PMCPA | Prescription Medicines Code of Practice Authority

Annual report 2006

Contents

Foreword

I am pleased to contribute to the Annual Report for 2006 of the Prescription Medicines Code of Practice Authority (PMCPA).

This was my first year as Chairman and it coincided with a revised ABPI Code of Practice for the Pharmaceutical Industry and changes to the Constitution and Procedure of the PMCPA.

The number of complaints to the PMCPA in 2006 was 134 - a substantial increase compared to the 101 received in 2005. Although the number of cases (128) was more than were considered in 2005 (107), the number of individual allegations (matters) considered in 2006 at 272 was similar to the number in 2005 (275). More matters were appealed in 2006 (40) than in 2005 (32). The number of matters successfully appealed in 2006 was 15 which was an increase on the 10 matters successfully appealed in 2005. Of the 40 matters appealed, 38% were successfully appealed and 62% were unsuccessfully appealed. The proportion of the Code of Practice Panel's rulings successfully appealed increased slightly to 6% (15/272) in 2006 compared with 4% (10/275) in 2005. The parties accepted without appeal 85% of the Panel's rulings compared with 88% in 2005. The Appeal Board has no hesitation in overturning the Panel's rulings where appropriate.

The average time taken to complete consideration of a case which was the subject of appeal increased in 2006 (19 weeks) compared to 2005 (17.5 weeks). Consideration of two appeals was deferred. However in such circumstances the use of the material at issue has usually ceased beforehand. Every effort is made to complete consideration of cases as quickly as possible and publish the outcomes. Transparency and openness are key requirements to maintain confidence. The detail given in the published case reports demonstrates that the system operates without fear or favour.

The Appeal Board required a number of audits and some

The Prescription Medicines Code of Practice Authority (PMCPA) was established on 1 January 1993 by The Association of the British Pharmaceutical Industry (ABPI) to be responsible for all matters relating to the ABPI Code of Practice for the Pharmaceutical Industry.

The PMCPA operates independently of the ABPI, has its own staff and reports directly to the ABPI Board of Management. The PMCPA operates impartially between complainants and respondents and between members of the ABPI and companies which are not members of the ABPI.

companies were required to have follow up audits. The Appeal Board reported one company to the ABPI Board of Management and details are provided in this report. The ABPI Board suspended this company from membership of the ABPI; the case concerned internal company material linking the provision of medical and educational goods and services to the promotion of a medicine.

In 2006, the Appeal Board used its additional sanctions that were previously only available to the ABPI Board - the ability to require corrective advertising or issue a public reprimand. Two new sanctions have also been introduced; these being advertising by the PMCPA in the medical and pharmaceutical press in certain circumstances, such as when a breach of Clause 2 is ruled and the facility for the Appeal Board or the ABPI Board to require materials to be submitted for pre-vetting following an audit.

Other changes include an increase in the number of members of the Appeal Board. We welcomed two new appointments to fill the new categories for independent members - a registered nurse prescriber appointed in consultation with the Royal College of Nursing and a member who is not a health professional.

The Appeal Board considers each case entirely on its own merits. Members take their responsibilities extremely seriously. I have been hugely impressed with members' firmness and impartiality in making decisions. I thank them all for their valuable contributions. I am also indebted to Heather Simmonds and her team at the PMCPA for assisting me assiduously at all times. I have enjoyed my first year as Chairman.

William Harbage QC.

William Harbage QC
Chairman, Code of Practice Appeal Board

Director's Report

The year was again an extremely busy one for the PMCPA, not just in dealing with complaints. The revised Code and the changes to its operation took up a considerable amount of time and resource particularly in relation to training. However the main focus of the PMCPA is of course the administration of the complaints procedure.
The number of complaints from pharmaceutical companies decreased (23 out of 134 in 2006 and 28 out of 101 in 2005) whereas there were more from health professionals (57 in 2006 and 52 in 2005). Usually the PMCPA receives more complaints from health professionals than from companies although in 1996, 1999, 2001, 2002 and 2003 the reverse was true. The increase in complaints from health professionals might be related to the PMCPA campaign to raise awareness about the Code with health professionals. The 2006 Code requires information about intercompany dialogue at a senior level, or an indication that such a request was refused, to be provided before an intercompany complaint can be accepted. Intercompany complaints are, however, an important feature of successful self regulation.

It is interesting to note that although there were more complaints in 2006 than in 2005, there were more which did not establish a *prima facie* case. Fewer cases were ruled in breach of the Code in 2006 (57%) than in 2005 (80%).

Details of the Panel's and Appeal Board's rulings are given elsewhere. The Panel has a good record with 94% (257/272) of its rulings in 2006 being accepted by the parties or upheld on appeal. The time taken to complete cases settled at Panel level increased in 2006 (9.2 weeks in 2006 and 8.4 weeks in 2005). The Panel is extremely aware of the need to deal with cases as quickly and efficiently as possible. However some cases require additional information before the Panel can reach a conclusion.

The appointment of a communications manager to the PMCPA in July 2006 has

raised the profile and awareness of the Code and its operation, with priority being given in the first instance to communicating with health professionals.

The implementation of the 2006 Code has reinforced the industry's commitment to, and support of, self regulation. Successful self regulation depends on transparency and meaningful sanctions. The swifter publication of detailed reports on completed cases and the disclosure of brief details about ongoing cases are important factors in the maintenance of effective self regulation. The additional work on communicating the Code has improved awareness and understanding by a wider audience.

The PMCPA has been able to carry out its functions successfully, independently of the ABPI and without interference. I would like to thank the staff of the PMCPA for their willing and able help throughout the year. It is our hope and intention to build on the successes of 2006 by being seen to be fair, independent and totally without bias.

Heather Simmonds
Director, PMCPA

Revised Code of Practice 2006

The revised ABPI Code of Practice for the Pharmaceutical Industry came into effect on 1 January 2006 with transitional provisions until 30 April 2006.

The introduction of the revised Code followed extensive consultation with stakeholders in 2005, including the Medicines and Healthcare products Regulatory Agency (MHRA), the Department of Health (DoH), health professionals, patient advocacy, consumer and public sector groups, regulators and trade bodies, as well as anybody else who wanted to comment.

Specific market research was carried out with key stakeholders, including patient advocacy groups. ABPI members and the Code of Practice Appeal Board also commented on the existing Code and the proposals to amend it. During the review process the House of Commons Health Select Committee announced an inquiry into the pharmaceutical industry and its report was considered as part of the review.

Key changes made in the 2006 edition:

- All printed promotional material to include prominent information about reporting adverse drug reactions.
- Further restrictions on what can be provided to health professionals in the way of promotional aids, hospitality, subsistence, travel, and accommodation.
- Additional detail about relationships with patient groups etc and the provision of information to the public.
- A reduction in the permitted number of pages of medicines advertising in journals and an outright ban on all promotional competitions.
- Specific limitations on the number of mailings about a medicine that can be sent to health professionals.
- Additional requirements for certification of educational materials for the public which relate to diseases or medicines, including materials relating to patient organisations.
- Representatives must be entered for the ABPI examination within their first year of employment and the former exemptions from the examination have been deleted.

Key changes to the Constitution and Procedure:

- Moves to speed up the process of determining complaints, so that decisions can be made and sanctions imposed more quickly.
- Materials or activities ruled in breach of the Code may, under certain circumstances, be suspended pending an appeal.
- Results of some more serious cases are advertised in the medical and pharmaceutical press.
- Pre-vetting of material can be required by the Appeal Board or ABPI Board of Management following an audit of a company's procedures.
- Vacancies for independent members other than the Chairman to be advertised in appropriate journals and/or the national press.
- Two additional independent members have been appointed to the Appeal Board - a registered nurse prescriber and a lay member.
- An ongoing list of cases is published on the PMCPA's website.

Other changes within the Authority

As part of the review of the Code it was decided that a communications manager should be appointed to the staff of the PMCPA to raise awareness of the Code and its operation, particularly amongst health professionals.

Niamh MacMahon (pictured right) was appointed to this position in July 2006.

Different levels of administrative charges were introduced in 2006 for members and non-members of the ABPI.

Complaints in 2006

One hundred and thirty four complaints were received in 2006 compared with one hundred and one in 2005. There were 128 cases for the PMCPA to deal with. The number of individual allegations to be considered within these cases, at 272, was similar to the corresponding figure for 2005 which was 275.

The largest number of complaints in 2006 came from health professionals.

Time to deal with complaints

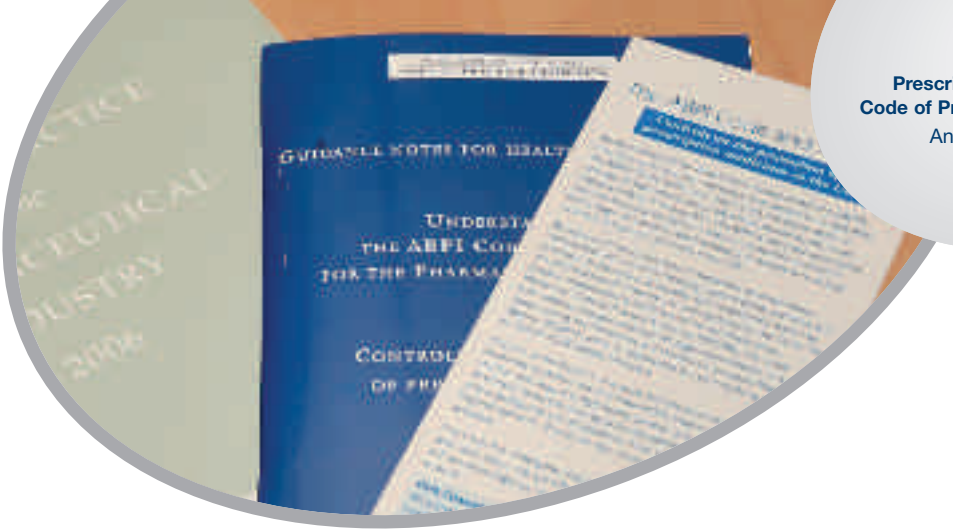
There was an increase in the overall time taken to deal with complaints. The figure for 2006 was 10.9 weeks compared to 2005 at 9.9 weeks. There was a small increase in the time taken to complete cases finalised at Panel level from 8.4 weeks in 2005 to 9.2 weeks in 2006. There was an increase in time taken to complete cases that went to appeal at 19 weeks in 2006 compared to 17.5 weeks in 2005.

Reports to the Code of Practice Appeal Board

Six formal reports were made by the Code of Practice Panel to the Code of Practice Appeal Board in relation to complaints received in 2006.

One report concerned a voluntary admission of a breach of undertaking. The Panel ruled a breach of the Code. The Appeal Board subsequently required an audit and a re-audit.

One report concerned the linking of medical and educational goods and services to the promotion of a medicine in internal documents. The Appeal Board required an audit and re-audit. The company was publicly reprimanded and required to issue a corrective statement. The Appeal Board reported the matter to the ABPI Board of Management.



One report concerned the provision of medical and educational goods and services. The Panel's ruling of breaches of the Code was overturned on appeal by the company. Thus no further action was taken by the Appeal Board.

One report concerned a company that failed to provide accurate information to the Panel. The Appeal Board publicly reprimanded the company and an audit followed by a re-audit were required.

Two further reports were made to the Appeal Board; these cases will be finalised in 2007.

Reports to the ABPI Board of Management

One formal report was made by the Code of Practice Appeal Board to the ABPI Board of Management in relation to complaints made in 2006 for it to consider whether further sanctions should be applied. The report concerned a case reported to the Appeal Board by the Panel which is outlined above.

The company concerned was suspended from membership of the ABPI for three months. The ABPI Board required the company to be re-audited in 2007.

Audits by the PMCPA

Five complaints received in 2006 resulted in audits and in three of these re-audits were required in relation to the company's procedures. Five of the initial audits were required by the Appeal Board. Three re-audits were required by the Appeal Board and the ABPI Board required one re-audit.

One of the initial audits and a re-audit were carried out in 2006 and the other four initial audits were to be carried out in 2007. Three re-audits were to be carried out in 2007.

Four complaints received in 2005 resulted in audits and re-audits. One of the initial audits was carried out in 2005 and the three others were carried out in 2006. Three re-audits were carried out in 2006.

Four complaints received in 2004 resulted in audits and re-audits. Three of the re-audits were carried out in 2006.

Eleven audits and re-audits were carried out in 2006 in total.

ABPI members and non members

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

Nearly every relevant company is thus covered.

Complaints involving non member companies are dealt with on the same basis as those involving members.

If a complaint were to be received about one of the very few companies which have refused to accept the jurisdiction of the PMCPA then, if it was a matter covered by UK law, the complainant would be advised to take the matter up with the Medicines and Healthcare products Regulatory Agency (MHRA) directly.

Cases arising from media criticism

During 2006 the Code of Practice Appeal Board decided that it would be helpful to look at the established procedure for dealing with cases arising from articles in the media.

The Appeal Board considered it was very important for the reputation of the industry and the continued effectiveness of self regulation that articles etc in the media, from which it appeared that a company might have breached the Code, were taken up and dealt with as complaints

under the Code. This has been established practice for a number of years.

The existing procedure - whereby the Director instigates the complaints procedure when it appears from something published in the press that a company might have contravened the Code, with the rights of the complainant being given to the author of the article, will continue.

If no author is named, the editor of the publication will be given the rights of the complainant. However, the author, or editor, will now be asked if they want to be involved in the case and whether they have any additional information to submit; the consequences of not being involved (no right of appeal and no right to comment on a respondent's appeal) will be explained in writing. If the author or editor declines involvement, this will now be stated in the case report.

The ABPI Board of Management has agreed this procedure and considers it is important for self regulation that articles and the like, criticising the activities of pharmaceutical companies, are taken up and dealt with under the Code irrespective of whether the author or editor want to be involved.

Advice and training on the Code

Many requests for informal guidance and advice on the operation of the Code were received in 2006 from various sources including pharmaceutical companies, health professionals, public relations agencies and patients. A number of enquiries were also received from newspapers, radio and television about the Code and the complaints made under it. The introduction of the revised Code at the beginning of 2006 saw an increase in the number of requests for advice.

Anyone can call the PMCPA for informal advice on the Code on 020 7747 8880.

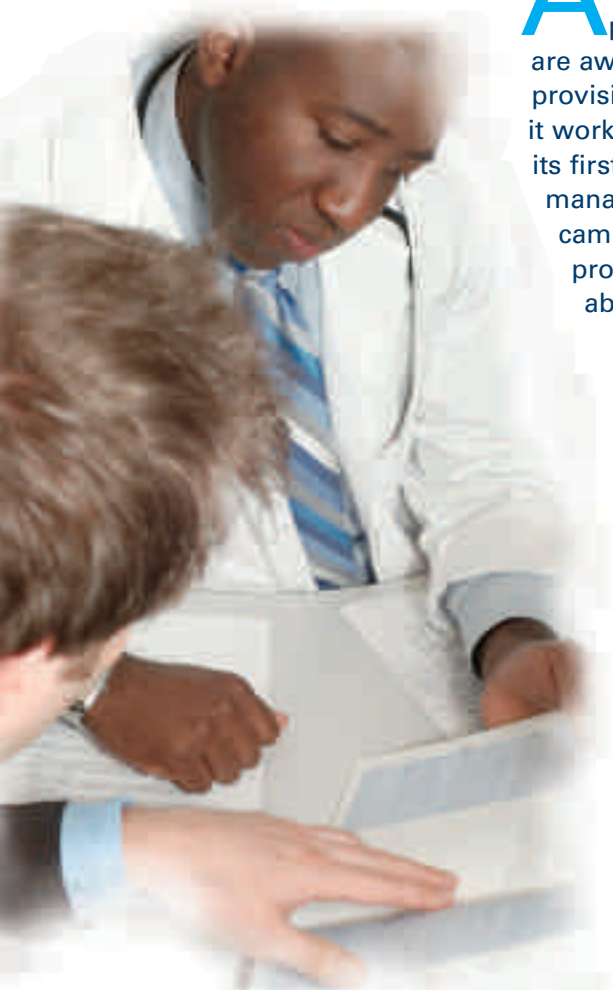
Training on the Code

Seminars designed to explain the requirements of the Code are held by the PMCPA in central London on a regular basis. These seminars are open to all. Eight such seminars were held in 2006 and demand for places was high with all seminars fully booked. One of the key elements in the seminars is the syndicate work and in that regard the PMCPA thanks those who act as syndicate leaders.

In addition, over forty presentations on the Code were held for individual companies and other organisations, including public relations companies and advertising agencies.

The PMCPA is regularly invited to lecture on training courses run by professional organisations and universities and to speak at conferences. Thirteen such speaking engagements were undertaken in 2006.

Communicating the Code



Additional efforts are being made to ensure that more people and organisations are aware of the Code and its provisions and understand how it works. The PMCPA appointed its first communications manager in July 2006. The campaign to inform health professionals and others about the Code is ongoing.

Code Awareness Day

The first ever Code Awareness Day took place on 25 April 2006 when more than 8,000 sales representatives from 50 pharmaceutical companies across the UK talked to health professionals about the Code, its provisions and how to make a complaint.

Highlights from the day included:

- 7,500 clinicians were exposed directly to Code Day messages at two major congresses.
- Over 22,000 doctors were sent personal e-alerts.
- A targeted media campaign resulted in more than 15 features.
- A Parliamentary Motion supporting Code Awareness Day and the Code was signed by 41 MPs.
- Many companies ran in-house events for staff.

The PMCPA published updated **Guidance Notes for Health Professionals** on the Code to clarify its main provisions and this was offered to health professionals on the day together with a leaflet outlining the Code.

The Code awareness campaign, 'It Takes Two to Tango', won the Communiqué award for Best Professional Campaign. It was run by Santé communications. Code Awareness Day was part of this campaign.

The Communiqué judges said that this was a highly effective awareness-raising campaign that demonstrated the ethics and transparency of the industry and delivered outstanding results. The campaign was praised for handling a profoundly challenging topic with creativity and great thought.

House of Commons Health Select Committee

Representatives from the PMCPA met with members of the House of Commons Health Select Committee in November 2006 to update them on the impact of the revisions to the Code and the PMCPA's increased efforts to communicate the Code to wider audiences.

Advertisements in the medical and pharmaceutical press

Under new provisions in the revised Constitution and Procedure, the PMCPA now advertises brief details of all cases where companies were ruled in breach of Clause 2 of the Code, were required to issue a corrective statement or were the subject of a public reprimand. These advertisements both act as a sanction and highlight what constitutes a breach of the Code.

Two such advertisements were placed in the BMJ and The Pharmaceutical Journal in 2006 with others to be published in 2007. The advertisements are also published on the PMCPA website at **www.pmcpa.org.uk**.

Code of Practice Review

Detailed reports of all completed cases are published in the Code of Practice Review on a quarterly basis. The Review is widely distributed and available from the PMCPA's website or on request. Case reports from all complaints received from 1 January 2006 onwards are also available to download individually from the website. The Review also carries comment on matters of current interest for the benefit of companies and others.

Ongoing cases

Brief details on the status of all ongoing cases can be found on the PMCPA website. This is a new requirement of the 2006 Constitution and Procedure.

PMCPA press releases in 2006

The PMCPA issued seven press releases in 2006. They are also published on the PMCPA website. Below is a selection of these releases.

ABPI Code of Practice: Informing Doctors
6 March

Nearly half of doctors are unaware of the Code of Practice that governs relationships between the pharmaceutical industry and its healthcare partners, according to a survey by the Association of the British Pharmaceutical Industry (ABPI) - and an updated booklet published today is the first step in a campaign to boost their knowledge.

Major drive to tell doctors about industry Code
25 April

More than 8,000 employees from 50 pharmaceutical companies across the UK will unite on one day - Tuesday, April 25 - to talk to doctors and other health professionals about the Code of Practice that governs their work.

New guidance for doctors on dealing with pharmaceutical companies welcomed by PMCPA
23 October

The Prescription Medicines Code of Practice Authority (PMCPA) has today welcomed the launch of revised guidance for doctors from the General Medical Council (GMC) which focuses, in part, on the need for doctors to declare conflicts of interest and not accept any inducement, gift or hospitality that may influence, or be seen to influence prescribing.

European and international codes

Work started in 2006 on updating the European Federation of Pharmaceutical Industries and Associations (EFPIA) Code of Practice on the Promotion of Medicines. The Director of the PMCPA is a member of the EFPIA group working on the update.

The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) amended its Code of Pharmaceutical Marketing Practices in 2006 to be implemented by 1 January 2007.

The Director of the PMCPA was appointed as a member of an *ad hoc* group to adjudicate on complaints covered by the IFPMA Code complaints procedure which operates only in relation to countries that do not have local arrangements, be that by self regulation or external regulation.

The Code of Practice Panel

The Code of Practice Panel consists of the Director, Secretary and Deputy Secretary of the PMCPA. The Panel considers all complaints made under the Code in the first instance with the benefit of independent medical and other such expert advice as appropriate.

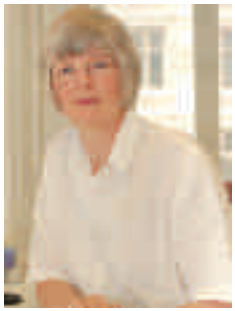
The Panel met 63 times in 2006 (compared with 57 times in 2005). As its three members are all full-time staff, the Panel can meet at short notice as and when required.

Heather Simmonds is the Director of the PMCPA.

Heather chairs the Code of Practice Panel and is responsible for the overall running of the organisation. Heather also works with the IFPMA and EFPIA in relation to their codes of practice. Heather has a degree in pharmacology and joined the ABPI in 1984. She has worked full time on the Code of Practice since 1989 and has been Director of the PMCPA since 1997.

Etta Logan is the Secretary of the PMCPA.

Etta is a solicitor and joined the PMCPA in 1997 from private practice in London where she specialised in medical negligence and professional indemnity litigation.



Jane Landles is the Deputy Secretary of the PMCPA.

Jane is a pharmacist and spent the early part of her career in hospital pharmacy. Jane then spent 10 years in the pharmaceutical industry, first as a medical information officer, later moving into the area of promotional affairs and was ultimately a nominated signatory. She joined the PMCPA in 1996.

The Code of Practice Appeal Board

A complainant whose complaint has been rejected or a company ruled to be in breach of the Code may appeal the Panel's ruling to the Code of Practice Appeal Board. In serious cases a company may be required by the Panel to suspend the material or activity at issue pending the outcome of an appeal.

The Appeal Board has an independent chairman and eight other independent members. There are also twelve senior executives from pharmaceutical companies on the Appeal Board. In addition to its role in relation to appeals, the Appeal Board receives reports on all cases considered by the Panel and oversees the work of the PMCPA.

Following changes to the Constitution and Procedure, two additional independent members were appointed to the Appeal Board in 2006, a registered nurse prescriber and a lay member. They were the first independent members to be appointed following advertising in the national press which was introduced in the 2006 Constitution and Procedure.

The Appeal Board met 11 times in 2006 (compared with 13 times in 2005) and considered appeals in 22 cases in 2006 (compared with 17 cases in 2005).

Membership and attendance during 2006

Chairman
Mr William Harbage QC (11/11)

Independent members
Mrs Mary Baker MBE
(Representing patients' interests) (10/11)

Professor Steve Chapman
(Member from an independent body involved in providing information on medicines) (from October 2006) (1/3)

Professor Richard Hobbs
(University Academic/General Practitioner) (5/11)

Professor Peter Hutton
(Hospital Consultant) (from October 2006) (3/3)

Mrs Aileen Palanisamy
(Nurse Prescriber) (from September 2006) (4/4)

Mr Andrew Reid
(Member who is not a health professional) (from September 2006) (4/4)

Mrs Linda Stone OBE
(Pharmacist) (8/11)

Dr Michael Wilson
(General Practitioner) (10/11)

Industry members

Mr Bob Armitage
(Business Unit Director, Merck Sharp & Dohme Limited) (until October 2006) (2/6)

Dr Susan Bews
(Previously Medical Director, Astellas Pharma Ltd) (from January 2006) (8/11)

Dr Stuart Dollow
(Vice President - Medical, GlaxoSmithKline UK Limited) (6/10)

Dr Robert Donnelly
(Medical Director, Janssen-Cilag Limited) (until June 2006) (1/5)

Ms Helen Roberts
(Legal Director and Company Secretary, Sanofi-Aventis) (7/11)

Dr Rhiannon Rowsell
(Medical and Regulatory Affairs Director, AstraZeneca UK Limited) (4/11)

Mr John Russell
(Sales Director, Eli Lilly and Company Limited) (6/11)

Dr Mark Sampson
(Senior Director, Medical Affairs - Europe, Gilead Sciences Europe Limited) (7/11)

Mr Philip Watts
(Sales Director, Pfizer Limited) (3/11)

Coopted members

The Chairman can co-opt members for meetings of the Appeal Board so as to enable a quorum to be achieved. During 2006, the following were each co-opted for at least one meeting:

Dr Peter Bowen-Davies
(Promotional Affairs Consultant, Pfizer Limited)

Dr John Drake
(Medical Director, Roche Products Limited)

Dr David Farrow
(General Practitioner)

Dr Mike Geraint
(Medical Director, Norgine Limited)

Dr Gillian Shepherd
(Executive Medical Director, Bristol-Myers Squibb Pharmaceuticals Limited)

Statistics on complaints

Complaints are ruled upon in the first instance by the Code of Practice Panel which is made up of the Director, Secretary and Deputy Secretary of the PMCPA, with the benefit of independent medical and other such expert advice as appropriate.

A complainant whose complaint has been rejected or a company ruled to be in breach of the Code may appeal the Panel's ruling to the Code of Practice Appeal Board. In serious cases a company may be required by the Panel to suspend the material or activity at issue pending the outcome of an appeal.

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.

The PMCPA publishes reports of all completed cases in its quarterly Code of Practice Review and on its website at **www.pmcpa.org.uk**. The website also carries brief details of complaints which are under consideration or, if resolved, details of those cases not yet published.

Additional sanctions can also be imposed. These can include:

- the carrying out by the PMCPA of an audit of a company's procedures to comply with the Code; the principal elements of an audit are an examination of documentation and the questioning of appropriate members of staff; following an audit, a company can be required to submit its promotional material to the PMCPA for pre-vetting for a specified period;
- requiring a company to take steps to recover material from those to whom it has been given;
- requiring the publication of a corrective statement;
- a public reprimand; or
- suspension or expulsion from membership of the ABPI for ABPI members. In the case of a non member company, the MHRA can be advised that responsibility for that company under the Code can no longer be accepted.

The PMCPA advertises in the medical and pharmaceutical press brief details of all cases where companies are ruled in breach of Clause 2 of the Code, are required to issue a corrective statement or are the subject of a public reprimand.

Complaints received by the PMCPA

	2006	2005	2004
Complaints received	134	101	119
No *prima facie* case established	15	4	3
Covered by a previous case	-	1	-
Complaints withdrawn	1	1	2
Company declined to accept the PMCPA's jurisdiction before proceedings commenced	1	1	1
Insufficient information to proceed	-	1	-
Complaints considered	117	93	113
Cases arising from these complaints	128	107	119
Individual matters considered	272	275	424

Some complaints involve a number of allegations. Some complaints give rise to more than one case as they involve more than one company. Each individual issue alleged to be in breach is one 'matter'.

Outcomes of complaints considered

	2006	2005	2004
Cases where a breach found	73	86	88
Cases where no breach found	55	21	31
Number of matters in these cases			
- in breach	112	158	236
- no breach	160	117	188
Breaches of undertaking ruled	3	4	3
Breaches of Clause 2 ruled	13	17	9
Reports to the Code of Practice Appeal Board	6	3	8
Reports to the ABPI Board of Management	1	4	4

Sources of complaints

	2006	2005	2004
Health professionals			
General practitioners	22	20	15
Hospital doctors	2	6	4
Other doctors	5	2	3
Pharmacists	7	9	8
Medical/ pharmaceutical advisers	18	14	16
Nurses	1	-	1
Pharmacy technicians	-	1	-
Managers	2	-	1
	57	52	48
Pharmaceutical companies			
ABPI members	21	21	35
Non members	2	7	11
	23	28	46
PMCPA Director			
Arising from media criticism	13	2	3
Arising from other complaints	4	1	1
Alleged breach of undertaking	1	4	11
Arising from voluntary admissions	8	1	3
Arising from scrutiny	1	-	1
	27	8	19
Organisations			
Medicines and Healthcare products Regulatory Agency	2	-	1
Royal College of General Practitioners	-	-	1
Insulin Dependent Trust	-	1	-
Gays against Genocide	-	2	-
Other organisations	2	-	-
	4	3	2
Others			
Members of the public	3	1	1
Anonymous	13	6	2
Employees	5	-	1
Anonymous employees	2	3	-
	23	10	4
Total	**134**	**101**	**119**

Appeals to the Code of Practice Appeal Board

	2006	2005	2004
Total number of matters ruled upon by the Code of Practice Panel	272	275	424
Rulings accepted by complainants and respondents involved	232	243	357
Number of cases appealed	22	17	23
Rulings successfully appealed	15	10	19
Rulings unsuccessfully appealed	25	22	48

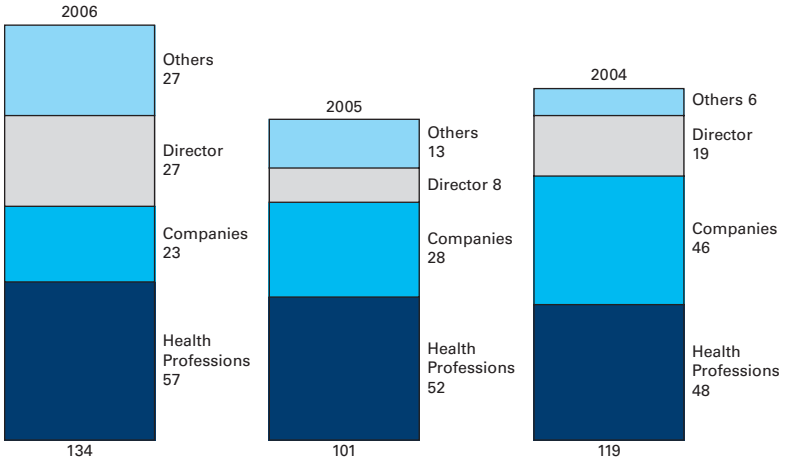
Sources of appeals

	2006	2005	2004
Cases appealed by complainants	5	4	8
Cases appealed by respondents	19	15	18

In two cases in 2006 and two cases in 2005, both the complainant and respondent appealed.

	2006	2005	2004
Appeals by complainants			
successful	1	-	4
partly successful	1	2	1
unsuccessful	3	2	3
	5	4	8
Appeals by respondents			
successful	7	3	-
partly successful	3	4	5
unsuccessful	9	8	13
	19	15	18

Complaints received

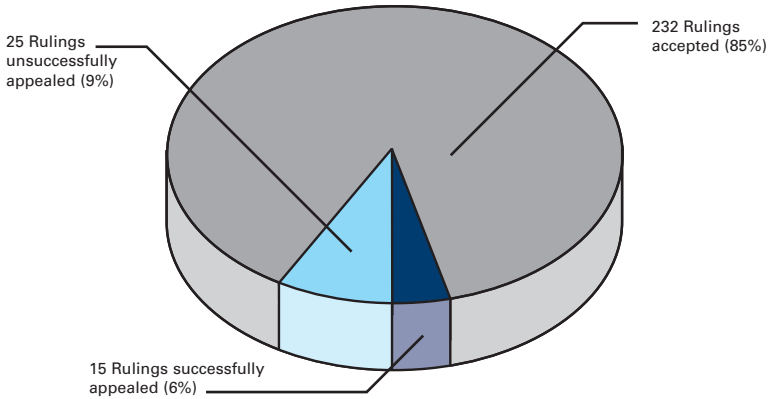


Complaints nominally made by the Director frequently result from media criticism of the promotion of prescription medicines. Such criticism is always examined in relation to the Code.

Complaints nominally made by the Director can also arise as a result of:

- *the routine scrutiny of advertisements;*
- *from the detection of other possible breaches when a complaint is being considered;*
- *when it is alleged that a company has failed to comply with an earlier undertaking to cease a particular method of promotion; and*
- *from voluntary admissions.*

Code of Practice Panel Rulings



In 2006 the Code of Practice Panel made 272 rulings. Of these, 232 (85 per cent) were accepted by the complainants and respondents involved. A further 25 (9 per cent) were the subject of unsuccessful appeals to the Code of Practice Appeal Board. The remaining 15 (6 per cent) were successfully appealed to the Appeal Board.

Average time taken to complete cases (in weeks)

	2006	2005	2004
Cases settled at Code of Practice Panel level	9.2	8.4	9.7
Cases which were the subject of appeal	19	17.5	20.4
All cases	10.9	9.9	11.8

Scrutiny

The PMCPA scrutinises a sample of all advertisements issued by pharmaceutical companies in accordance with the provisions of its Constitution and Procedure and takes up with the companies concerned any advertisements potentially in breach of the Code.

In 2006 ten advertisements were taken up as potentially being in breach of the Code. Nine were satisfactorily resolved with the companies concerned and the tenth was taken up as a formal complaint.

Accounts 2006

The PMCPA has been self financing from the beginning of 1996. In 2006 there was a surplus of £28,571 (£20,000 after tax). The PMCPA currently holds reserves of £200,822.

From 1993 until 1995, the PMCPA was subsidised by the ABPI as its income was insufficient to meet expenses. This subsidy was repaid to the ABPI in 2003.

Annual levy

All members of the ABPI are required to pay an annual Code of Practice levy (in addition to their ABPI subscriptions) to fund the PMCPA.

The levy is £3,000 to £24,000 depending on the size of the company. Sixty per cent of the levy due was called up in 2006. However, the costs of the PMCPA are mainly covered by administrative charges which are paid by companies actually involved in cases.

Administrative charges

Administrative charges are payable by companies (both members and non members of the ABPI) in relation to complaints made under the Code.

Companies which are not members of the ABPI do not pay the levy, so the administrative charges for them are consequently higher. No charges whatsoever are payable by complainants from outside the industry.

Charges are paid either by the company found to be in breach of the Code or, where there is no breach of the Code, by the company which made the unfounded allegations. The charges are assessed per matter ruled upon and a number of matters may arise in a particular case.

The charge per matter in 2006 was £2,500 for member companies and £3,500 for non member companies where the decision of the Code of Practice Panel was accepted.

Where the decision of the Panel was unsuccessfully appealed, the charge per matter in 2006 was £10,000 for member companies and £11,000 for non member companies.

Seminars

Additional income is generated by the PMCPA training seminars on the Code. These seminars, designed to explain the requirements of the Code, are held by the PMCPA on a regular basis in London or in-house for pharmaceutical companies and others.

Income

	2006 £	2005 £	2004 £
Levy	334,620	327,563	75,963
Administrative charges	341,825	395,250	440,625
Seminars/ meetings	194,367	117,908	112,106
Company audits	48,000	32,000	28,000
Contributions to advertising costs	7,500	-----	------
	£926,312	£872,721	£656,418
Expenditure	£897,741	£765,627	£656,418

Expenditure includes salaries, fees, administration costs and the cost of office accommodation.

More information

If you would like to find out more about the PMCPA or its work, please go to our website at **www.pmcpa.org.uk**.

Alternatively you can contact the PMCPA at:

Prescription Medicines Code of Practice Authority (PMCPA)
12 Whitehall
London SW1A 2DY

Tel: 020 7747 8880
Fax: 020 7747 8881
Email: **info@pmcpa.org.uk**

The following publications are available to download from the PMCPA's website or from the PMCPA upon request:

- The ABPI Code of Practice for the Pharmaceutical Industry.
- The quarterly Code of Practice Review - which contains comment on current issues and reports on the outcome of complaints made under the Code.
- Guidance Notes for Health Professionals: Understanding the ABPI Code of Practice for the Pharmaceutical Industry - a booklet that focuses on the most relevant parts of the Code for health professionals.
- The Code and You leaflet - which briefly introduces what the Code is.
- Information leaflets about the PMCPA and the Appeal Procedure.

Reports of completed cases are available from the PMCPA's website which also carries brief details of ongoing cases or, if resolved, cases for which the case report is not yet published.

Complaints about the promotion of medicines for prescribing or the provision of information about prescription only medicines should be submitted to:

The Director
Prescription Medicines Code of Practice Authority
12 Whitehall
London SW1A 2DY

Tel: 020 7747 8880
Fax: 020 7747 8881
Email: **complaints@pmcpa.org.uk**