summaries of product characteristics

The Medicines Act 1968 (Amendment) Regulations 1995 (SI 1995 No 2321) came into operation on 29 September 1995. Copies are available from branches of HMSO, price £0.65.

The provisions as to data sheets in the Medicines Act 1968 will no longer apply in respect of those products which are required to have a summary of product characteristics (SPC).

Two systems will thus run in parallel until all products have an SPC. For those products which do not have an SPC, the current requirements as to data sheets will continue to apply and data sheets will continue to have to be provided to doctors at intervals of not less than fifteen months in relation to those products which are being promoted.

These requirements will not apply to products which are required to have an SPC. SPCs do not have to be sent out prior to promotion but have to be made available in certain circumstances, for example when samples are given to doctors. Medical representatives must provide a copy of the SPC or have one available when they promote to doctors.

When there is an SPC, this is the prime document to which all promotional material must conform.

New Deputy Secretary Appointed

As reported in the August review, Karen Falkner retired from the Authority in July. In her place as Secretary to the Authority, the ABPI Board of Management appointed Heather Simmonds who was previously Deputy Secretary.

The ABPI Board has now appointed Jane Landles to be the new Deputy Secretary to the Authority. Jane is currently a Medical Information Officer and a nominated Code of Practice signatory with Zeneca Pharma. Jane will join the Authority at the beginning of 1996 and the Authority looks forward to the useful contribution to its work which it believes she will make.

"Good Medical Practice"

"Good medical practice" recently published by the General Medical Council as part of a set of four guidance booklets jointly entitled "Duties of a doctor" includes items relevant to the relationship between doctors and the pharmaceutical industry.

Under the heading "Accepting gifts or other inducements", the guidance says "You should not ask for or accept any material rewards, except those of insignificant value, from companies that sell or market drugs or appliances. You must not ask for or accept fees for agreeing to meet sales representatives".

Under the heading "Hospitality", "You may accept personal travel grants and hospitality from companies for conferences or educational meetings, as long as the main purpose of the event is educational. The amount you receive must not be more than you would normally spend if you were paying for yourself".

Copies can be obtained from the General Medical Council at 178-202 Great Portland Street, London W1N 6JE (0171-580 7642).

Substantiation of claims

Clause 7.4 of the Code states that "Substantiation for any information, claim or comparison must be provided without delay at the request of members of the health professions or appropriate administrative staff."

Instances have arisen where companies have said that they could not substantiate claims because of copyright problems in relation to the material which would be necessary to substantiate a claim.

This is not an acceptable defence to an allegation of a breach of Clause 7.4. Companies must be able to substantiate claims and if they are not prepared to do so, or are unable to do so for any reason whatsoever, such claims cannot be made.

Maps as promotional aids

While the provision of a detailed local map to a general practitioner might be an acceptable gift under Clause 18.2 as being relevant to the doctor's practice, the same cannot be said for the provision of large scale atlases. These are not relevant to the practice of medicine or pharmacy and should not be given as promotional aids.

White or pale coloured print on a black or dark background.

Problems of legibility are arising in relation to prescribing information when it is in white or pale coloured print against a dark background. It is noticeable that legibility in the same advertisement can differ as between one publication and another. Dark print on a light background is preferable but, if light out of dark is used, then companies should note that it may be necessary to use a larger size of type than would otherwise be the case in order to achieve satisfactory legibility.

Information in Abbreviated Advertisements

Companies are reminded that abbreviated advertisements are restricted in content as set out in Clauses 5.4 and 5.5 of the Code and that the following information should not be included.

- product licence numbers
- references
- dosage particulars
- details of pack sizes
- cost
- quantitative particulars unless the quantitative information forms part of the licensed name of the medicine.

As indicated in the supplementary information to the Code, there may be exceptions to the above if the information provided, for example the cost of the medicine or the frequency of its dosage or its availability as a patient pack, is given as the reason why the medicine is recommended for the indication or indications referred to in the advertisement. They should not, however, otherwise be included.

Scrutiny of abbreviated advertisements by the Authority, particularly in recent issues of MIMS, shows that many contain product strengths and the like which are not acceptable. Please check your abbreviated advertisements carefully and amend as necessary. The Authority will shortly be commencing to take unacceptable advertisements up with the companies concerned.

CODE OF PRACTICE TRAINING

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

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

Forthcoming Code of Practice seminar dates are:

Friday, 12 January 1996
Wednesday, 14 February 1996
Friday, 8 March 1996

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

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

CASES AUTH/270/2/95, AUTH/285/4/95 & AUTH/286/4/95

GENERAL PRACTITIONER/SMITHKLINE BEECHAM v WELLCOME

Promotion of Zovirax and video on Valtrex

SmithKline Beecham complained about presentations at meetings on antivirals sponsored by Wellcome and about a medical information department letter and a journal advertisement. It was alleged that the risk/benefit ratio was being distorted against famciclovir (SmithKline Beecham's product Famvir) and in favour of aciclovir (Wellcome's product Zovirax). Similar allegations were subsequently made by a general practitioner and by SmithKline Beecham in relation to a Wellcome video on antivirals.

The Panel ruled that the meetings, the medical information letter and the video were misleading and disparaging of Famvir as they implied there were potential toxicity problems associated with Famvir on the basis of theoretical considerations without any supporting animal or clinical data. The medical information letter was also ruled in breach as it was a promotional item and prescribing information had not been included. No breach was found in relation to the journal advertisement. The Panel's ruling that the meetings were in breach was upheld by the Appeal Board upon appeal by Wellcome.

Case AUTH/270/2/95

SmithKline Beecham Pharmaceuticals UK complained that a variety of The Wellcome Foundation Limited's promotional activities were resulting in the distortion of the risk/benefit ratio against famciclovir (SmithKline Beecham's antiviral Famvir) and in favour of aciclovir (Wellcome's product Zovirax). SmithKline Beecham alleged this was being achieved by the use of highly selective, unbalanced and inaccurate misinformation which strongly inferred that famciclovir was associated with significant toxic hazards. A series of regionally based meetings in the UK, a "Dear Doctor" letter issued by the Wellcome medical information department and a journal advertisement for Zovirax were the subject of complaint.

1 Wellcome sponsored meetings on antivirals

COMPLAINT

SmithKline Beecham referred to two letters it had received from general practitioners who had attended separate meetings on antivirals sponsored by Wellcome at which a hospital doctor had spoken. One letter, written by two general practitioners, stated that the information provided by the speaker was that famciclovir could be carcinogenic due to the fact that it was not an obligate chain terminator. This had greatly alarmed the doctors and caused them to stop prescribing Famvir. The doctors had requested clarification from SmithKline Beecham on the subject. The second letter, written by another general practitioner, gave a detailed account of a meeting attended which was largely concerned with the differences between aciclovir and penciclovir. The issues raised gave the doctor great cause for concern. Either the lecturer was wrong or SmithKline Beecham was promoting a potentially fatal drug.

SmithKline Beecham alleged that although the opinions expressed at the meetings might be the personal views of individual lecturers, Wellcome had condoned them by sponsorship and affiliation and had not seemed to regress spurious misrepresentation when aciclovir was compared to famciclovir.

SmithKline Beecham presented detailed information challenging the issues raised at the meetings sponsored by Wellcome and alleged breaches of Clauses 7.2 and 8.1.

RESPONSE

Wellcome submitted that the meetings to which SmithKline Beecham referred were not part of a regionally based meetings programme but were a small number of educational meetings held by an individual doctor. The meetings were generally initiated by Wellcome and were all Postgraduate Education Allowance (PGEA) approved. The speaker had put his own slides together for these meetings and did not seek any input into his presentation whatsoever from Wellcome. Wellcome's only involvement was its normal practice of providing sponsorship for local educational/postgraduate meetings.

Wellcome submitted that whilst it was not possible for it to comment on the exact content of the meetings as it was not the author, it considered there were numerous scientific inaccuracies and omissions in SmithKline Beecham's complaint with which it took issue. A detailed paper was submitted by Wellcome responding on a line by line basis to the points raised.

Wellcome explained that the speaker had been invited because of his high local reputation and his expertise in virology. Each meeting was attended by two or three representatives from Wellcome but no material was distributed by Wellcome within the meeting although an exhibition stand was placed outside the meeting containing data sheets and dosage cards etc.

The speaker concerned, who had been advised of the complaint by Wellcome, wrote direct to the Authority stating that he had been passed correspondence relating to two talks which he had given to two small groups of general practitioners. He was somewhat upset by the reaction that this had generated from SmithKline Beecham, implying that it was part of a preconceived strategy by Wellcome involving meetings all over the country and numerous speakers on the same theme. The aim of his talk was to introduce general practitioners to basic molecular biology. He had no support at all from Wellcome including advice, script and slides and he did not receive any payment or honorarium for the talks. He had not discussed the contents of his presentation with Wellcome either before or after the meeting. The views expressed were entirely his own and were not part of any

organised campaign on a national scale.

PANEL RULING

The Panel accepted that the speaker involved, as with any clinician, was entitled to hold his own opinions on an issue and to express them. The Panel considered that it would not be appropriate for companies in inviting speakers to meetings to control the content of the speakers' presentations. That would be only to the detriment of the value of industry sponsored educational meetings. It was not, however, possible for a company to completely disassociate itself from the contents of meetings which it sponsored especially where those meetings were initiated by the sponsoring company. It would be expected that a company in approaching a speaker to make a presentation at a meeting it sponsored or organised would be aware of the general views and opinions of the speaker and the likelihood that those views would be expressed in their presentation at the meeting. Otherwise, it was unlikely that the speaker would be so invited.

The Panel considered that if the contents of the speaker's presentation was unacceptable in terms of the requirements of the Code then Wellcome was responsible. In this regard, the Panel noted that the Code covered information about medicines and the sponsorship of scientific meetings which would include meetings such as in this case.

The Panel noted that although it had not been supplied with any direct evidence as to what had been said or presented at the meetings, neither the speaker nor Wellcome had refuted the detailed description of the issues covered at one of the meetings as outlined by the doctor who had written the second letter to SmithKline Beecham referred to above.

The Panel noted that two subsequent complaints had been received regarding a video on the history of antivirals produced by Wellcome in association with the promotion of Valtrex, the successor to Zovirax. The Panel considered that the issues raised in those complaints were essentially those raised by SmithKline Beecham in relation to the presentations at the meetings and the letter from Wellcome's medical information department discussed under 2 below. The ruling with regard to the Wellcome sponsored meetings was therefore considered in relation to those cases (AUTH/285/4/95 & AUTH/286/4/95) below.

2 Medical information department letter

COMPLAINT

SmithKline Beecham alleged that support for its concerns that Wellcome was attempting to discredit and disparage famciclovir also came from a standard Wellcome medical information department letter entitled "Safety of Zovirax (aciclovir) and other antiherpes nucleoside analogues" which it considered was unbalanced, misleading and disparaging of famciclovir in breach of Clauses 7.2 and 8.1. Detailed criticisms of the letter were submitted. SmithKline Beecham alleged that the whole approach in the letter was promotional and served to discredit and disparage Famvir and that with such promotional overtones the letter should have included prescribing information for Zovirax which it did not. A breach of Clause 4.1 was therefore also alleged.

RESPONSE

Wellcome explained that the letter was written by its medical information department and had been supplied only to individually named doctors or pharmacists who had specifically requested information on the safety of antiviral agents. Since the letter's preparation in March 1994, it had been sent to 11 health professionals in total. A detailed response to the individual allegations made by SmithKline Beecham was submitted. The company did not accept that the letter was promotional.

PANEL RULING

The Panel noted that replies made in response to individual enquiries from members of the health professions were outside the scope of the Code and that the medical information department letter in question was clearly intended to come within that exemption. A number of concerns about such letters had been aired in a number of cases last year and the Authority had commented in its October 1994 Review that the exemption allowed for such responses applied only to particular answers to particular questions. It was not an opportunity to provide wide ranging promotional information which was free from the requirements of the Code.

The particular example of the letter supplied by SmithKline Beecham had been sent to a retail pharmacist. No information had been supplied by either party as to the exact nature of the enquiry to which it was a response. It appeared from the information supplied by Wellcome that the letter was intended for anyone who raised any issues regarding safety of Zovirax and other antiherpes nucleoside analogues. The Panel expressed concern at certain statements in the letter which, far from being the presentation of factual evidence, were speculative in nature, these being:

"If ongoing work confirms these findings, [regarding penciclovir's inhibitory activity against the hepatitis B virus HBV and the method by which penciclovir becomes activated] it would suggest that penciclovir may not be as specific or selective in its action in comparison to aciclovir."

"Thus penciclovir and ganciclovir have the potential for incorporation into growing DNA, rather than causing chain termination".

Further, the Panel considered that the concluding paragraphs in the letter went beyond that which was appropriate in a medical information department letter unless it was in direct response to a specific question on these points, for which there was no evidence. The concluding paragraphs were:

"To date, only a relatively small number of patients have been exposed to famciclovir, the oral pro-drug of penciclovir. The long term effects of famciclovir treatment are not known. Extensive safety monitoring of famciclovir will have to be undertaken before its full safety profile can be evaluated and compared to that of aciclovir. The highly selective mode of action of Zovirax has led to an exceptional safety record in clinical practice (5).

To conclude, in choosing the most appropriate therapy, physicians need to seriously consider the risks of switching from a drug with demonstrated clinical efficacy in published placebo-controlled studies and a remarkable safety profile (aciclovir). It is important that antiviral agents are not assessed and categorised in the same way as antibacterial agents, and that each potential new agent, whether it be penciclovir, ganciclovir, sorivudine, 882C or FIAU, is judged on its own merits through extensive safety monitoring. As stated earlier, small changes in the molecular structure of nucleoside analogues can lead to significant changes in antiviral activity and safety profiles. There can be no class effects amongst antiherpes agents."

With regard to the latter paragraph, the Panel considered this constituted the promotion of Zovirax.

The Panel therefore considered that the letter as a whole was a promotional item and was thus not exempt from the Code. As the letter did not include prescribing information for Zovirax, the Panel ruled there was a breach of Clause 4.1. The Panel observed that medical information department letters sent in response to enquiries were not in themselves a suitable vehicle for promotion.

With regard to the detailed contents of the letter, the Panel again observed that the issues were covered in Cases AUTH/285/4/95 and AUTH/286/4/95 considered below.

3 Zovirax journal advertisement

COMPLAINT

SmithKline Beecham drew attention to a journal advertisement for Zovirax, which included the claim "Obligate chain terminator - terminates viral DNA chain with just one molecule" which was followed by the statement "No other antiviral agent currently available works in the same way as Zovirax". SmithKline Beecham alleged that these claims were clearly designed to lead the reader to conclude that the obligate chain terminator mechanism of action conferred clinical advantages with the product and this mode of action was in SmithKline Beecham's view of no clinical relevance. This was misleading in breach of Clause 7.2.

RESPONSE

Wellcome pointed out that the claim concerning obligate chain termination was one of three stab points in the advertisement listing key characteristics of Zovirax, which were all statements of fact. Wellcome pointed out that in an earlier complaint by SmithKline Beecham (Case AUTH/149/4/94) no breach had been ruled with regard to a reference to obligate chain termination in a journal advertisement for Zovirax. The advertisement now at issue simply stated that all antivirals were not the same and provided short statements which explained how Zovirax worked.

PANEL RULING

The Panel considered that the three points listed in the advertisement were factual statements about the product and that it was not unacceptable in itself to draw attention to these features. The Panel did not consider that the advertisement was misleading and ruled that there was no breach of the Code.

Cases AUTH/285/4/95 & AUTH/286/4/95

COMPLAINT

A general practitioner complained about a video "Antivirals: does the molecule matter?" shown by a medical representative from Wellcome at an educational meeting at his surgery. He and his colleagues were rather concerned because the video indicated that famciclovir was potentially toxic because of its mode of action, being structurally similar to other agents which the video explained as having serious toxicity. Should famciclovir have this same potential toxicity (as the video suggested) then the complainant could not believe it would have been allowed on the market. He felt that the video must have misled him.

SmithKline Beecham had also written subsequent to its complaint in Case AUTH/270/2/95 above, complaining about the same video which it considered was part of Wellcome's strategy to link the molecular structure of famciclovir to other more toxic nucleoside analogues with strong inferences that non obligate chain terminators such as famciclovir were inherently unsafe and might pose significant toxic hazards to patients because of their mode of action. SmithKline Beecham believed that the audience viewing the video would be led to believe that compounds which worked as non obligate chain terminators (such as famciclovir) were risky treatments which interfered with human DNA unlike compounds with an obligate chain terminator mode of action such as aciclovir. SmithKline Beecham alleged that these claims and inferences were based on no clinical or preclinical evidence and could not be substantiated.

RESPONSE

Wellcome submitted that the video was intended to be informative and factual. It explained in detail the background to antiviral drugs development, describing the difficulties encountered in designing effective antivirals which were not toxic to host cells, and ending with a description of the most recently licensed antiviral, Wellcome's product Valtrex (valaciclovir). The video looked at a number of antiherpes compounds (ganciclovir, sorivudine, fialuridine and 882C) which had all shown toxicity at various stages of their development. The exact mechanism or mechanisms for their toxicity were not known; however, possible reasons put forward in the video were non obligate chain termination, activation in uninfected cells, and slow rates of clearance.

In order to explain why certain characteristics of antiviral molecular structure and modes of action were important, Wellcome provided detailed background information. The company submitted that most molecular and clinical virologists would agree that three of the key desirable characteristics of an antiviral (particularly an antiherpes drug) were selective activation in virus infected cells, specificity for viral, but not host cell, DNA polymerase and obligate chain termination.

Wellcome pointed out that the issue of obligate chain

termination had previously been considered in relation to a Zovirax journal advertisement (Case AUTH/149/4/94). No breach had been ruled on the point in that case.

Wellcome said that progress in the development of new antiviral drugs had been hindered by the fact that minor changes in the molecular structure could dramatically alter the safety and efficacy profile of the molecule. In other words, there was no "class effect" with antiviral drugs. Each new molecule must undergo thorough, individual, evaluation. The importance of this was illustrated by the examples of ganciclovir (associated with marked toxicity), FIAU (fialuridine) (the clinical trial programme for which was terminated following a number of fatalities), 882C for which the research programme was terminated by Wellcome following unexplained toxicity in chronic dosing animal studies and sorivudine (BVaraU) and HPMPC which had demonstrated toxicities at certain stages in their development. Famciclovir, 882C, sorivudine (BVaraU) and HPMPC were all non obligate chain terminators. It was of course true that obligate chain termination was not the sole factor in antiviral safety. Some antivirals drugs with known toxicity profiles, such as the antiretrovirals zidovudine (AZT) and zalcitabine (ddC) were obligate chain terminators. These compounds were, however, activated solely by host cell kinases and the only selectivity they demonstrated was in their inhibition of HIV polymerase and this low level of selectivity did indeed lead to a measure of toxicity. In the absence of any alternative therapy with a better safety profile, these drugs were used to treat AIDS.

Wellcome summarised the position thus. In the treatment of herpes virus infections (eg shingles, chicken pox, genital herpes simplex), most of which were not life threatening, the risk/benefit ratio for an antiviral required a very rigorous safety profile. The development therefore of a new antiviral, particularly an oral antiherpes agent, should focus upon the need to be selectively activated in virus-infected cells, specifically inhibit the target viral enzyme without inhibiting host cell enzymes, and would also preferably allow no possibility of incorporation into functional host cell DNA.

Wellcome explained that the video discussed penciclovir and its prodrug famciclovir in the context of a recently licensed oral antiherpes compound. It stated, quite factually, that "like the other compounds, penciclovir is not an obligate chain terminator and can become incorporated into growing DNA chains *in vitro*. The short term safety profile of famciclovir seems to be adequate although the long term safety is yet to be established."

PANEL RULING

The Panel considered that the strong inference of the video was that obligate chain termination was of key significance with antivirals and that antivirals which were not obligate chain terminators, such as famciclovir, were potentially toxic. This was expressed for example in the citing of the four antivirals with either very restricted use (ganciclovir) or which had been withdrawn due to toxicity, (sorivudine, fialuridine and 882C) with the statement that "... these molecules all have the potential to be incorporated into a chain of DNA without immediately terminating it" which was a clear invitation to link toxicity with this feature.

The Panel considered that the implications concerning the potential harmful effects of non obligate chain termination as presented in the video were all based on theoretical considerations. There was no supporting animal or clinical data presented. Although it might be acceptable to draw attention to the fact that aciclovir and valaciclovir were obligate chain terminators, as for example in the journal advertisement complained about in Case AUTH/270/2/95, to draw inferences from this feature to question the safety of a competitor was quite unacceptable without there being any solid evidence in support.

The Panel considered that the video was misleading in implying that there were potential toxicity problems associated with famciclovir on the basis of theoretical considerations without any supporting animal or clinical data. The Panel also considered that this was disparaging of Famvir. The Panel therefore ruled there were breaches of Clauses 7.2 and 8.1 of the Code.

The rulings above also applied to the presentation of any similar information on the role of obligate chain termination and the efficacy and safety of famciclovir. In this regard, on the basis of the reports of the Wellcome sponsored meetings on the history of antivirals complained about in Case AUTH/270/2/95, the inferences from those meetings regarding the safety of famciclovir were unacceptable and also in breach of the Code. Similarly the medical information department letter also complained about in that case was unacceptable as it also implied on the basis of theoretical considerations that there was a potential safety issue with famciclovir. The Panel therefore ruled that the meetings and the letter were also in breach of Clauses 7.2 and 8.1 of the Code.

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Wellcome appealed the Panel's ruling that the meetings were in breach of Clauses 7.2 and 8.1 of the Code (Case AUTH/270/2/95). The remainder of the Panel's rulings were accepted.

Case AUTH/270/2/95

APPEAL BY WELLCOME

Wellcome appealed on the basis of principle. The Panel had accepted that the speaker, and indeed any other clinician, was entitled to hold his own opinions on an issue and to express them. It was normal practice within the pharmaceutical industry to provide unconditional support for educational and scientific meetings relevant to the company's areas of interest. It was also normal practice for companies to seek appropriate speakers for such meetings.

The speaker was approached by Wellcome's local representative because of his high local reputation as an infectious diseases physician, his considerable expertise in the field of molecular biology, and his keen interest in the history and development of antiviral drugs. The representative was also aware that the speaker was already in the process of preparing a lecture on this subject for educational purposes and he was delighted to be provided with the opportunity to present his lecture to local general practitioners. He even requested that his

honorarium be given to charity as he did not require any payment for the presentations. The small number of local meetings which ensued were all PGEA approved. Wellcome had no input whatsoever into the preparation of the presentation; indeed, the speaker was a physician and academic who greatly valued his independence and would have been most offended by any attempt on the part of Wellcome to interfere with his talks. Furthermore, even if Wellcome had been granted sight of the slides beforehand, it would have been impossible to predict or control what the speaker actually said during the course of his unscripted talk, or the debate which followed. Despite all of this, Wellcome had been ruled in breach of the Code because the speaker was alleged to have made statements or inferences which had since been ruled in breach of a Code by which he was no way bound.

Wellcome was surprised and concerned about this ruling as it believed that it set an alarming precedent for the practice of industry sponsorship of talks from independent speakers. The implication of the ruling was that companies would be advised to "pre-vet" all presentations which they were initiating and sponsoring in order to ensure that the content was aligned with the Code. This precedent would surely also have to be extended to cover industry support for independently written articles intended for publication and other such activities. Wellcome felt certain that such industry "pre-vetting" would cause great concern within the medical profession and academia and would only serve to decrease the value and credibility of industry sponsored activities.

The final point to consider was that if Wellcome had not sponsored the meetings at which the presentation was made, it was likely that the speaker would have delivered the same lecture at other meetings sponsored by other pharmaceutical companies (and indeed may continue to do so). In fact this had already occurred as one of the meetings in question was co-sponsored by a number of other companies. Wellcome believed that the principle at stake was very important for the pharmaceutical industry, for independent speakers and for the whole provision of continuing postgraduate medical education.

APPEAL BOARD RULING

The Appeal Board agreed with the Panel that the speaker, as with any clinician, was entitled to have his own opinions on an issue and to express them. The Appeal Board agreed also that it would be inappropriate for companies inviting speakers to meetings to control the content of speakers' presentations as this would be to the detriment of industry sponsored educational meetings. The Appeal Board considered, however, as had the Panel, that it was not possible for a company to disassociate itself completely from the content of meetings that it sponsored especially where those meetings were initiated by the sponsoring company. The question in this case was not whether it was appropriate for the speaker to have made the presentations that he did, but whether or not it was appropriate for Wellcome to have sponsored them.

The Appeal Board noted that there had been a total of five meetings. Wellcome had been involved in the choice of speaker even if others had also been involved in the arrangements. The speaker was known to Wellcome and the Appeal Board considered that Wellcome would have been aware of his general views on the subject even though it had not been involved in preparing the presentation or been aware of its detailed contents. Wellcome would have been aware of the content of the presentation after the first meeting.

The Appeal Board noted Wellcome's concerns about the precedent its ruling would set for industry sponsored educational meetings. Each case, however, should be considered on its own facts. The Appeal Board considered that in this case the sponsorship of the meetings by Wellcome amounted to promotion and thus came within the scope of the Code. The Appeal Board agreed with the Panel's view that the inferences from the meetings regarding the safety of famciclovir were unacceptable and upheld the rulings that there had been breaches of Clause 7.2 and 8.1 of the Code.

The appeal therefore failed.

Complaints received

Case AUTH/270/2/95	**24 February 1995**
Case AUTH/285/4/95	**3 April 1995**
Case AUTH/286/4/95	**3 April 1995**

Cases completed

Case AUTH/270/2/95	**10 August 1995**
Case AUTH/285/4/95	**25 July 1995**
Case AUTH/286/4/95	**25 July 1995**

CASE AUTH/296/5/95

GENERAL PRACTITIONER v GLAXO

Booklet on peptic ulcer disease not up to date

A general practitioner complained that a booklet on peptic ulcer disease sent by Glaxo with an accompanying circular letter was in direct conflict with current medical opinion as no mention was made of *H pylori* eradication. Glaxo submitted that the mailing was intended to heighten awareness amongst NHS managers of peptic ulcer disease as a significant cause of morbidity and mortality. The mailing was not promotional.

The Panel considered that, although not product specific, the mailing was subject to the Code as it was company produced material in a disease area in which the company was commercially interested. The material was clearly produced as part of the general promotional background for specific products. The Panel ruled that the booklet was in breach of the Code as it should have included some acknowledgement of the role of *H pylori* eradication. It was therefore not up to date. The Appeal Board upheld the Panel's ruling following an appeal by Glaxo.

COMPLAINT

A general practitioner complained about a booklet entitled "Realities of Peptic Ulcer Disease" (ref: NHS 21956-CP/April 1993) sent out by Glaxo Pharmaceuticals UK Limited with a circular letter headed "The Burden of Peptic Ulcer Disease". The complainant stated that the booklet recommended long term maintenance therapy for peptic ulcer disease which, in his view, was in direct conflict with current medical opinion on the use of eradication therapy for *H pylori* to achieve a cure and so avoid the need for long term therapy. The complainant said that no mention was made of the organism which he considered was probably one of the most important discoveries of the decade.

RESPONSE

Glaxo explained that the mailing was sent to NHS managers only. The circular letter accompanying the booklet summarised the morbidity and mortality associated with peptic ulcer disease with neither the circular letter nor the booklet being product promotional items as a proportion of the recipients were non medical. The booklet was one of a of series of publications addressing the application of the "Health Gain Cycle" to various therapeutic areas in which the company specialised.

Since many recipients were non medical the intention was to highlight general approaches rather than give advice on detailed management. The sections of the booklet criticised gave general guidance on the management of peptic ulcer disease suggesting that GPs should have a systematic approach to diagnosis, a stepped care approach management and an understanding and acceptance of the need for maintenance. It was suggested that this could be done by setting up agreed protocols for both management and audit. It was considered that details about the role of *H pylori* eradication and the management of some types of peptic ulcer disease would be included in the management protocols which the booklet suggested GPs should agree with FHSAs and health boards. It should be noted that while *H pylori* was not specifically mentioned neither was specific advice on the healing of ulcers, nor the management of gastric and duodenal ulcers differentiated nor was reference made to ulcers related to non steroidal anti inflammatory drugs (NSAIDs). *H pylori* was not considered an important causative factor in NSAID related ulcers which were believed to be associated with over half of the 4,500 deaths from peptic ulceration referred to in the circular letter. Only in duodenal ulceration was there any consistent association with *H pylori* and, while it was true that the need for long term maintenance could be avoided if eradication of *H pylori* could be achieved, there were still many ulcer patients in whom long term maintenance was the preferred option. It would therefore seem reasonable to mention this in the management section.

The *H pylori* consensus group established by the US National Institute of Health, whilst advocating *H pylori* eradication in ulcer patients found to have the infection, did not feel confident enough to advise reliance on *H pylori* eradication as a means of preventing long term ulcer complications such as bleeding or perforation. Maintenance treatment with long term acid suppression remained the only medical therapy shown to reduce these risks. A copy of a recent article outlining those categories of patients in whom maintenance treatment might be preferable was submitted.

In promotional materials addressed to doctors and pharmacists, Glaxo referred to the role of *H pylori* as a major causative factor in duodenal ulceration and, since Zantac's product licence had been extended to the treatment of duodenal ulcers associated with *H pylori*, the company had promoted its use in an effective eradication regimen.

PANEL RULING

The Panel considered that the material in question, although not product specific, was subject to the Code as it was company produced material on a disease area in which it was commercially interested. The material was clearly produced as part of the general promotional background to specific products.

The Panel noted that the booklet was dated April 1993 and that many of the developments in terms of emerging opinion on the role of *H pylori* eradication in peptic ulcer disease had taken place more recently. The US National Institute of Health Consensus Conference on the issue was published in July 1994. The Panel observed that although Glaxo submitted that the booklet was not intended to provide detailed information on available therapeutic approaches to the management of peptic ulcer disease, the booklet did refer to NSAIDs in the aetiology of the disease. The booklet stated for example that "it has been suggested that the increase in the mortality may be

related to the increased prescription of non-steroidal anti-inflammatory drugs (NSAIDs) and a consequent increase in NSAID-induced ulcers". The Panel also noted that the booklet, in discussing the cost of peptic ulcer disease and setting the right targets, referred to Australian and US studies showing that appropriate maintenance therapy could help to bring costs associated with peptic ulcer disease down by reducing the need for repeated investigations, consultation and hospital admission. This was referenced to a management plan for peptic ulcer disease based on round table discussion at the World Congresses of Gastroentrology in August 1990 which, in the context of current views on *H pylori* eradication, appeared to the Panel to be somewhat out of date.

The Panel considered that the booklet should have included some acknowledgement of the role of *H pylori* eradication in its discussion of the "Realities of peptic ulcer disease" which was the title of the booklet. The Panel considered that the booklet was not up to date as required under Clause 7.2 of the Code and ruled that there was a breach of that Clause.

APPEAL BY GLAXO

Glaxo submitted that the purpose of the booklet was to provide the type of concise, relevant information which was most likely to help decision makers identify health needs. No product promotional information was included and there was no reference to any specific class of drugs.

Glaxo accepted that interest in *H pylori* and its association with certain types of peptic ulcers had increased during the early 1990s but it was felt that the general principles described in the booklet remained valid and up to date in 1995. The booklet was not an appropriate vehicle to explain to NHS managers the controversial issues surrounding *H pylori* infection and eradication. If the general principles detailed in the booklet were followed by clinicians, ie management protocols drawn up with secondary care colleagues, audit carried out and so on, then the place of *H pylori* infection and eradication would be clearly defined within these. The place of maintenance therapy had not disappeared in certain patient groups such as the elderly and others at particular risk of haemorrhage or perforation.

Glaxo submitted that if the Panel's decision was upheld it would establish a precedent which would have serious implications for pharmaceutical companies in that all educational material issued by a company relating to a therapeutic area in which the company had a commercial interest could potentially be found in breach of the Code, especially if the views expressed were controversial. Such a precedent would also have serious implications for medical education in general, with the potential that information provided at medical meetings for example would need to conform to a defined brief. In this particular case the company believed the complainant viewed the booklet as a clinician rather than as an NHS manager and misunderstood its purpose.

APPEAL BOARD RULING

The Appeal Board agreed with the Panel's view that the booklet, although not product specific, was subject to the Code as it was company produced material on a disease area in which the company had a commercial interest.

The Appeal Board considered that the booklet should have included some acknowledgement of the role of *H pylori* eradication in its discussion. This would be relevant to the intended audience of NHS managers. The Appeal Board agreed with the Panel's view that the booklet was not up to date and upheld that there was a breach of Clause 7.2 of the Code. The appeal therefore failed.

Complaint received **4 May 1995**

Case completed **11 August 1995**

CASES AUTH/302/5/95 & AUTH/306/5/95

GLAXO v LEDERLE/SMITHKLINE BEECHAM

Mailing on Zoton - various allegations

Glaxo complained about a booklet on Zoton sent to general practitioners by Lederle Laboratories. Glaxo stated that a graph headed "Four weeks drug costs per patient healed in RO and DU" based on assumptions made in a study by Jones *et al* was misleading as the major assumptions were not explained in the graph. Glaxo referred to previous cases in which it had been ruled that major assumptions should be stated. Glaxo alleged that the presentation of a quotation in the booklet "...[Zoton] is the most cost effective option as it provides fast symptom relief in more patients and does so for a lower overall cost" taken from the Jones study, was misleading as in the actual paper the word faster was used instead of fast. Glaxo also commented that the quotation appeared to be referring to the use of Zoton for the empirical treatment of undiagnosed dyspepsia and not specifically reflux oesophagitis and duodenal ulcer, the subject of the booklet.

The Panel ruled no breach of the Code regarding the first allegation as the claim had not been derived from the Jones study. The ratio of reflux oesophagitis to duodenal ulcer had been stated and the source of healing rates explained. The Panel ruled a breach of the Code as the quotation was not accurate. The Panel also considered that it was misleading to use the quotation in a mailing relating specifically to reflux oesophagitis and duodenal ulcer.

COMPLAINT

Glaxo Pharmaceuticals UK Limited complained about a mailing for Zoton, reference ZOT172, sent by Lederle Laboratories to general practitioners in January 1995. The mailing consisted of a booklet comparing Zoton and ranitidine. It was alleged that the mailing contained a number of misleading claims in breach of Clause 7.2 of the Code.

As Zoton was jointly promoted by Lederle Laboratories and SmithKline Beecham Pharmaceuticals UK, the complaint was taken up with both companies.

Glaxo said that its concerns arose from the use of promotional claims derived from a Lederle sponsored economic evaluation paper (Jones *et al*) which had previously been considered by the Panel and the Code of Practice Appeal Board. It had previously been ruled (Cases AUTH/187/7/94 and AUTH/189/7/94) that if claims derived from such studies were used in promotional material, then the major assumptions made should be stated. In the booklet in question, promoting Zoton for the treatment for reflux oesophagitis (RO) and duodenal ulcer (DU), claims were made about the "4 week drug costs per patient healed in RO and DU" which were referenced to "Data on File" and based upon assumptions made in the Jones study. However, the only assumption stated was "RO:DU incidence 1.85:1" in small print below a graph headed "4 week drug costs per patient healed in RO and DU" which gave a figure of £39.74 for Zoton and £52.50 for ranitidine. Glaxo did not believe that the statement RO:DU incidence 1.85:1 explained the major assumptions from which the calculations had been derived, not least of which would be the selection of healing rates. Indeed, there was nothing to indicate that these drug costs had been derived entirely from theoretical calculations based on many assumptions and not, as a casual reader might think, from a comparative clinical study. Although the "Data on File" provided to Glaxo by Lederle following two requests gave information about the healing rates from which these calculations had been derived, it did not indicate how such healing rates had been selected. If a range of healing rates from published studies had been used then a more realistic range of drug costs per patient healed would have been produced.

Glaxo also alleged that a sentence was presented as though it were a quotation from the Jones *et al* paper to which it was referenced. The original sentence stated "The results therefore show that lansoprazole is the most cost-effective option as it provides faster symptom relief in more patients, and does so for a lower overall cost". This had been altered in the booklet to ".....[Zoton] is the most cost effective option as it provides fast symptom relief in more patients, and does so for a lower overall cost". Presumably the word "faster" had been changed to "fast" because the Panel had already ruled that Lederle could not claim that Zoton provided faster symptom relief than omeprazole. It was misleading in breach of Clause 7.2 to present this as though it were a quotation from the publication. In addition, in the Jones paper, the statement appeared to be referring to the use of lansoprazole for the empirical treatment of undiagnosed dyspepsia and not specifically reflux oesophagitis and duodenal ulcer, the subject of the booklet.

RESPONSE

Lederle said that it had not been remiss in dealing with Glaxo's enquiries and set out the sequence of events. Use of the booklet had been suspended following the receipt of Glaxo's letter in February 1995.

With regard to the Jones economic evaluation paper, Lederle said that the graphical representation was referenced to data on file and was not based upon the Jones study or its assumptions at all. The only assumption made was the ratio of RO to DU and this was clearly stated. In relation to the selection of healing rates, there had been no "selection" of rates. These were based on mean rates of published comparative European studies in reflux oesophagitis and duodenal ulcer. The studies and ranges were described in detail on the previous two pages of the booklet and it could be seen that all studies showed a highly statistically significant benefit in favour of lansoprazole (Zoton).

In response to a request for further information, Lederle sent copies of the six studies referred to at the bottom of the pages in the booklet headed "In duodenal ulcer" and "In reflux oesophagitis" which had been used to calculate the mean healing rates. Lederle confirmed that the graph in question and the figures used for the calculation were

not derived from the paper by Jones. In relation to the request for an explanation as to exactly what was the basis of the ratio of 1.85:1 of incidence of reflux oesophagitis to duodenal ulcer, Lederle said that this was derived from an analysis of the prescribing data provided by IMS audit. In response to the request for further information regarding the calculation of the figures in the graph, Lederle said that this was done by first calculating the mean healing rates from comparative clinical data for ranitidine and lansoprazole in both duodenal ulcer and relux oesophagitis. Details of the method of calculation were provided.

In relation to the use of the quotation, Lederle said that it would very much have liked to use the original sentence. However, to avoid an obvious accusation of a hanging comparison, the word "faster" was changed to "fast" which should have been printed in brackets and this would be rectified. In relation to Glaxo's comment concerning the use of lansoprazole in undiagnosed dyspepsia, this issue had been reviewed before in the previous case (Case AUTH/187/7/94) and it had been agreed following the appeal that the Jones paper used the term to describe patients (who constituted the majority in general practice) who had unconfirmed diagnoses in RO and DU. Lederle was not promoting Zoton in an unlicensed indication.

SmithKline Beecham said that it had nothing to add although it understood that the mailing was considered acceptable by the Medicines Control Agency. The mailing had been sent out by Lederle and it had had no involvement in its design or approval.

RULING

The Panel considered that the first part of Glaxo's complaint was largely based on the erroneous assumption that the claim about the 4 week drug costs per patient healed in RO and DU made in the mailing was derived from the paper by Jones which had been before the Panel and the Appeal Board on previous occasions.

The Panel considered that Lederle had responded adequately to Glaxo's criticisms in relation to the claim in question. The assumption that the ratio of the incidence of reflux oesophagitis and duodenal ulcer was 1.85:1 had been stated. The source of the healing rates had been explained. The Panel noted, however, that one of the studies relating to the healing rate in duodenal ulcer showed no significant differences. This was stated on the page headed "In Duodenal Ulcer" and was in contradiction to Lederle's submission that all studies showed a highly statistically significant benefit in favour of Zoton. Nonetheless, the Panel did not accept that the claim was misleading as alleged and ruled no breach of the Code.

In relation to the second allegation concerning the purported quotation from the Jones paper, the Panel ruled that there had been a breach of Clause 7.2 because it was not an accurate quotation. The Panel noted that Lederle proposed to put the word "fast" in brackets to show that it was different from the original statement but considered that that also would be in breach because the amendment of the word "faster" to "fast" changed the meaning of the quotation. Amendment to quotations used in promotional material could only be on non-substantive aspects, such as to eliminate the use of a competitor trade name and replace it with the generic name. In relation to the allegation that the statement quoted referred to undiagnosed dyspepsia rather than specifically to reflux oesophagitis and duodenal ulcer, the Panel considered that the context of the statement in the Jones paper implied that it was referring to the generality of peptic ulceration, reflux oesophagitis and undiagnosed dyspepsia. The Panel considered that it was misleading to use the quotation in a mailing relating specifically to reflux oesophagitis and duodenal ulcer and ruled another breach of Clause 7.2.

Complaint received **22 May 1995**

Cases completed **30 August 1995**

CASE AUTH/303/5/95

DIRECTOR v NON MEMBER COMPANY

Drug and Therapeutics Bulletin article criticising the promotion of a product

An article published in the Drug and Therapeutics Bulletin criticising the promotion of a product was taken up as a complaint under the Code. The Panel decided that references to effects of the product and references to stopping therapy were not unreasonable. No breach of the Code was ruled.

COMPLAINT

An article in the Drug and Therapeutics Bulletin criticising the promotion of a non member's product in relation to its effects and to stopping therapy was taken up as a complaint in accordance with established procedure.

RESPONSE

The company concerned, although not a member of the ABPI, had nevertheless agreed to comply with the Code. The company provided a detail aid with its response.

The company explained that it had had several communications with the Drug and Therapeutics Bulletin but the Drug and Therapeutics Bulletin had refused to review the data for the product in its entirety, confining itself only to fully published manuscripts. Data on file and abstracts were ignored. Some of the studies in question were pivotal in the submissions made to the Medicines Control Agency (MCA) and the United States' Food and Drugs Administration.

The company provided evidence to support the claims criticised and explained that the MCA had requested that certain statements be included in materials and the data sheet.

RULING

The Panel examined the detail aid and considered that the references to the product's effects and to stopping therapy were not unreasonable in the circumstances and therefore ruled no breach of the Code.

Complaint proceedings commenced 24 May 1995

Case completed 28 July 1995

CASE AUTH/304/5/95

DIRECTOR v BOEHRINGER MANNHEIM

Claims in Eucardic promotional material regarding scope of therapy and unwanted effects

An article in the Drug and Therapeutics Bulletin on Boehringer Mannheim's product Eucardic criticised two claims for the product. Firstly that it extended the scope of beta blocker therapy and secondly that its use resulted in fewer of the unwanted side effects associated with standard beta blockers.

The Panel accepted that the first claim related to the use of Eucardic in patient groups where standard beta blockers should not be used or should be used with caution and ruled no breach of the Code. The Panel considered that the second claim criticised would be interpreted as a statement about side effects generally associated with beta blockers and not as referring to patients with special needs as submitted by the company. The Panel ruled that the claim was misleading.

COMPLAINT

An article published in the Drug and Therapeutics Bulletin, May 1995, criticising the promotion of carvedilol (Eucardic) by Boehringer Mannheim UK (Pharmaceuticals) Limited was taken up as a complaint under the Code in accordance with established procedure.

The article referred to claims that carvedilol's dual mode of action "extends the scope of beta blocker therapy" and "results in fewer of the unwanted effects typical with standard beta blockers". The article concluded that there was no evidence that its dual mode of action enhanced antihypertensive efficacy and that it might cause additional unwanted effects. The article stated that it might cause fewer adverse metabolic effects than conventional beta blockers, such as changes in lipid profile, but the clinical significance of this was as yet uncertain. The article further stated that in the treatment of hypertension carvedilol did not appear to offer any advantages over, and was more expensive than, a standard beta blocker such as atenolol.

Boehringer Mannheim provided copies of the promotional material for Eucardic these included "Dear Doctor" letters, brochures and leaflets, a product monograph and detail aids.

1 "Extends the scope of beta blocker therapy"

RESPONSE

Boehringer Mannheim submitted that it made no claims for superior antihypertensive efficacy relative to any other antihypertensive agent. The company did not make any claims that Eucardic's ability to increase the scope of beta blockers was either dependent upon, or a consequence of, increased antihypertensive efficacy. The company submitted that it had used the claim because Eucardic could be used in patients where pure beta blockers would not normally be used, or would be used with caution, such as patients with peripheral vascular disease, chronic renal failure, non insulin dependent diabetes and patients with treated hyperlipidaemia and on these grounds it was claimed to extend the scope of beta blocker therapy.

RULING

The Panel accepted that the claim was in relation to patient groups where standard beta blockers should not be used or would be used with caution as submitted by the company and therefore ruled there was no breach of the Code.

2 "Results in fewer of the unwanted effects typical with standard beta blockers"

RESPONSE

Boehringer Mannheim submitted that it had not made the claim that was the subject of complaint and therefore asked the Authority to dismiss this aspect of the complaint. The Panel noted that one of the "Dear Doctor" letters made the claim "This refinement of beta blockade means that many of the unwanted side effects associated with traditional beta blocker therapy, are not significantly noticeable in patients treated with Eucardic" which it considered was in effect the same as the claim queried by the Drug and Therapeutics Bulletin and Boehringer Mannheim was asked to comment upon this.

Boehringer Mannheim submitted that the claim in the "Dear Doctor" letter was qualified and substantiated by four references. The company submitted that the references and content of the rest of the letter

demonstrated that the claim was referring to those side effects which limited the use of traditional pure beta blockers in patients with co-existing disease. This was further specified in a later paragraph in the letter under a heading "Extending the scope of beta blockade" which referred to patients with special needs.

RULING

The Panel did not accept that the claim in the "Dear Doctor" letter "This refinement of beta blockade means that many of the unwanted side effects associated with traditional beta blocker therapy, are not significantly noticeable ..." referred to patients with special needs as submitted by the company. The reference to patients with special needs appeared later in the letter than the claim at issue. The Panel considered that the claim would be interpreted to be a statement about side effects generally associated with beta blockers which the patient might become aware of or which the doctor might detect on relatively simple clinical examination, such as cold extremities, shortness of breath, fatigue and bradycardia. The Panel considered that the reader would be misled by the claim and therefore ruled a breach of Clause 7.2 of the Code.

Complaint proceedings commenced **24 May 1995**

Case completed **23 August 1995**

CASES AUTH/309/6/95 & AUTH/310/6/95

GENERAL PRACTITIONER CHAIRMAN OF A MEDICAL AUDIT ADVISORY GROUP v BOEHRINGER INGELHEIM/INNOVEX

Conduct of a nurse adviser

A general practitioner chairman of a medical audit advisory group complained about the conduct of a nurse adviser employed by Innovex and funded by Boehringer Ingelheim to assist general practices in the audit of chronic obstructive pulmonary disease (COPD). The complainant alleged that when the nurse adviser made an appointment with him at his practice she led the practice to believe that she might be coming from the family health services authority. The complainant alleged that the nurse adviser knew little about COPD and audit. Her presence in the practice was alleged to be for the promotion of Boehringer Ingelheim's product, Combivent.

The Panel considered that the COPD Response project came within the scope of the Code as it concerned a disease area in which Boehringer Ingelheim was commercially interested.

The Panel ruled that the nurse adviser had not maintained a high standard of ethical conduct as she had misled the receptionist when making the appointment. The Panel ruled no breach of the Code in relation to the allegation that the nurse adviser was inadequately trained. The Panel did not accept that the COPD Response project was a "hard sell" for Combivent, as alleged, and ruled no breach of the Code.

COMPLAINT

A general practitioner who was the chairman of a medical audit advisory group (MAAG), complained about the conduct of an employee of Innovex (UK) Limited whose appointment as a nurse adviser was funded by Boehringer Ingelheim Limited. The complainant raised two issues. Firstly, that when the employee made an appointment at his practice she led the practice to believe that she was a nurse adviser and it appeared that she might be coming from the family health services authority (FHSA). The complainant said that he thought it unlikely that the nurse adviser lied when making her appointment but she was certainly economical with the truth. The practice audit manager had received complaints that this was not the first occasion on which the individual had tried to gain access to practices with misleading information.

The second matter concerned the audit of chronic obstructive pulmonary disease (COPD) which the nurse proposed. The complainant alleged that it was clear from the outset that the nurse adviser knew very little about chronic airways disease, even less about audit, and had no idea as to whether the process she was suggesting would have any benefit to the patient. From the discussion they identified that her presence in the practice was basically a hard sell for Combivent (Boehringer Ingelheim's product) and that the process had nothing to do with auditing.

The complainant alleged that the approach was entirely unacceptable. The complainant had considerable expertise regarding the audit process and the approach of the nurse, who the complainant gathered was one of 30 employed in the UK, grossly devalued what was a beneficial educational tool. The complainant had written directly to Boehringer Ingelheim and had copied his letter to the appropriate FHSA in order that practices might be warned about the inappropriate nature of the actions of these "so called" primary care nurse advisers.

The matter was taken up with both Boehringer Ingelheim and Innovex. Attention was drawn to Clauses 10.1 and 15. Both companies provided detailed responses to the complaint.

RESPONSE FROM BOEHRINGER INGELHEIM

Boehringer Ingelheim described the COPD Response service it had developed in support of the diagnosis, investigation and management of chronic obstructive pulmonary disease in general practice in the UK. The company submitted that it had become clear that COPD

might be under diagnosed and under treated in the UK partly because of a belief in the irreversibility of the condition and partly because a diagnosis was either not reached or because patients were misclassified.

The company submitted that COPD Response was a *bona fide* public health project designed with the help of individuals experienced in the field and to high standards of ethical conduct. Chest physicians, general practitioners and FHSAs had been made aware of the project and many had endorsed it. This was the only complaint the company had received about the project which was a healthcare initiative developed on a complimentary basis to assist practices which were already running asthma clinics to be aware of COPD as a separate entity. The company submitted that an advisory service at the nursing level would assist general practitioners and their respiratory practice nurses to review, assess and subsequently treat, patients who had morbidity and mortality significantly in excess of that sustained by patients suffering from asthma. To this end Innovex Health Management Services was commissioned by Boehringer Ingelheim to develop the service. As part of the preparation, a pilot programme was carried out which received enthusiastic endorsement from a local respiratory consultant and was readily accepted by five general practices. This pilot study confirmed the finding that COPD was under diagnosed in the primary healthcare setting.

The recruitment of the nurse advisers was aimed at employing experienced Registered General Nurses ideally with an additional respiratory qualification. The nurse advisers all undertook a two week training course which covered diagnosis and management of reversible airways obstruction, audit and its application, personal communication skills, the United Kingdom Central Council for Nursing, Midwifery and Health Visitors (UKCC) Code of Professional Conduct, nurse indemnity and liability. The course also included a section on the ABPI.

Throughout the training it was stressed to the nurse advisers that they must abide by the UKCC Code of Professional Conduct and that their objective was to provide a service to primary health care teams in order to enhance the current care management of patients with respiratory disease. Specifically the UKCC Code of Professional Conduct stipulated that nurses must ensure that their registration status was not used in the promotion of commercial products or services and ensure that professional judgement was not influenced by any commercial considerations. It was a clear policy that the nurse advisers must not promote the products of Boehringer Ingelheim. However, they should promote, help to set up and help conduct the COPD Response audit project. The nurse advisers were supplied with a number of items with which to carry out their duties (copies were provided). These included a business card, mailings to doctors (refs BIL4487A & 4486A), a leaflet entitled "Practice Nurse Advisory Service" (ref BIL4487C) a "COPD assessment records" for patients (ref BIL 4502), a "COPD clinic assessment results" document for the Practice (ref BIL 4509), a proforma letter for the practice to use to invite patients to attend a respiratory clinic (ref BIL 4485) and a confidentiality agreement between the nurse adviser and the practice (ref BIL 4499). All items carried the name of the sponsoring company, Boehringer Ingelheim, and none of them included any product promotion [note: the proforma letter to patients did not carry the company name]. All the other materials also included the COPD Response logo together with an explanation that COPD Response was provided as a service to medicine by Boehringer Ingelheim & Gemini.

The nurse advisers were also supplied with a reference book "Unmask COPD with COPD Response" to answer the specific query about the need for such an audit.

There was a deliberate policy to involve FHSAs in the programme to the extent of consulting with nursing members and MAAGs of FHSAs informing them and seeking opinion and advice. This was accomplished through the teams of nurse advisers and their supervisors. In this way some 90% of FHSAs were fully informed as to the proposed activities and no objections were received, there being several who were actively supportive of the project.

At all stages of the development of the project, key members of the British Thoracic Society (BTS) were consulted and informed. The chairman of the BTS working group on treatment guidelines for the management of COPD (to be issued soon) and the chairman of the BTS Standards of Care Committee had both actively advised and supported the COPD Response intiative.

Boehringer Ingelheim submitted that it had interviewed the nurse adviser who was able to recount with clarity what had occurred during the meeting with the complainant and his practice nurse. A detailed report on this interview was submitted.

In respect to Clause 10.1, the company submitted that all material supplied for initial use was designed to promote solely the concept of COPD Response and the audit of patients on the asthma registers. Thereafter the material was designed to support the practice in investigating these patients and was donated as a service to the practice. The material did not concern itself with products. The booklet entitled "Unmask COPD with COPD Response" included prescribing information on the back cover and this was the only mention of any product name in any material used by the nurse advisers. It was a reference document designed for use with doctors or practice nurses who wished to query or discuss the project and its likely benefits in relation to workload. The document concerned itself with the rationale for conducting the audit and unmasking COPD and options for treatment in generic terms. The product name was not prominent on the last page of the document for the very reason that the document was concerned with disease and promoted the COPD Response project. Prescribing information had been included because the data on one of the pages came from a clinical trial of salbutamol alone compared with a metered aerosol formulation of salbutamol plus ipatropium.

The company provided a copy of the relevant briefing material which had been made available by Boehringer Ingelheim and Innovex.

RESPONSE FROM INNOVEX

Innovex said that the concept and title of the "nurse

adviser" acting directly or indirectly on behalf of the sponsor company was now well established in the UK. Prior to commencing this programme the company sought independent opinion regarding the job title and was advised that the term nurse adviser would be more appropriate than nursing practitioner or nurse facilitator which were more commonly adopted by FHSAs. It had since come to its attention that some misunderstanding might have been unintentionally introduced in this instance as the job title "nurse adviser" shared similarities with the term primary care adviser provided by the relevant FHSA. Nevertheless any prior misunderstanding was rectified at the outset of the interview with the complainant and his practice nurse when the nurse adviser introduced herself as an employee of Innovex working as a nurse adviser for the sponsor company. It was not until the end of the interview that it became apparent that the complainant had misunderstood the nurse adviser's original position. Moreover all her presentation materials and her business card clearly depicted her responsibility in association with Boehringer Ingelheim.

Innovex did not understand the allegation that the complainant's audit manager had received reports that the nurse adviser had tried to gain access to practices with misleading information. The nurse adviser had operated for over four months involving over 200 calls to approximately 100 practices. Until the complaint, Boehringer Ingelheim, Innovex and the nurse adviser were all unaware of any complaints regarding her approach. The company submitted that the nurse adviser's academic work experience qualified her to function as a nurse adviser for the COPD Response project. She had worked as a registered general nurse for three years during which she earned exemplary service records. She worked as a practice nurse for over two years at two busy practices during which she acquired a Diploma in Asthma Care (endorsed by the Royal College of General Practitioners) and before joining Innovex she worked as a respiratory care associate for a pharmaceutical company where she provided training to practice nurses on asthma audit programmes.

The company submitted that all its nurse advisers had been carefully trained and instructed to promote the concept of the COPD Response project. The company submitted that any direct references to Combivent raised during the interview were initiated by the complainant. Responses by the nurse adviser were restricted to the use of therapies in the context of auditing and enhancing care for the management of patients with COPD. She had indicated that specific therapies for the treatment of COPD were for the complainant to choose. The only reference to Combivent by name appeared in the reference document entitled "Unmask COPD with COPD Response" and was restricted to the prescribing information for the product. This was considered necessary as one of the graphs extracted from a study referred to the active generic ingredients for Combivent as one of a range of options for managing patients with COPD. It should be emphasised that these generic products were available separately and independently.

RULING

First the Panel considered the principle of pharmaceutical companies sponsoring nurses to undertake projects on their behalf. The Panel noted that this practice was increasing and generally the sponsored nurse would be involved in a project in a therapeutic area or a disease area in which the pharmaceutical company had an interest, as in these cases. The Panel considered that people outside the industry might well have reservations about such arrangements but decided nonetheless that the principle was not unacceptable. Clearly, whether any individual project was acceptable would depend upon the particular arrangements adopted.

The Panel considered that the involvement of companies in sponsoring nurses to carry out projects could come within the scope of the Code. The Panel noted that Clause 1.2 of the Code defined promotion as being any activity undertaken by a pharmaceutical company or with its authority which promoted the prescription, supply, sale or administration of its medicines. The Panel noted that no promotion of products was intended under the COPD Response project. The Panel nevertheless considered that the COPD Response project came within the definition of promotion. Although not intended to be product specific, the project did concern a disease area in which Boehringer Ingelheim was commercially interested.

The Panel noted that Clause 1.6 of the Code defined a representative as being a person whose duties comprised or included calling upon doctors and/or dentists. The Panel considered that as the nurse adviser called upon doctors she was a representative as defined by the Code and would need to comply with all the relevant clauses of the Code.

With regard to the allegation that the nurse adviser was economical with the truth when making her appointment with the complainant, the Panel noted that the nurse adviser had introduced herself to the receptionist by name and stated that she was a practice nurse adviser. She had not left her business card or mentioned on whose behalf she was calling and nor had she explained the purpose behind her request for an interview. The Panel considered that the title "practice nurse adviser" could be taken to be an official title. The Panel accepted that there was no evidence that the nurse adviser had deliberately deceived the practice as to her role and in this regard noted that she gave a full explanation of her title, her job and the purpose of her visit at the commencement of her interview with the complainant and his practice nurse. The Panel considered, however, that the nurse adviser had misled the receptionist, even though this might have been inadvertent, when arranging the appointment. The nurse adviser had not maintained a high standard of ethical conduct and a breach of Clause 15.2 was ruled. This ruling applied to both Boehringer Ingelheim and Innovex.

The Panel considered, in light of the information provided by the companies, that there was no evidence that the nurse adviser had been inadequately trained for her role. The Panel therefore ruled no breach of the Code. This ruling applied to both companies.

The Panel noted that as with all cases of this nature it was difficult to be certain as to what had been said and whether what had been said was acceptable in relation to the Code. Having reviewed the detailed responses provided by both companies, the Panel decided that the COPD Response project as a whole was not a hard sell for Combivent as alleged by the complainant. The Panel

considered that on balance the COPD Response project was not unacceptable and therefore ruled no breach of the Code in this regard. This ruling applied to both companies.

Notwithstanding its ruling, the Panel considered that the use of the document "Unmask COPD with COPD Response" in the circumstances described by Boehringer Ingelheim ie when doctors initiated discussions about treatments or requested information about the outcome of pilot studies, amounted to promotion of Combivent and this undermined the concept that the nurse adviser should act in a non promotional manner and should not be concerned with the promotion of any particular product. In the Panel's view Boehringer Ingelheim should discontinue the use of this particular document.

Complaint received **7 June 1995**

Cases completed **18 August 1995**

CASE AUTH/312/6/95

ZENECA v SERVIER

Leaflet on Coversyl - misleading presentation of data

Zeneca alleged that a section on trough/peak ratios in a leaflet on Coversyl produced by Servier did not represent a true and balanced view of all the published data. Firstly, the trough/peak ratio was given as a percentage for Coversyl and a number of other ACE inhibitors whereas only a quotation from the Physicians Desk Reference entry for Zestril (lisinopril) was given for lisinopril although values for the trough/peak ratio of lisinopril were available in the literature. Secondly, the literature reported a range of trough/ peak ratios for perindopril but only the higher two figures were given in the leaflet.

The Panel noted that Servier submitted that its literature search had failed to find an acceptable study with lisinopril which met with its criteria of being a prospective, placebo-controlled, crossover study. The Panel considered that a study submitted by Zeneca appeared to meet Servier's criteria and ruled that it was misleading not to use the data from this study. With regard to the second matter, the Panel considered that the paper used by Zeneca to support its allegation could be criticised as the scientific relevance was open to question and the methodology was at odds with current requirements. The Panel did not accept the allegation and ruled no breach of the Code.

COMPLAINT

Zeneca Pharma complained about a leaflet on Coversyl (perindopril) (ref C951C3) issued by Servier Laboratories Ltd. Servier, although not a member of the ABPI, had nonetheless agreed to comply with the Code. Zeneca alleged that a section headed "Trough/Peak Ratio" was in breach of Clauses 7.2 and 7.6 of the Code as it misled by not representing the balance of all of the available evidence.

The section in the leaflet in question was headed "Trough/Peak Ratio(%)" followed by a bar chart which compared the trough/peak ratios of Coversyl with several other ACE inhibitors. The ratios quoted for Coversyl, enalapril, ramipril and fosinopril were represented graphically. In contrast, no ratio was given for lisinopril, but instead a quotation from the Physicians Desk Reference entry for Zeneca's product Zestril (lisinopril) was given which read "At all doses studied, the mean antihypertensive effect was substantially smaller 24 hours after dosing than it was 6 hours after dosing".

Zeneca explained that the term "trough/peak ratio" was a relatively recent addition to the list of parameters which might be used to establish the clinical efficacy and correct dose interval of an antihypertensive drug. It was first proposed by the United States' Food and Drug Administration (FDA) as a means of providing an index of how well the antihypertensive effect of a drug was sustained over the dose interval. It was usually expressed as a percentage and was determined by the ratio of the blood pressure reduction at the end of the dosage interval and before the next dose was given (trough) relative to the drug pressure reduction at the time of peak effect (peak). Guidelines issued by the FDA recommended that a trough/peak ratio should be 50-66% for once daily dosing.

Zeneca alleged that the section did not represent a true and balanced view of all the published data in two respects. Firstly, there was considerable published data on the trough/peak ratio of lisinopril. Salvetti reported placebo-corrected trough/peak ratios for lisinopril of 60.2% for the 5mg dose, 70.2% for the 10mg dose and 77.5% for the 20 mg dose. Zannad's retrospective analysis of seven clinical studies of lisinopril involving 148 patients reported a mean diastolic blood pressure (DBP) trough/peak ratio of 56% (range 40-80%) and mean systolic blood pressure (SBP) trough/peak ratio of 64% (range 40-100%). Secondly, the literature reported a range of trough/peak ratios for perindopril (DBP trough/peak ratio of 30%, 87% and 100% and SBP trough/peak ratio of 50%) but only the higher two figures were presented in the leaflet. Thus the range of trough/peak ratios for lisinopril was 40-100% and for perindopril 30-100%.

RESPONSE

Servier said that the bar chart in question represented the trough/peak ratios of some ACE inhibitors. It had used data from trials which complied with the current "best practice", ie, prospective placebo-controlled, crossover studies. Thus the figures quoted for perindopril, enalapril, ramipril and fosinopril had been obtained from studies which were of the accepted rigorous scientific design. Unfortunately, Servier's literature search at the time failed to reveal such a study for lisinopril and so it had used data from the Physicians Desk Reference as the United States' FDA was, as far as Servier knew, the only regulatory body which required such data for the registration of antihypertensive drugs. Servier accepted

that the whole area of trough/peak ratios was still open to debate and the methodology was still not adequately defined.

The quote for lisinopril was put at the bottom of the bar chart for purely aesthetic reasons.

With regard to the figures for Coversyl quoted by Zeneca, Servier pointed out that these came from a publication by Zannad, the exact scientific relevance of which was open to question as the methodology was at odds with current requirements. Servier provided detailed criticism of the Zannad paper. Among other comments, attention was drawn to the fact that the paper was a retrospective study; the trough/peak ratios were mean values rather than a mean of individual ratios and no correction had been made for placebo effects or circadian variations as recommended by the FDA.

RULING

The Panel noted that the trough/peak ratio data was presented as a bar chart and that for Coversyl, enalapril, ramipril and fosinopril a bar giving the data was featured. On the other hand, for lisinopril in the position where a bar would have appeared there was the statement "At all doses studied, the mean antihypertensive effect was substantially smaller 24 hours after dosing than it was 6 hours after dosing". The Panel noted that Servier stated that its literature search had failed to find an acceptable study with lisinopril which met the criteria of being a prospective, placebo-controlled, crossover study. The Panel considered that the study by Salvetti *et al* appeared to meet Servier's criteria. The Panel considered that it was misleading not to use the data from this study in the bar chart. The quotation from the Physicians Desk Reference was at most qualitative and its use put lisinopril in a poor light. The use of the word "substantially" gave no indication as to what its trough/peak ratio might be. The Panel ruled there had been a breach of Clause 7.2 of the Code.

In relation to the allegations concerning the trough/peak ratios quoted for Coversyl, the Panel considered that Zeneca's reliance on the Zannad paper was subject to the criticisms raised by Servier. Zannad himself had commented that figures in excess of 50% had been reported elsewhere. Thus the lower figures for both products could be the result of unsatisfactory methodology. The Panel ruled that there had been no breach of the Code in this respect.

Complaint received **23 June 1995**

Case completed **23 August 1995**

CASE AUTH/313/6/95

GENERAL PRACTITIONER v MEMBER COMPANY

Disease area campaign to the public

A general practitioner complained about a disease area campaign to the public undertaken by a member company. The complainant had received a mailing from the company about the campaign. It was alleged that a telephone helpline constituted advertising a prescription only medicine to the public.

The Panel did not consider that the helpline was an advertisement to the public. The Panel did not consider that the helpline would encourage patients to ask their doctors to prescribe the company's product as there were a number of products available that met the criteria mentioned on the helpline. No breach of the Code was ruled.

COMPLAINT

A general practitioner complained about a "Dear Doctor" mailing giving details of a disease area campaign sponsored by a member company.

The "Dear Doctor" letter referred to a new educational initiative that aimed to increase the general level of awareness and knowledge of a disease area. The campaign theme (printed on the letter) would be used in newspaper advertisements and sports centre posters to highlight the availability of a free telephone helpline and an information booklet for sufferers. Advice leaflets would also be available from pharmacies and clinics. The letter concluded by stating that if doctors wanted to know more about the campaign they could contact the local company representative.

The complainant said that he had listened to the telephone helpline which advised people to go to see their general practitioner who would be able to give them the necessary treatment of a prescription only medicine.

The complainant could not remember having seen a similar notice by a pharmaceutical company which would increase GP's workload and drug costs and which related to prescription only medicines. The complainant had no objection to over-the-counter medicines being advertised but advertisements for prescription only medicines seemed to be unethical.

RESPONSE

The company submitted that the aim of the campaign was to provide helpful information to the public about care of a particular part of the body generally, as well as alerting people who suffered from some of the common associated problems. The company provided a number of materials and a transcript of the telephone helpline. The campaign had been devised to be in accordance with the Code and to encourage patients to take more interest and responsibility for their own healthcare. The materials contained therapeutic area information and advice. No reference was made to any prescription medicine.

The company submitted that the campaign was based on

research indicating that there was a large untreated group of patients who did not recognise that they had a particular condition or who had received ineffective therapy in the past which had led them to believe that their condition was untreatable. If untreated, infection could spread and it had been postulated that without an effective public health campaign, this level of ignorance would lead to an increased prevalence of infection.

The mailing in question was sent as a courtesy to all UK health professionals who might come into contact with patients sensitised by the campaign.

Following a request for further information, the company provided details about the products currently available and prescribable for the treatment of the conditions. This included one of its products.

RULING

The Panel noted that the telephone helpline opened by stating that it was expected that callers wanted to know something about particular conditions or to find out more about looking after a particular part of the body. The telephone helpline referred to the conditions stating that they rarely went away without treatment and then advised that doctors could now prescribe effective treatments. Reference was made to oral treatments and callers were advised that those who had tried various treatments in the past might find it was worth visiting their doctor for further advice. A free booklet was offered.

The Panel noted the requirements of Clause 20.1. It did not consider that the helpline was an advertisement to the general public for the company's product.

The Panel noted the requirements of Clause 20.2 that statements must not be made for the purpose of encouraging members of the public to ask their doctors to prescribe a specific medicine. It considered that the helpline would encourage callers to discuss treatments with their general practitioners and this might lead to patients asking their doctors for prescriptions. The Panel considered that this was not necessarily unacceptable. The patient would not be able to ask for any treatment by name as no names were given. There were a number of products other than the company's that were within the criteria referred to in the helpline. It was for the doctor to decide which product to prescribe. The Panel considered that on balance the content of the helpline was reasonable. The Panel therefore ruled no breach of Clauses 20.1 or 20.2 of the Code.

Complaint received **26 June 1995**

Case completed **8 August 1995**

CASE AUTH/314/6/95

CONSULTANT PHYSICIAN v MEMBER COMPANY

Mailing to doctors promoting a product

A consultant physician complained about a mailing sent by a member company on its product. The complainant alleged that a statement describing certain features of the product and a reference to guidelines of a particular society were misleading. A chart which failed to state a disadvantage with the product and a claim referring to the effects of the product which appeared beneath the chart were also alleged to be misleading.

The Panel did not accept that the material was misleading as alleged and ruled no breach of the Code.

A consultant physician made a number of allegations about a mailing consisting of a "Dear Doctor" letter and a brochure sent by a member company as follows:

1 Front cover of brochure

COMPLAINT

The complainant alleged that a statement which described certain features of the product was misleading.

RESPONSE

The company pointed out that the complainant had misquoted the statement. It submitted that the statement indicated that the product offered limited improvement, the nature and extent of which was elaborated in the text.

RULING

The Panel noted that the complainant had misquoted the statement on the front of the brochure. The statement was not saying that the product was the only product of this nature. The Panel did not accept that the statement was misleading and therefore ruled no breach of the Code.

2 References to guidelines of a society

COMPLAINT

The complainant alleged that it was misleading to refer to particular guidelines to encourage doctors to prescribe the product as the guidelines only referred to products with certain features and not the type of product in question.

RESPONSE

The company submitted that given the type of product in question and the content of the guidelines it was entirely appropriate to refer to them.

RULING

The Panel noted that the guidelines had been quoted correctly in the material and that the quotation could only be in breach of the Code if its presence was misleading. The Panel considered that as the product did have the features referred to in the guidelines it was not misleading to include the quotation and therefore ruled no breach of the Code.

3 Chart comparing certain features of different types of products

COMPLAINT

The complainant alleged that the chart failed to make the point that the product and similar products were likely to have a substantial disadvantage over other types of products shown in the chart. The failure to state the disadvantages as well as the advantages was alleged to be misleading. The complainant also alleged that a claim appearing beneath the chart referring to the effects of the product was misleading and illogical.

RESPONSE

The company pointed out that full prescribing information was supplied which included all the relevant information on side effects, precautions etc. The company provided clinical evidence with regard to the disadvantage noted by the complainant. The company provided a detailed response regarding the effects of the product.

RULING

The Panel considered that in the context of the chart it was not misleading to omit information relating to the disadvantage noted by the complainant. The page did not state that there were no side effects associated with the product. There was no mention of side effects at all. The prescribing physician would consult the data sheet or prescribing information which gave details of side effects before deciding whether to prescribe the product. The Panel considered that in the circumstances the chart was not misleading and ruled no breach of the Code. The Panel accepted the submission with regard to the claim and ruled no breach of the Code.

Complaint received **26 June 1995**

Case completed **23 August 1995**

CASE AUTH/317/7/95

ALLERGAN v NON MEMBER COMPANY

Exhibition stand at a meeting of a society

Allergan alleged that an exhibition panel promoted a non member's product prior to the grant of a licence. The Panel ruled no breach of the Code as the exhibition panel merely described an area of research by the company.

COMPLAINT

Allergan sent a photograph taken of an exhibition panel on the stand of a non member company at a meeting of a society. The photograph of the stand referred to a class of products and a disease area.

Allergan alleged that the stand was clearly an attempt to promote a product prior to the grant of a licence. A breach of Clause 3.1 of the Code was alleged.

RESPONSE

The company concerned although not a member of the ABPI had nevertheless agreed to comply with the Code. The company submitted that it had a long standing commitment in the disease area and over recent years published research data had been produced by both independent research centres and pharmaceutical companies to suggest that the class of products referred to on the panel might become a therapeutic option in the treatment of a particular disease.

The company submitted that the panel at issue addressed this important research data and referred to a class effect. Nowhere was mentioned a specific entity or a product and nor did the company state that a product was in development or likely to be available.

In response to an enquiry from the Authority for further information about the company's role and research into the area further details were provided including information about product licence applications.

The only information that appeared on the company's stand relating to the class of products in the disease area was on the panel itself. The main part of the exhibition stand had been devoted to other products. The company provided copies of the correspondence with Allergan about the matter.

RULING

The Panel noted that the company was researching into the class of products named on the stand and that product licence applications had been submitted. The Panel considered that the text on the exhibition panel was a general statement. There was no stated or implied reference to the fact that the company had a product in the area. The Panel did not accept that the statement was a claim for a product without a product licence. It was merely a description of an area of research by the company. The Panel therefore ruled no breach of Clause 3.1 of the Code.

Complaint received **11 July 1995**

Case completed **21 August 1995**

CASE AUTH/320/7/95

FHSA MEDICAL DIRECTOR v FISONS

Letter from a hospital consultant advocating use of Aerocrom and Aerocrom Syncroner

The medical director of a family health services authority complained that a pharmaceutical company appeared to have had a part in the production of a letter sent to doctors by a local consultant which advocated the use of branded products.

The area sales manager for Fisons had arranged for the reproduction and posting of the letter which referred favourably to Aerocrom and Aerocrom Syncroner. There had been a failure on the part of the area manager to comply with the Code and a breach was ruled.

COMPLAINT

The medical director of a family health services authority complained about a letter distributed by a local chest physician advocating the use of a branded product. The complainant said that the style of the letter and the fact that the brand name was highlighted in bold capital letters seemed to suggest that the manufacturing company had a considerable part to play in the production of the letter. The complainant considered this to be unprofessional, unethical and in breach of the Code.

As the letter in question referred to Aerocrom and Aerocrom Syncroner, the matter was taken up with Fisons plc, Pharmaceutical Division.

RESPONSE

Fisons said that what appeared to have happened was that the consultant concerned decided that he wished to write a letter to local general practitioners highlighting the problems of compliance in asthma. Included in the letter was reference to one of Fisons' products, Aerocrom, which might be of use in patients who failed to comply with regular preventative asthmatic therapy. The local area sales manager had been in contact with the consultant concerned and had arranged for the photocopying of the letter and its postage. Such action was in breach of Fisons' written instructions and standard procedures. The area sales manager concerned had been severely disciplined. The company accepted that a breach of the Code had occurred and this was a matter of regret.

RULING

The Panel noted that the letter, which was on university notepaper, referred to non compliance with anti-inflammatories as one of the greatest challenges to the successful management of asthma. It also referred to the use of combination therapy and recommended the use of Aerocrom if this approach was to be used. The words Aerocrom and Aerocrom Syncroner were in capital letters.

The Panel considered that the fact that the letter had been reproduced and posted at Fisons' expense meant that it had to be regarded as promotional material subject to the Code. In consequence, certain requirements of the Code had not been met, these being the requirement for the inclusion of the prescribing information and the requirement to certify promotional material. In addition, the letter might well be regarded as being disguised promotion. The Panel considered that the area sales manager had failed to comply with the relevant requirements of the Code and ruled that there had been a breach of Clause 15.2.

Complaint received **20 July 1995**

Case completed **16 August 1995**

CASE AUTH/325/8/95

COMMUNITY HEALTH COUNCIL CHIEF OFFICER v NON MEMBER COMPANY

Video on general practice income generation

The chief officer to a community health council complained about a video produced by a non member company which illustrated ways in which general practitioners could increase their practice income by methods which did not produce any significant benefits for patients.

The Panel took the view that if there were unsatisfactory features of the system for remunerating general practitioners then the blame lay with those who allowed them to remain and not with those who drew attention to them. No breach of the Code was ruled.

COMPLAINT

The chief officer to a community health council complained about a video produced by a company which, although not a member of the ABPI, had nonetheless agreed to comply with the Code. The complainant said that a representative of the company was showing the video in question to local general practitioners and he assumed that it would also be shown in other parts of the country.

A particular concern that had been expressed to him was

that the video illustrated ways in which general practitioners could increase their practice income using methods which did not produce any significant benefits for patients. The concerned individual who contacted him had watched the video and felt that it was extremely unethical in this regard, even though a statement was included that the opinions of the general practitioners shown were "not those of the company".

RESPONSE

The company concerned said that the video concerned had been commissioned in order to provide an information and education service in response to an increasing number of requests from general practitioners for such subject matter. The increasing market forces within the NHS, exemplified by the need for more financial skills by doctors, had led to enormous interest in such topics. The video was, indeed, being shown across the country and by virtue of its style, content and non promotional nature, was proving to be very popular with general practitioners. Contrary to the views expressed in the complaint, the participants stressed (on a number of occasions) the improvement to patient services which would occur as a result of running the practice on profitable lines.

RULING

The Panel decided that the video as a whole came within the scope of the Code. In this particular instance this was clear from the fact that the video commenced and ended with promotional material for one of the company's products but the Panel considered that any such video being shown by representatives would come within the scope of the Code whether it referred to medicines or not.

The Panel noted that the video was principally concerned with ways in which doctors could increase their income and considered that some of these might be thought by the public at large to be of a somewhat dubious nature. The Panel took the view, however, that if there were unsatisfactory aspects of the system for remunerating general practitioners under the NHS, then the blame lay with those who allowed them to remain and not with those who revealed them. It was considered that the video was not unacceptable and the Panel ruled that there had been no breach of the Code.

Complaint received **9 August 1995**

Case completed **12 September 1995**

CASE AUTH/326/8/95

BOEHRINGER MANNHEIM v BOEHRINGER INGELHEIM

Promotion of Bonefos - various allegations

Boehringer Mannheim complained about a number of items used in the promotion of Bonefos (sodium clodronate) by Boehringer Ingelheim.

The Panel ruled that a claim "Delivering the right amount of oral clodronate" and a quotation "The dose required for long term treatment is 1600mg daily. Smaller doses give less complete effects..." could not be substantiated as Boehringer Mannheim's product Loron 520 was licensed at a daily dose of oral clodronate of 1040mg for the same indications as Bonefos at a daily dose of clodronate of 1600mg. The Panel ruled that the material was inaccurate and disparaging of Loron as it gave the impression that doses of oral clodronate under 1600mg were not adequate treatment and this was not true. An allegation that two claims referring to clinical trials implied that Bonefos had some special merit or property compared to Loron was not accepted by the Panel and no breach was ruled.

Boehringer Mannheim UK (Pharmaceuticals) Limited complained about a number of promotional items issued by Boehringer Ingelheim Limited in relation to the promotion of Bonefos 800mg (sodium clodronate). The items at issue were: a representatives' detail aid entitled "When Life Isn't Fair" (ref HD1444/Jun95), a dosage card (ref HD1445/Jun95), an introductory letter to hospital pharmacists (ref HD1455/Jun95) which was accompanied by a booklet headed "Oral Bonefos 1600mg information for pharmacists" (ref HD1460/Jun95), two clinicians' leave pieces, one entitled "Breast cancer clinical trial summary" (ref HD1461/Jun 95) and the other entitled "Multiple myeloma clinical trial summary" (ref HD1462/Jun95).

Boehringer Mannheim used the representative detail aid "When Life Isn't Fair" (ref HD1444/Jun 1995) as the basis for its complaints. The Panel decided that there were, in effect, three complaints which were considered as follows:

1 Failure to substantiate

COMPLAINT

Boehringer Mannheim alleged that the a claim "Delivering the right amount of oral clodronate" and a quotation "The dose required for long term treatment is 1600mg daily. Smaller doses give less complete effects..." were in breach of Clause 7.4 as they had not been substantiated.

Boehringer Mannheim had previously asked Boehringer Ingelheim to supply the data showing that treatment with 1040 mg sodium clodronate in the form of Loron 520 was not delivering the right amount of sodium clodronate, was not an effective long term dose and was less effective than 1600 mg sodium clodronate daily provided as Bonefos.

RESPONSE

Boehringer Ingelheim submitted that the claim and the

quotation referred to sodium clodronate in the Bonefos formulation. The double page upon which they appeared was headed "New Bonefos 800mg tablets" and these delivered the clinically proven dose of 1600mg for which the product was licensed. The quotation "The dose required for long term treatment is 1600mg daily. Smaller doses give less complete effects.." was taken from a review article by Kanis *et al* published in September 1994 in the International Journal of Oncology. The article was received by the Journal for review on 27 May 1994, four months after the launch of Loron 520. Boehringer Ingelheim also referred to a paper by O'Rourke *et al* published in 1995 which concluded that as there was no significant difference between 1600mg and 3200mg doses in terms of efficacy at 4 weeks, 1600mg/day of oral clodronate could be recommended for long term treatment.

RULING

The Panel considered that as both the claim and the quotation appeared in Boehringer Ingelheim's promotional material it was for that company to substantiate them and not, as Boehringer Ingelheim had written to Boehringer Mannheim, for Boehringer Mannheim to substantiate them.

The Panel noted that the quotation was taken from the Kanis review which referenced the quotation to a thesis by O'Rourke 1994. The Panel noted that the O'Rourke 1995 study cited by Boehringer Ingelheim had been carried out on placebo and doses of 400mg, 1600mg or 3200mg clodronate daily for 4 weeks. Loron 520 had not been used in the study. It further noted that the study concluded that 1600mg per day was appropriate for long term use.

The Panel did not accept the submission that the statements referred specifically to the Bonefos formulation because the double page was headed "New Bonefos 800mg tablets". The statements as presented referred to oral clodronate. The Panel considered that as Loron 520 was licensed at a daily dose of oral clodronate of 1040mg for the same indications as Bonefos 800mg at a daily dose of 1600 mg of oral clodronate, neither the claim nor the quotation could be substantiated. The Panel therefore ruled a breach of Clause 7.4 of the Code.

2 Claims that a minimum dose of 1600mg sodium clodronate daily is required to produce an effective clinical response

COMPLAINT

Boehringer Mannheim drew attention to a series of claims as follows:

a) "Delivering the right amount of oral clodronate"

"The dose required for long term treatment is 1600mg daily. Smaller doses give less complete effects...."

b) "Why settle for less?"

"Why allow your patients to settle for less?"

"Why allow patients with metastatic bone disease to settle for less?"

"New Bonefos 800mg. Should patients with metastatic bone disease settle for any less?" [Note: the Panel could not find this claim in the detail aid "When Life Isn't Fair" which had been used by Boehringer Mannheim as the basis of its complaints. A similar claim appeared in the "Dear Pharmacist" letter]

c) "Two 800mg Bonefos tablets deliver the lowest dose producing the optimum response" followed by "Smaller doses have less complete effects"

Boehringer Mannheim pointed out that Loron 520 was widely prescribed for the same indications as Bonefos at a licensed dose of 1040mg daily. The British National Formulary stated that "Due to greater bioavailability one Loron 520 tablet (520mg) is equivalent to two Loron capsules (2 x 400mg).

Boehringer Mannheim alleged that the above claims were in breach of Clauses 7.2, 7.3, 8.1 and 8.2 as they implied that Loron 520 which was used in a dosage less than 1600mg daily was less effective. The implication was that the 1600mg dosage of sodium clodronate was the only right dose. This was not accurate, not based on an up-to-date evaluation of all the evidence and was therefore misleading. The claims were not capable of substantiation since they referred to sodium clodronate and were not restricted to Bonefos. The claims were disparaging as they implied that Loron 520 used at 1040mg per day was not providing the correct amount of sodium clodronate.

RESPONSE

Boehringer Ingelheim referred to its response in 1 above regarding the claims at issue in 2(a) which it submitted were substantiated by a published quotation from the review by Kanis *et al* and further supported by the study by O'Rourke *et al* 1995.

With regard with the claims in 2(b) above with the central theme "Why settle for less?", Boehringer Ingelheim said that this was a rhetorical question. It was a challenge to doctors to use clodronate for their patients in the circumstances described eg metastatic breast cancer. A study by Patterson *et al*, used as one of the references in respect of breast cancer, compared 1600mg clodronate daily with placebo and showed the clinical benefit of treating these patients with clodronate. It was clear that by allowing patients to settle for less, ie no treatment, they were denied significant clinical benefit. Four other references were provided to support the submission. It was also important that the full dose of 1600mg Bonefos daily was given rather than 800mg for which there was some evidence of prescribing.

Boehringer Ingelheim submitted that its response to the claims in 2(c) above was covered by its response in 1 above.

Boehringer Ingelheim pointed out that all the claims were fully supportable by published evidence and as there was no mention of other companies' products etc there was no disparagement.

RULING

The Panel examined the detail aid and considered that it gave the general impression that doses of sodium clodronate under 1600mg per day would not be adequate treatment and this was not true as Loron 520 was licensed

at a lower daily dose of 1040mg sodium clodronate. The Panel also considered the detail aid disparaged Loron 520. It did not accept the submission that references to "Why settle for less" referred to no treatment or to treatment with 800mg Bonefos per day. The Panel ruled breaches of Clauses 7.2 and 8.1 of the Code.

3 Claims referring to clinical trials

COMPLAINT

Boehringer Mannheim alleged that two claims "Proven effective in clinical trials - 1600mg Bonefos" and "A body of evidence supports use of oral Bonefos 1600mg daily" were in breach of Clause 7.8 of the Code. The claims implied that Bonefos had some special merit or property compared to Loron and this was not so. Boehringer Mannheim pointed out that the clinical study programme was conducted with capsules supplied by licensors of Bonefos, Leiras OY of Finland, which were of a different formulation to Bonefos capsules marketed in the UK and were bioequivalent to Loron capsules marketed in the UK.

RESPONSE

Boehringer Ingelheim submitted that both the claims were true and references to support them were given in the promotional piece. There was no exaggerated claim nor claim of special merit. The claims for Bonefos were in accordance with the product licence and supported by published clinical data. The clinical trials had been carried out on capsules supplied by Leiras which were an earlier formulation of sodium clodronate. The present formulation of Bonefos capsules was bioequivalent to the earlier form.

RULING

The Panel did not accept the allegation that the claims implied that Bonefos had some special merit or property compared to Loron. The Panel considered that there was no comparative aspect to the claims at issue and no breach was ruled.

The Panel considered, however, that the claim "Proven effective in clinical trials - 1600mg Bonefos" should be substantiated by data from clinical trials on the product being promoted, Bonefos 1600mg, and this did not appear to be so. It was not sufficient to support the claim as worded with data on another version of the product albeit bioequivalent to the product being promoted. This had been mentioned in the complaint but had not been formally alleged. The Panel requested that both parties should be advised of its views.

Complaint received 14 August 1995

Case completed 2 October 1995

CASE AUTH/327/8/95

DIRECTOR OF PHARMACY SERVICES v MEMBER COMPANY

Purchasing agreement for a product

A director of pharmacy services was concerned that a member company's request for information on treatment as part of a pricing agreement was contrary to Executive Letter EL (94) 94, a policy letter issued by the NHS Executive. The complainant was also concerned about the use of price reduction to influence clinical judgement.

The Panel appreciated that some people might be concerned about the pricing arrangements but did not consider that in the circumstances it was unreasonable to ask for details about the hospital policy/protocol. No breach of the Code was ruled.

COMPLAINT

A hospital director of pharmacy services complained about correspondence consisting of a letter and a price agreement form that he had received from a member company regarding purchasing arrangements for one of its products. The complainant was concerned that the request from the company for information on treatment as part of the company's price agreement was contrary to Executive Letter EL (94) 94 (a letter from the NHS Executive to NHS Executive Regional Directors, District General Managers, FHSA General Managers, NHS Trust Chief Executives and General Managers of Directly Managed Units relating to commercial approaches to the NHS regarding disease management packages). Secondly, the complainant was concerned about the effects of the pharmaceutical industry using a "carrot" of price reduction to influence clinical judgement on the wider use of therapy or amendment to existing guidelines.

RESPONSE

The company submitted that it was faced with doctors amending their treatment protocols to take account of recent evidence but finding that budgetary constraints were affecting their wish to increase use of the product. Accordingly the company sought to accommodate the purchasers by introducing a pricing policy. The agreement was a response to an evidence based change in clinical practice and not an attempt to generate greater prescribing. The agreement was commercial and not promotional. The request on the price agreement form to indicate what treatment protocol would apply was included merely to confirm that the product had been included in a standard treatment protocol thus forming the basis of the need for an agreement on the price and constituting an assurance to the company in advance of actual sales.

With regard to the complainant's reference to EL (94) 94, which concerned itself with commercial approaches to the NHS regarding disease management packages, the company submitted that neither the covering letter nor the price agreement related to a disease management package but to a means whereby a discount could be negotiated by hospitals according to usage. It was specific to the product without associated treatments for the condition. NHS data on prescribing was confidential with respect to patients but not to practice. The company submitted that specific information on the treatment protocol was not a breach of confidentiality, such protocols being common in the literature and relevant to evidence based prescribing. The company drew attention to paragraph 9 of EL (94) 94 which excluded the established practice of negotiating discounts on straightforward purchases of medicines from the contents of the letter.

RULING

The Panel noted that EL (94) 94 was concerned with disease management packages. The issues raised in EL (94) 94 were not directly the concern of the Panel which was only concerned with the requirements of the Code. The Panel noted, however, that EL (94) 94 included a section on confidentiality which stated that NHS data, including that on prescribing was confidential. The Panel queried whether disclosure of a hospital treatment protocol would come within EL (94) 94 at all.

The Panel considered that in an ideal world clinical judgement would not be influenced by financial factors but it had to be accepted that financial considerations were amongst those that were in practice taken into account.

The Panel appreciated that some people might be concerned about the pricing arrangements but did not consider that in the circumstances it was unreasonable to ask for details about the hospital treatment policy/protocol in the price agreement. The Panel did not consider that the arrangements constituted an unacceptable inducement to prescribe the product contrary to Clause 18 of the Code and neither did they fail to recognise the special nature of medicines. The Panel therefore ruled no breach of the Code.

Complaint received **16 August 1995**

Case completed **20 September 1995**

CASE AUTH/330/9/95

CONSULTANT PHYSICIAN AND ENDOCRINOLOGIST v BOEHRINGER INGELHEIM

Conduct of a representative - use of a gift to gain an interview

A consultant physician and endocrinologist complained that a representative from Boehringer Ingelheim had used a gift to gain a meeting with the complainant.

The Panel ruled a breach of the Code as it considered that the representative had used the delivery of the gift as an inducement to gain an interview, albeit unwittingly.

COMPLAINT

A consultant physician and endocrinologist complained about the conduct of a representative from Boehringer Ingelheim Limited.

The complainant explained that he had received in the post a mailing offering a gift. The complainant had completed a form which had been returned to the company. Following this a representative from the company had contacted the complainant's secretary and had stated that the gift would not be available unless the complainant was prepared to meet with the representative. The complainant pointed out that the gift was unsolicited and that any linkage of it with arranging an appointment was in breach of Clause 15.3 of the Code.

RESPONSE

Boehringer Ingelheim submitted that it had discussed the matter with the representative in question, who had denied stating that the gift would not be available unless the complainant was prepared to meet with the representative. The representative stated that he had not yet met the complainant and had asked the secretary how he should go about making an appointment. The representative had therefore written his telephone number on the card which the complainant had used to request the gift. The card had been left with the secretary so that she or the complainant could telephone to arrange an appointment.

Boehringer Ingelheim acknowledged that unfortunately the representative had neglected to leave the gift for the complainant and it therefore appeared that its provision was conditional upon a meeting. The company submitted that it was clear how this misunderstanding had arisen as, on the one hand, the representative was seeking a first meeting with the complainant, and on the other hand, he had failed to leave the requested gift.

The company accepted that the representative had acted carelessly in the matter by not leaving the gift but he had not intended to create the impression that the provision of the gift was conditional upon meeting with the complainant.

RULING

The Panel observed that, as with all cases of this nature, it was difficult to be certain of what had been said and whether what had been said was acceptable in relation to the Code.

There appeared to be some conflict of evidence in this particular case. The Panel considered, however, that by putting his name and telephone number on the reply paid card which had been completed by the complainant to request the gift, the representative had given the complainant the impression that the gift would only be delivered to the complainant in person. The representative had used the delivery of the gift as an inducement to gain an interview, albeit unwittingly. The Panel therefore ruled a breach of Clause 15.3 of the Code.

Complaint received **6 September 1995**

Case completed **29 September 1995**

CASE AUTH/331/9/95

GP v MEMBER COMPANY

Photograph in a mailing alleged to be inappropriate

A general practitioner alleged that a photograph in a mailing of a model wearing see-through clothing was inappropriate.

The Panel did not consider that the photograph was unacceptable and no breach was ruled.

COMPLAINT

A general practitioner complained about a mailing sent by a member company to general practitioners. The complainant alleged that the use of a photograph of a model with see-through clothing was not appropriate for a pharmaceutical product and was in breach of Clause 9.1 of the Code.

RESPONSE

The company submitted that the photograph depicted a light hearted scene and the model was used in order to reflect the promotional message for the product. The company accepted that the lower part of the model's dress was translucent. It was not the company's intention nor its belief that this in itself attracted attention to the advertisement.

RULING

The Panel examined the advertisement and noted that the model was wearing a translucent dress. The Panel noted that taste was a subjective matter but did not consider that the photograph was in bad taste or that it was inappropriate. Nor did it fail to recognise the special nature of medicines or the professional standing of the audience. The photograph of the model did not attact attention to the advertisement in an unacceptable way. The Panel ruled no breach of the Code.

Complaint received **6 September 1995**

Case completed **9 October 1995**

CODE OF PRACTICE REVIEW - NOVEMBER 1995

CASES

270/2/95 285/4/95 286/4/95	SmithKline Beecham } GP } v Wellcome SmithKline Beecham }	Promotion of Zovirax }Valtrex Video }	Breach 4.1, 7.2, 8.1	Appeal by respondent
296/5/95	GP v Glaxo	Booklet on peptic ulcer disease not up to date	Breach 7.2	Appeal by respondent
302/5/95 306/5/95	Glaxo v Lederle Glaxo v SmithKline Beecham	Mailing on Zoton - various allegations	Breach 7.2,	No appeal
303/5/95	Director v Non member company	Drug & Therapeutics Bulletin article criticising the promotion of a product	No breach	No appeal
304/5/95	Director v Boehringer Mannheim	Claims in Eucardic promotional material regarding scope of therapy and unwanted effects	Breach 7.2	No appeal
309/6/95 310/6/95	GP chairman of MAAG v Boehringer Ingelheim GP chairman of MAAG v Innovex	}Conduct of a nurse }adviser }	Breach 15.2	No appeal
312/6/95	Zeneca v Servier	Leaflet on Coversyl - misleading presentation of data	Breach 7.2	No appeal
313/6/95	GP v Member company	Disease area campaign to the public	No breach	No appeal
314/6/95	Consultant physician v Member company	Mailing to doctors	No breach	No appeal
317/7/95	Allergan v Non member company	Exhibition stand at a meeting of a society	No breach	No appeal
320/7/95	FHSA medical director v Fisons	Letter from consultant advocating use of Aerocrom and Aerocrom Syncroner	Breach 15.2	No appeal
325/8/95	Community health council chief officer v Non member company	Video on general practice income generation	No breach	No appeal
326/8/95	Beohringer Mannheim v Boehringer Ingelheim	Promotion of Bonefos - various allegations	Breach 7.2, 7.4, 8.1	No appeal
327/8/95	Director of pharmacy services v Member company	Purchasing agreement for a product	No breach	No appeal
330/9/95	Consultant physician and endocrinologist v Boehringer Ingelheim	Conduct of representative - use of a gift to gain an interview	Breach 15.3	No appeal
331/9/95	GP v Member company	Photograph in a mailing alleged to be inappropriate	No breach	No appeal

PRESCRIPTION MEDICINES
CODE OF PRACTICE AUTHORITY

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

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

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

It covers:

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

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

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

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