PRESCRIPTION MEDICINES
CODE OF PRACTICE AUTHORITY

Quarterly Review

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QUARTERLY REVIEW JULY 1993

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QUARTERLY REVIEW

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This is the first issue of the Prescription Medicines Code of Practice Authority Quarterly Review.

Case Reports

Each issue of the Review will include reports of cases settled by the Prescription Medicines Code of Practice Authority (PMCPA) and the first of these case reports are included in this issue. There are still a few cases remaining from 1992 which are being dealt with under the old procedure and reports of these will be issued in due course.

Progress

The Prescription Medicines Code of Practice Authority started work on 1 January 1993. At the same time the new Eighth Edition of the Code of Practice for the Pharmaceutical Industry came into operation and the new procedures for dealing with complaints were introduced.

By the end of June, forty–five complaints were in hand leading to fifty–one cases, of which thirty–four had been completed. This compares with seventy–nine complaints in the whole of 1992.

The Code of Practice Panel

Under the new procedure, the Code of Practice Panel, which is comprised of the Director, Secretary and Deputy Secretary of the PMCPA, considers all complaints made under the Code. The Panel can meet as required at short notice and this flexibility is helping to speed up the processing of complaints. The Panel has already met thirty–three times.

The Code of Practice Appeal Board

The Code of Practice Appeal Board has met four times so far this year but has largely been completing cases remaining from 1992 which are being dealt with under the old complaints procedure. It has, however, heard one appeal from a decision of the Code of Practice Panel under the new procedure. This was the first ever from a complainant in relation to a rejected allegation. Under the new procedure complainants have the right of appeal if their complaints are rejected by the Code of Practice Panel. The report for this case is attached (AUTH/9/2/93).

Four companies ruled by the Code of Practice Panel to be in breach of the Code have given notice that they wish to appeal to the Code of Practice Appeal Board in relation to one or more of the matters on which they were ruled to be in breach and these appeals will be heard shortly.

The Code of Practice Appeal Board has also received reports on all cases settled by the Code of Practice Panel and has advised the Panel on a number of matters relating to procedure.

The membership of the Appeal Board is essentially that of the previous Code of Practice Committee but augmented by two new independent members. These are Mrs Linda Stone, a pharmacist and a Past President of the Royal Pharmaceutical Society of Great Britain, and Mr Nick Hough, also a pharmacist and Director of the Medicines Resource Centre (MeReC) in Liverpool. There are thus now five independent members in addition to the Chairman, Mr Philip Cox QC, the others being Dr D J D Farrow, Dr E B Lewis and Dr M A Wilson.

EC Directive on the Advertising of Medicinal Products for Human Use

The EC Council Directive on the advertising of medicinal products for human use (92/28/EEC) was due to be implemented by member states by 1 January 1993, but few did so. The United Kingdom has not so far done so.

Current information is that the Medicines Control Agency intends to reconsult on the question of the implementation of the Directive in the UK and that the document setting out its proposals will be out at the end of July or the beginning of August. The Association of the British Pharmaceutical Industry will circulate the consultative document to its members when it comes to hand.

When the Code of Practice for the Pharmaceutical Industry was redrafted in 1992, it was done with a view to incorporating in it all of the requirements of the Directive in the form which it was understood they would take when implemented in the UK. That still remains the position and it is anticipated that only minor changes to the Eighth Edition will prove to be necessary. It is hoped to put proposals for any necessary changes to the Half–Yearly General Meeting of the ABPI in October, but that will only be possible if final details of the mode of implementation in the UK are available well ahead of that time.

Signatories

Clause 14.2 of the Code of Practice now requires companies to notify the names of the signatories responsible for the certification of their promotional material to the PMCPA as well as to the Pharmacovigilance Business Unit of the Medicines Control Agency.

Those companies which have not yet notified their signatories to the PMCPA are asked to do so as soon as possible.

Legibility of Prescribing Information:

There are continuing problems with prescribing information in advertising not being readily readable. Factors to be borne in mind are type size and style, distance between the lines, excessive line length (the width of a journal page, for example) and poor contrast. The supplementary information to Clause 4.1 of the Code gives further guidance.

Companies are asked to examine the prescribing information in all of their advertisements to ensure that it can easily be read.

Seminars

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

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

Wednesday, 8 July (fully booked)
Wednesday, 15 September (only a few places left)
Monday, 4 October
Wednesday, 10 November
Friday, 10 December

Seminars can also be arranged for individual companies.

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

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CASE REPORTS
JULY 1993

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

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AUTH/3/1/93

KABI PHARMACIA LTD V CLINTEC NUTRITION LTD

Allegations concerning claims & failure to provide substantiating data in relation to a journal advertisement and detail aid on Ivelip

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

Kabi Pharmacia Ltd complained about a journal advertisement which appeared in "The British Journal of Intensive Care", December 1992, and a detail aid on Ivelip issued by Clintec Nutrition Ltd. It was alleged that claims appearing in both the journal advertisement and detail aid that Ivelip was "specifically formulated for improved stability" and claims in the detail aid that "sodium oleate has been added to Ivelip to improve the stability of the emulsion" and "Small particle size and the addition of sodium oleate for improved stability", were in breach of Clauses 5.1 as there was no evidence for these claims, 5.2 in implying a special merit, 5.5 in using a hanging comparative and 6.1 in that the complainant alleged that the only inference from "improved" was that it was an improvement on Kabi Pharmacia's product Intralipid. A breach of Clause 4.4 was also alleged as Clintec Nutrition had refused to respond with substantiating data for these claims when requested by the Medical Director of Kabi Pharmacia.

Clintec Nutrition Ltd although not a member of the ABPI had agreed to comply with the Code. The company submitted that the objective of the development of Ivelip was to improve the stability of the lipid emulsion per se by decreasing the droplet size and increasing electrostatic force using a co-emulsifier (sodium oleate). This was in accordance with the general principles governing lipid emulsion stability and with a background of twenty years of research and development in the field. Reference was made to the results of comparative

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stability studies which showed improved stability of Ivelip and admixtures manufactured with Ivelip.

The company explained that it always responded to requests for information of any kind to clinicians making their requests to assist them in the safe treatment of their patients. It did not consider that the request from Kabi Pharmacia fell into that category.

The Code of Practice Panel noted in relation to the claim for Ivelip as "specifically formulated for improved stability" that it was axiomatic for any product that it was formulated in order to achieve a desired property or properties. Furthermore, there was evidence to show that Ivelip did offer improved stability as was implied in the phrase. The Panel did not accept that in the context of the advertisement the word "improved" was a hanging comparison. With regard to the references to the small particle size and the addition of sodium oleate, the Panel considered that it was accepted scientific opinion that these factors would be favourable to improved stability.

The Panel therefore ruled there was no breach of the Code with regard to the allegations concerning the claims for improved stability.

The Panel noted that the provisions of Clause 4.4 of the Code, which required substantiation of information in advertising to be provided without delay to members of the medical profession on request, applied whether the member of the medical profession requesting that information was employed by a competitor company or not. The Panel therefore ruled that there was a breach of Clause 4.4 as Clintec Nutrition had failed to provide substantiation of the claims when requested by a member of the medical profession.

[Under the Eighth Edition of the Code of 1 January 1993, these provisions have been expanded to apply to requests for substantiation from members of the health professions and to administrative staff in hospitals and health authorities and the like and not just to medical and dental practitioners (Clause 7.4 of the Eighth Edition refers)].

Complaint received 20 January 1993

Case completed 8 March 1993

AUTH/5/1/93

PHARMACEUTICAL ADVISER WITH A FAMILY HEALTH SERVICES AUTHORITY v ASHBOURNE PHARMACEUTICALS LTD

Misleading information in document sent to dispensing doctors

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

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A pharmaceutical adviser with a family health services authority complained about a document called an "Aide Memoire" sent by Ashbourne Pharmaceuticals Ltd to dispensing doctor customers. The "Aide Memoire" consisted of a price list with a section providing general information relating to the prescription of Ashbourne Products.

There were three heads of complaint. That a paragraph in the letter referring to EC Directives as requiring "all products, including generics, to be packed in original pack multiples of 28, and contain a patient information leaflet" was incorrect in breach of Clauses 4.3, 4.4 and 5.1 of the Code.

That a paragraph in the letter ....."An Ashbourne Brand Name Prescription, for an original pack of a continuously recognisable and compliance ensuring product (which in many key therapeutic groups actually costs less than a Tariff generic) not only saves valuable NHS funds but also contributes positively to the physicians control of personal PACT cost." was similarly in breach of Clauses 4.3, 4.4 and 5.1 of the Code. It was alleged to be misleading to imply that prescribing Ashbourne products would save the NHS money when most Ashbourne products were more expensive than their equivalent generics, that the term "compliance ensuring" would be difficult to substantiate and that it was misleading to state that Ashbourne products cost less than the Tariff price in "many" key therapeutic groups, when the price list showed only four products at less than Tariff price.

Finally, the complainant was unsure whether it was fair for Ashbourne to say, as stated in the letter, that there was no likelihood that their products varied in size, shape and colour as the company bought their products from other generic manufacturers. Further, that it implied that the use of generic drugs might not provide reliable bio-availability which was misleading and disparaging of competitor products. Overall, the complainant alleged that the "Aide Memoire" was in breach of Clause 2 of the Code as it reduced confidence in the pharmaceutical industry as prohibited under that Clause.

Ashbourne Pharmaceuticals Ltd although not a member of the ABPI had agreed to comply with the Code. The company accepted that there was no EC Directive requiring all products to be packed in multiples of 28 and explained that there had been a misunderstanding on its part. The company stated that in an overall comparison between the costs of Ashbourne brands, other brands and some generics, Ashbourne products represented for the most part a considerable saving to the NHS. There were six Ashbourne products in four therapeutic groups which were priced less than the Tariff generics and the labelling code on the "Aide Memoire" alongside each of the Ashbourne products clearly showed which products were less than or equal to the Tariff prices. It was acknowledged that it would be difficult to substantiate the claim "compliance ensuring", but the company pointed out that it had received no complaints with regard to patient compliance and its products.

The company objected to the suggestion that any statement in the letter implied that the use of generics would not provide reliable bioavailability. All Ashbourne products were rigorously controlled as to size, shape, colour and continued quality.

First, the Code of Practice Panel decided that the "Aide Memoire" was subject to the Code as it was a promotional item which contained more information than that permitted in a trade advertisement exempt from the conditions of the Code.

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The Panel ruled there was a breach of Clause 4.3 of the Code which requires all information to be accurate and not misleading, due to the inaccurate statement in the "Aide Memoire" that EC Directives required all products, including generics, to be packed in original pack multiples of 28.

With regard to the second matter of complaint, the Panel considered that the paragraph as a whole was misleading and ruled there was a further breach of Clause 4.3 of the Code. Prescribing Ashbourne brands would not be cheaper than prescribing generics in most instances. Further, it was misleading to state than in "many" key therapeutic groups the Ashbourne products cost less than the Tariff generic. This was the case in only four of the therapeutic groups listed out of a total of twenty in the "Aide Memoire" and even then not all the products within each of the four therapeutic groups cost less than the Tariff generic. It was also misleading to claim that Ashbourne brand name prescriptions were "compliance ensuring". It might be possible to assist patient compliance but not to ensure it.

With regard to the third matter, the Panel did not accept the implication put on the paragraph by the complainant. The company indicated that it took steps to ensure a constant uniform product and no evidence had been put forward by the complainant to show that this was not so. The Panel therefore ruled that there was no breach.

Finally, the Panel did not accept that there was any breach of Clause 2 of the Code with regard to the "Aide Memoire".

Complaint received 27 January 1993

Case completed 4 March 1993

AUTH/6/1/93

ROYAL COLLEGE OF PHYSICIANS V LEDERLE LABORATORIES

Sponsorship of clinics in return for access by representative

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

The Royal College of Physicians complained about an offer made by a representative of Lederle Laboratories to sponsor a series of rheumatology clinics at GP surgeries in return for the practices allowing access to a representative of that company. It was alleged that this transgressed normal practice and must be considered unethical. A letter from the representative to a consultant indicated that the representative would be willing to sponsor four to five clinics at general practitioner surgeries with the consultant and another doctor choosing the practices.

Lederle Laboratories stated that it was actively involved in sponsoring rheumatology clinics through general practitioner surgeries. The letter which had been submitted by the complainant was dated June, 1990. It had been sent to the Royal College only as an example

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of ".... outreach clinics within general practitioner surgeries financed by drug companies" and not because the consultants involved were offended or believed the offer was inappropriate or tied to an inducement of access. The funding had been agreed in advance of the letter and was, therefore, not conditional on access being given. The letter had gone to a consultant and no approach was made direct to general practitioner surgeries offering finance as an inducement for access. The representative had not sought the consultant's assistance in gaining access. The letter merely expressed the "hope" that access would be given.

The Code of Practice Panel addressed the fact that the letter in question had been written in July, 1990, but noted that it had previously been established that it would be reasonable to take up any matter which had occurred within the previous three years if there was reasonable evidence to indicate a possible breach of the Code. In view of this, the Panel decided that the complaint would be accepted.

The Panel noted Lederle's contention that the letter had gone to the consultant rather than to the general practitioners and that it merely expressed the "hope" that access would be given. The Panel also noted, however, that the representative had said in his letter that ".....In return, I would hope that each practice would be willing to offer access to myself some 3-4 times a year". The words "in return" indicated that at least informally the sponsorship and the access were associated. The Panel did not accept the contention that the funding would not amount to an inducement because it had already been agreed.

The Panel ruled that there had been a breach of Clause 17.6 of the First Revision of the Seventh Edition of the Code which prohibits medical representatives from employing incentives to gain interviews.

Complaint received 28 January 1993

Case completed 25 February 1993

AUTH/9/2/93

PHARMACEUTICAL ADVISER V ASHBOURNE PHARMACEUTICALS LTD

"Dear Doctor" letter on branded generics

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

A pharmaceutical adviser with a family health services authority complained about a "Dear Doctor" letter sent by Ashbourne Pharmaceuticals Ltd in response to a bulletin sent by the pharmaceutical adviser to dispensing doctors throughout the area.

There were three heads of complaint. That a paragraph in the letter "The use of the term "Branded Generics" *[in the FHSA pharmaceutical adviser's bulletin]* for Ashbourne brands is incorrect. All the Ashbourne Brands referred to have unique product licences which specifically refer to the Ashbourne brand product and not to a generic. As such the size,

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shape, colour consistency and bio-availability must always be the same. This is not the case with branded generics." was in breach of Clauses 4.3, 4.4, 5.2, 6.1 and 6.2 of the Code as the complainant alleged that Ashbourne products were branded generics.

Secondly, that a statement in the letter that "The use of branded products provides complete product liability protection for the prescriber without having to spend time keeping careful records of suppliers, producer and batch number." was in breach of Clauses 4.3, 5.1 and 6.1 as the complainant alleged it implied that the use of generic products did not protect against product liability. Finally, a breach of Clause 2 of the Code was also alleged as the complainant considered that the comments implied that the quality and bio-availability of generics was not always reliable and this reduced confidence in the pharmaceutical industry.

Ashbourne Pharmaceuticals Ltd, although not a member of the ABPI, had agreed to comply with the Code. The company explained that it had sent the letter to clarify certain matters in the pharmaceutical adviser's bulletin which it considered were unfair. The term "branded generics" was something of a misnomer. A product was either a brand or a generic; it could not in the company's view be both.

With regard to the second matter the company submitted that the statement was true as by prescribing Ashbourne branded products the prescriber did not have to spend time keeping careful records of suppliers, manufacturer and batch numbers. The company denied there was any reference or implication in the letter querying the quality and/or bio-availability of generic products.

The Code of Practice Panel decided that the letter in question was subject to the Code as it was a promotional item for Ashbourne products and as it did not meet the definition of a trade advertisement which would be exempt from the requirements of the Code.

The Panel considered that the expression "branded generic" was to some extent a contradiction in terms but was generally understood to apply to a medicine sold under a brand name which was a generic version of the originator's product. The Ashbourne branded products were thus branded generics. Further, the reference to unique product licences in the Ashbourne letter was misleading in that all medicines had unique product licences. The Panel therefore ruled that the paragraph as a whole was misleading in breach of Clause 4.3 of the Code.

The Panel accepted that by prescribing Ashbourne branded medicines the prescriber would not have to spend time keeping careful records of suppliers, producers and batch numbers. The Panel considered however that doctors could remain exposed to product liability claims in certain circumstances, for example where the medicine had been improperly stored leading to a defect in the medicine. The claim that the use of branded products provided "complete" product liability protection for the prescriber was therefore exaggerated and the Panel ruled there was a breach of Clause 5.2 of the Code.

The Panel did not accept the allegation concerning Clause 2 of the Code.

The complainant appealed in relation to the final matter of his complaint which he submitted referred to the statement in the Ashbourne letter that "As such the size, shape, colour, consistency and bio-availability must always be the same. This is not the case with branded

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generics." The complainant submitted that whilst he appreciated that the size, shape and colour may vary from generic to generic, the bio-availability must surely be consistent before a product licence was granted and that to imply that there were variations in the bio-availability between generics was to reduce confidence in both the quality of generics and the pharmaceutical industry in breach of Clause 2 of the Code.

Ashbourne in its written submission on the appeal submitted that the letter specifically referred to Ashbourne products and the fact that size, shape, colour consistency and bio-availability would not change. No other product or generic was mentioned or alluded to.

The Code of Practice Appeal Board considered the papers bearing in mind that the application of Clause 2 of the Code was restricted to exceptionally serious matters involving safety issues or where particular censure was warranted because of the gravity of a company's conduct. It concluded that Clause 2 did not apply in this Case. Furthermore it accepted that bio-availability might differ between different generics and this could have clinical significance in certain circumstances. The Appeal Board therefore rejected the appeal from the complainant against the Panel's ruling that there was no breach of Clause 2 of the Code.

Complaint received 11 February 1993

Case completed 1 April 1993

AUTH/10/2/93

GENERAL PRACTITIONER V PFIZER LIMITED

Misleading chart in Lustral detail aid

A general practitioner complained about a chart in a detail aid on Lustral issued by Pfizer Limited which compared it with paroxetine and fluoxetine and which he considered at best misleading and, at worst, dishonest. The implication of the chart was that Lustral did not interact with any of the medicines listed beneath a heading "No specific data sheet warning of drug interaction" and this was not meaningful when the data sheet said that the potential of Lustral to interact with certain of them had not been fully assessed. Further, diazepam was given as not interacting with Lustral though a statement over the chart indicated that Lustral should not be administered concomitantly with benzodiazipenes to persons who drove or operated machinery. A further point was that the chart said that the data sheets recommended dosage reduction for the elderly with fluoxetine and paroxetine and this was a misrepresentation as the data sheet for fluoxetine specified the same dose in the elderly as in an adult and the data sheet for paroxetine specified the same normal dose, though the maximum dose for the elderly was less than the maximum adult dose.

Pfizer Limited said that the document, which was not intended to be left with the physician, accurately reflected the data sheets from which it was sourced. It had highlighted relevant differences between the data sheets for the products compared which might be of importance to clinicians and the information was supported by published data. Pfizer had been careful to ensure that the absence of a specific interaction warning genuinely reflected the interaction potential. In relation to Lustral, where the data sheet said that the interaction potential of

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certain substances had not been assessed, interaction studies had subsequently demonstrated no clinically relevant interactions. In relation to diazepam, the warning in the data sheet did not preclude its use with Lustral but cautioned against concomitant administration of benzodiazepines in patients who drove or operated machinery. There was no warning of a potential for interaction between Lustral and any benzodiazepine.

In relation to use in the elderly, Pfizer advised that a superseded data sheet had been used for the fluoxetine comparison and this had now been changed on the chart. In relation to paroxetine, the maximum dose was 40 mg for the elderly and 50 mg for a normal adult and this represented a dosage reduction.

The Code of Practice Panel considered that the chart was literally true in respect of the information regarding Lustral in view of its heading "No specific data sheet warning of drug interactions with ...". The Panel considered it to be nonetheless misleading as the data sheet actually said that "The potential of Lustral to interact with, eg, digoxin, warfarin, propranolol and phenytoin, has not been fully assessed". The clear implication of a tick on the chart against warfarin, for instance, was that the data sheet was either silent or positive on the point. The same applied with a reference to diazepam where the tick alongside was misleading as at first sight it appeared to indicate that there was no problem with concomitant administration. It was true that Lustral and diazepam did not interact but there was a caution in relation to their use together in the small print over the chart itself. The Panel ruled that the chart was in breach of Clause 7.2 on these counts.

In relation to the question of reduced dosage in the elderly, it was noted that the erroneous reference in respect of fluoxetine was based on a superseded data sheet. The one used was apparently that appearing in the 1990/91 edition of the ABPI Data Sheet Compendium as the data sheet was different in this regard in both the 1991/92 and 1993/94 editions. In respect of paroxetine, the usual dose was the same for both elderly people and adults, only the maximum was different. The Panel did not consider that this represented a dosage reduction. The Panel accordingly ruled that there had been a further breach of Clause 7.2 of the Code.

Complaint received 17 February 1993

Case completed 5 April 1993

AUTH/11/2/93

HOSPITAL PHARMACIST V SANDOZ PHARMACEUTICALS

Absence of prescribing information in "Dear Pharmacist" letter

A hospital pharmacist complained about a "Dear Pharmacist" letter concerning Sandimmun issued by Sandoz Pharmaceuticals. He pointed out that two other products were referred to in the letter, these being Lamisil and Metrogel, and their uses given, but prescribing information for them had not been included. He alleged that there had been breaches of Clauses 4.1 and 4.2 of the Code.

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Sandoz Pharmaceuticals indicated that it had not appreciated that this could be interpreted as "promotion" as it was not the aim of the mailing to "promote the prescription, supply, sale or administration" of Lamisil and Metrogel and the company felt it difficult to understand that it could have this effect, bearing in mind the minimal information the letter contained.

The Code of Practice Panel considered that the prescribing information was generally necessary when a product was mentioned in promotional material even if the item was primarily concerned with another product. Accordingly, the Panel ruled that there had been a breach of Clause 4.1 of the Code which required the inclusion of prescribing information.

Complaint received 22 February 1993

Case completed 5 March 1993

AUTH/12/2/93

COMMUNITY PHARMACIST V NOVO NORDISK PHARMACEUTICALS LTD

Misleading Advertisement for Penmix 30/70

A community pharmacist complained about a mailing for PenMix 30/70 issued by Novo Nordisk Pharmaceuticals Ltd. This showed a pen with a needle and stated that it was prescribable on FP10. In relation to this, the complainant stated that "The pens are, but the needles are not. This is causing patients to be given bad advice from GPs and being in a position where they have later to buy the needles, or go back to the GPs for another prescription. Often they will make the purchase with protest." A similar complaint was subsequently received from a pharmaceutical adviser to a family health service authority, this time in relation to a journal advertisement.

Novo Nordisk Pharmaceuticals Ltd, although not a member of the ABPI, had agreed to comply with the Code. The company considered that Clause 7.2 did not apply as this related to claims as to the nature or quality of medicines or their uses or effects. In any event, the situation as to needles was well known to diabetologists, general practitioners, pharmacists and patients. It would have been misleading to have shown the pen without a needle as this would have implied that it was non-invasive. The pen was clearly differentiated from the needles in the text, the needles had been referred to as "detachable" to make it clear that they were not integral and there was no real likelihood of confusion as the needles were recommended for single use whereas the pens lasted for up to a week. The advertisement said prescribable on FP10 in packs of five to indicate that the pen was now so prescribable.

The Code of Practice Panel considered that Clause 7.2 of the Code was relevant as an advertisement could be misleading in relation to any aspect of its contents.

The Panel noted that the pens had only recently become prescribable on FP10 and considered that it was not clear from the advertisement that only the pens and not the needles could be so prescribed. There was evidence from the first complainant that this was

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not in fact clear to all prescribers and users. It was ruled that the advertisement was misleading by implication and was in breach of Clause 7.2 of the Code.

Complaint received 22 February 1993.

Case completed 7 April 1993.

AUTH/13/2/93

PRINCIPAL PHARMACIST WITH A REGIONAL HEALTH AUTHORITY V MEMBER COMPANY

Mailing alleged to be in bad taste

A principal pharmacist with a regional health authority complained that a mailing on a product issued by a member company was in breach of Clause 7.6 of the First Revision of the Seventh Edition of the Code in respect of a particular photograph and claim. As the mailing was sent after 1 January 1993, the complaint was taken up under the provisions of Clause 9.1 of the Eighth Edition of the Code which requires good taste to be observed in all promotion.

The Code of Practice Panel considered that neither the advertisement nor the claim was in bad taste and ruled there was no breach of the Code.

Complaint received 22 February 1993

Case completed 30 March 1993

AUTH/14/2/93

CIBA-GEIGY PHARMACEUTICALS V PARKE DAVIS & CO LIMITED

Claims of equivalence and tolerability and use of device in promotional material for Diclomax Retard

Ciba-Geigy Pharmaceuticals complained about the promotion of Diclomax Retard by Parke Davis & Co Limited. The material at issue was a journal advertisement published in "Pulse" on 13 February 1993, a "Dear Doctor" letter and a mailing.

The Code of Practice Authority was aware of the fact that legal proceedings were in progress between the two companies concerning similar matters but both companies nonetheless wanted consideration of the complaint to proceed.

It was alleged that the claim in the advertisement "Diclomax Retard offers everything you would expect from diclofenac retard with one crucial difference. The price. ", was in breach of Clauses 7.2, 7.3 and 7.8 of the Code. Ciba-Geigy considered the claim to be highly exaggerated as there were other differences besides the price. For example its product, Voltarol Retard, the only other diclofenac retard, was a slow release tablet and Diclomax

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Retard was a modified release capsule. This was a difference that could be crucial both to the patient who might find the larger capsule more difficult to swallow and to the doctor to whom it was being inferred that there was no difference except the price. It alleged that Parke Davis did not offer substantiation for its claim that its product was identical to Voltarol Retard nor was it thought that this was capable of substantiation. A similar allegation was made in respect of a claim in the "Dear Doctor" letter.

The Code of Practice Panel firstly noted that Parke Davis had not claimed that Voltarol Retard was identical and this allegation therefore fell. In relation to the claim that it offered everything you would expect from diclofenac retard, the Panel noted the response from Parke Davis to the effect that the application for the product licence for Diclomax Retard was made on an abridged basis relying upon the "essentially similar" approach which required data showing bio-equivalence for the purpose of establishing that the products would have the same safety and efficacy profile. Parke Davis further submitted evidence from a number of experts who had examined the data and this supported the view that the two preparations could be judged as being bio-equivalent.

The Panel did not accept that the fact that one preparation was a tablet and the other was a capsule meant that they were not equivalent preparations as the difference appeared to be clinically insignificant. The Panel considered that the allegation that the products were not clinically equivalent was unjustified and ruled that there had been no breach of the Code in that respect. This ruling applied equally to the similar allegation regarding the "Dear Doctor" letter.

In relation to the mailing, Ciba-Geigy complained about a statement that "Diclomax Retard is at least as well tolerated as the leading diclofenac retard". Ciba-Geigy said that the support for such a claim was limited to a study in 18 healthy volunteers and an open between-patient trial in which only 25 patients received Diclomax Retard.

The Panel took the view that the claim "at least as well tolerated" implied that it might be better tolerated than Voltarol Retard and considered that this was an exaggerated claim in view of the limited data available. It was ruled to be in breach of Clause 7.8 of the Code.

Ciba-Geigy further alleged that the use of a green apple device in the advertising for Diclomax Retard was a breach of Clause 9.3 of the Code as it was imitating its own device in a way that was likely to mislead or confuse. Ciba-Geigy also referred to Clause 7.10 of the Code which precluded the use of competitive trade marks and suggested that this Clause had been breached in spirit if not in the letter.

Parke Davis said that the comparison was being drawn between its own product and the market leader and it wished to do this in a vivid and striking, but also legitimate, manner. A direct comparison was necessary in order to provide a foundation for the price comparison. The apple used was somewhat different to that of Ciba-Geigy's but in any event Ciba-Geigy could not claim a monopoly in the use of apples in advertisements. In Parke Davis's view, no doctor would be confused by the incorporation of an apple with a bite out of it since the advertisement expressly referred to Diclomax Retard.

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Dealing first with the allegation concerning Clause 7.10, the Panel rejected the suggestion that this provision had been breached. It was a specific requirement and could relate only to the actual use of the brand name itself.

The Panel noted that Ciba-Geigy used an entire green apple in advertisements for Voltarol Retard and that Parke Davis had used a green apple with a bite out of it in the advertisements for Diclomax Retard.

In relation to the allegation of a breach of Clause 9.3, the Panel accepted that the apple was used to allude to the device used by Ciba-Geigy for Voltarol Retard, notwithstanding the fact that the Parke Davis apple had no leaf on it and had a bite out of it. The Panel decided, however, that it was not likely to mislead or confuse as it was clear that the advertisements were for the Parke Davis product Diclomax Retard. The Panel accordingly ruled that there had been no breach of Clause 9.3 of the Code.

Complaint received 24 February 1993

Case completed 2 April 1993

AUTH/15/3/93

GENERAL PRACTITIONER V BRISTOL-MYERS SQUIBB PHARMACEUTICALS LIMITED

Representative failed to provide accurate information

A general practitioner complained about the conduct of a representative from Bristol-Myers Squibb Pharmaceuticals Limited in relation to the promotion of Capoten in the treatment of heart failure. In the discussion with the representative, the complainant had mentioned that two other ACE inhibitors, Accupro and Coversyl, were both currently licensed for use in heart failure. The representative had stated that this was not correct as in her opinion neither product had a licence for use in treating heart failure by general practitioners. The complainant alleged that the representative had suggested that he should check his information more carefully before making such a statement.

Bristol-Myers Squibb Pharmaceutical Limited acknowledged that it was possible that a misunderstanding might have occurred as the representative was specifically discussing the initiation of Capoten in heart failure by general practitioners. The representative had informed the complainant that only Capoten and enalapril were licensed for initiation in heart failure by general practitioners and the complainant himself had brought up the use of the two other products in the treatment of heart failure. The representative had advised the doctor that she was unable to comment on these as they were not licensed for initiation by general practitioners in heart failure. The representative denied making any adverse or derogatory comment with regard to any other ACE inhibitors. A copy of the representatives briefing material was provided and the company advised that the representative had passed the ABPI Medical Representatives Examination.

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Following a procedure adopted previously by the Code of Practice Committee, permission was obtained from Bristol-Myers Squibb to pass its response to the complainant for comment. The complainant was therefore provided with a copy of the company's response for comment.

The complainant acknowledged that it was difficult to deal with cases concerning what a representative had said in an interview but submitted that the question of initiation of treatment with Accupro and Coversyl in general practice was not raised as far as he could remember. It had appeared that the representative was saying that because prescriptions for Accupro and Coversyl for the treatment of heart failure were not covered by their product licences, he should change to an ACE inhibitor that was properly licensed namely Capoten or Innovace. At this point the complainant had told the representative that he thought her information was incorrect and she had terminated the interview.

The complainant acknowledged that they could have been at cross purposes if the representative thought she was advising about initiation of treatment with an ACE inhibitor to a new patient with heart failure. The complainant submitted that this should have been made perfectly clear by the representative, especially in a situation where an apparent disagreement had arisen.

The Code of Practice Panel noted that following receipt of the response from Bristol-Myers Squibb, the complainant had not only reiterated his complaint but had provided more details about the interview. It appeared that the representative had been saying that Accupro and Coversyl were not licensed for use in general practice which was not true as the only restriction on their use was when therapy was initiated, which should be in hospital. The Panel considered that, on the balance of the evidence, the representative had not provided accurate information about the licensed indications for the use of the two competitor products in general practice and therefore ruled there had been a breach of Clause 15.2 of the Code.

Complaint received 3 March 1993

Case completed 27 April 1993

AUTH/16/3/93

GENERAL PRACTITIONER V MEMBER COMPANY

Allegations concerning Sony Walkman offer in association with a market research survey for an audio conference

A general practitioner complained that a free Sony Walkman personal stereo offer made by a market research agency in association with an invitation to an audio conference by a member company was in breach of Clause 19 of the First Revision of the Seventh Edition of the Code. As the offer was made after 1 January 1993, the complaint was taken up under the provisions of Clause 18 of the Eighth Edition of the Code which prohibits the provision of gifts and inducements except for promotional aids which are inexpensive and relevant to the recipient's profession or employment.

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The pharmaceutical company concerned explained that it had arranged a series of audio conferences. Each doctor invited had been sent an invitation together with a letter providing details of the local meeting and an invitation to participate in a communications survey organised by a market research agency on its behalf. The first part of the survey was sent with the mailing and for each completed reply a £1.00 donation would be paid to a certain relevant named charity. The reference to the Sony Walkman offer which appeared in the mailing referred to part 2 of the survey which was a questionnaire available at the audio conference. The Sony Walkman would be provided to those persons attending the meeting who completed part 2 of the survey in recognition of the time taken to complete it. The cost of each Sony Walkman to the company was £8.35. The item had been discontinued but the last known retail price was £15.99.

The Code of Practice Panel noted that the Sony Walkman offer was made in relation to the completion of the second part of the questionnaire and would be provided in recognition of the time taken by the physician to complete the questionnaire. The questionnaire was a fairly lengthy document which would take some time to complete.

The Panel noted that the British Medical Association currently recommended fees of between £19.00 and £46.50 for medical research questionnaires produced on behalf of the pharmaceutical industry. The Sony Walkman was valued at a relatively modest sum.

The Panel considered that the offer of the Sony Walkman was not a financial inducement for the purposes of sales promotion as it was payment for participation in a legitimate market research survey conducted in association with the audio conference and ruled there was no breach of the Code.

Complaint received 4 March 1993

Case completed 30 March 1993

AUTH/17/3/93

GENERAL PRACTITIONER V NOVO NORDISK PHARMACEUTICALS LTD

Unsolicited sample of Vagifem

A general practitioner complained that he had received an unsolicited mailing from Novo Nordisk Pharmaceuticals Ltd which contained a sample of Vagifem, contrary to Clause 18.3 of the Code of Practice for the Pharmaceutical Industry.

The attention of Novo Nordisk was drawn to Clause 17.3 of the Eighth Edition of the Code which requires that samples are only provided in response to a written request as this appeared to be the appropriate alternative to Clause 18.3 in the First Revision of Seventh Edition.

Novo Nordisk although not a member of the ABPI had agreed to comply with the Code. The company accepted that the mailing was in breach of Clause 17.3 of the Code. This had not

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been intentional but was due to an administrative error and steps had been taken to ensure that it did not happen again.

The Code of Practice Panel noted that the mailing had been prepared in January 1993 and the transitional provisions relating to the introduction of the Eighth Edition therefore did not apply. The Panel decided that the sample could not be regarded as a "starter pack" in view of the product's therapeutic purpose.

The Panel ruled that there had been a breach of Clause 17.3 of the Code because of the failure to obtain a signed request for the sample.

Complaint received 10 March 1993

Case completed 20 April 1993

AUTH/18/3/93

CONSULTANT PAEDIATRICIAN V NON MEMBER COMPANY

Graph in a journal advertisement

A consultant paediatrician complained about a graph in a journal advertisement issued by a company for one of its products. The company concerned although not a member of the ABPI had agreed to comply with the Code.

The complainant pointed out that although the graph was labelled as showing standard error bars these were not included. This was misleading because the graph was incomplete.

The company advised that the advertisement had been withdrawn and acknowledged that the graph was incomplete due to the omission of the standard error bars which was due to an oversight in proof-reading. The company provided a paper which included the original graph from which the one at issue was derived. The original graph showed that the standard error bars were "tight" and portrayed the product in a highly favourable way when compared with placebo. The company acknowledged that if, for example, standard error bars overlapped then one might gain from their omission.

The Panel noted that the standard error bars had been omitted in error and decided that the omission of the standard error bars in this instance did not mean that the graph was misleading. The Panel accepted the company's submission and therefore ruled there was no breach of the Code.

Complaint received 10 March 1993

Case completed 16 April 1993

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CODE OF PRACTICE FOR THE PHARMACEUTICAL INDUSTRY

NUMBER		SUBJECT	BREACH
3	Kabi Pharmacia v Clintec Nutrition	Journal advertisement	4.4*
5	FHSA pharmaceutical adviser v Ashbourne	Document sent to dispensing doctors	4.3*
6	Royal College of Physicians v Lederle Laboratories	Sponsorship of clinics	17.6*
9	FHSA pharmaceutical adviser v Ashbourne	"Dear Doctor" letter	4.3, 5.2* (A)
10	General practitioner v Pfizer	Booklet	7.2
11	Hospital pharmacist v Sandoz	"Dear Pharmacist" letter	4.1
12	Community pharmacist v Novo Nordisk	Mailing	7.2
13	Principal pharmacist v Member company	Mailing	None
14	Ciba-Geigy v Parke Davis	Journal advertisement, "Dear Doctor" letter, mailing	7.8
15	General practitioner v Bristol Myers-Squibb	Conduct of a representative	15.2
16	General practitioner v Member company	Offer of a Sony Walkman	None
17	General practitioner v Novo Nordisk	Unsolicited sample	17.3
18	Consultant paediatrician v Non member company	Journal advertisement	None

KEY

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