

Enforcement of codes governing pharmaceutical promotion: What happens when companies breach advertising guidelines?

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Abstract

SOME OR ALL OF THE PROMOTIONAL ACTIVITIES of pharmaceutical companies are typically governed through self-regulatory codes administered by industry associations. However, the conflicts between the commercial objectives and the ethical and scientific goals of promotion can potentially lead to serious weaknesses in the way in which these codes are enforced. This paper focuses on 5 critical aspects involved in the enforcement of codes governing pharmaceutical promotion: mechanisms for recognizing violations, composition of monitoring committees, sanctions for code violations, the quantity and quality of information in reports issued about complaints and code violations, and the circulation these reports receive. The Code of Marketing Practices of the Pharmaceutical Manufacturers Association of Canada (PMAC) has serious weaknesses in all of these areas. Although the Pharmaceutical Advertising Advisory Board's Code of Advertising Acceptance avoids many of the deficiencies of the PMAC code, it, too, has weaknesses. Proposals for strengthening the enforcement of both codes are offered.

Résumé

LES ACTIVITÉS DE PROMOTION DES SOCIÉTÉS PHARMACEUTIQUES sont habituellement régies en totalité ou en partie par des codes d'autoréglementation administrés par les associations de l'industrie. Les conflits entre les objectifs commerciaux et les buts éthiques et scientifiques de la promotion peuvent toutefois être la cause de graves faiblesses dans l'application de ces codes. Ce document porte avant tout sur 5 aspects critiques de l'application des codes régissant la promotion des produits pharmaceutiques : mécanismes de dépistage des infractions, composition des comités de surveillance, sanctions qu'entraînent les infractions au code, quantité et qualité des renseignements contenus dans les rapports publiés au sujet des plaintes et des violations du code et distribution de ces rapports. Le Code des pratiques de commercialisation de l'Association canadienne de l'industrie du médicament (ACIM) a de graves faiblesses dans tous ces domaines. Même si le Code d'agrément de la publicité du Conseil consultatif de la publicité pharmaceutique évite un grand nombre des lacunes de l'ACIM, il a ses faiblesses, lui aussi. On propose des moyens de muscler l'application des deux codes.

The pharmaceutical industry spends heavily promoting its products to physicians. In Canada it is estimated that 16% of sales is used for promotion.¹ With total 1995 sales of \$5.9 billion,² promotional expenses amounted to almost \$950 million.

The effects of promotion on prescribing behaviour are not benign. Studies in 4 industrialized countries (Belgium, the Netherlands, the United Kingdom and the United States) spanning a quarter of a century (1972–96) have consistently shown that the more physicians rely on promotion for their source of information about drugs, the less appropriately they prescribe.^{3–9} Even prescribers who think that they obtain their knowledge from the scientific literature can be influenced by promotional sources without being aware of it.¹⁰



Evidence

Études

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Pharmaceuticals also differ from ordinary products in other important respects: the person who chooses the medication is not the person who consumes it or pays for it. Prescription medications are therefore part of a captive market. These rather unique characteristics of pharmaceuticals, in addition to the adverse effects of promotion on the quality of prescribing, help explain why pharmaceutical promotion is a candidate for some form of regulation. Governments in nearly all industrialized countries, including Canada, have ceded day-to-day control over some or all aspects of pharmaceutical promotion to voluntary national industry associations. In turn, these associations have developed codes of marketing to which their member companies are expected to adhere.

Industry self-regulatory codes lay down principles and practices to be observed in promotion in an attempt to balance commercial objectives with the ethical and scientific objectives of providing accurate information to prescribers. However, this tension between the commercial and ethical underpinnings of codes can potentially lead to serious weaknesses in their enforcement.

In this paper I focus on 5 critical aspects involved in the enforcement of codes governing pharmaceutical promotion: mechanisms for recognizing violations, composition of monitoring committees, sanctions for code violations, the quantity and quality of information in reports issued about complaints and code violations, and the circulation these reports receive. To put the Canadian situation into an international perspective I will first summarize the experiences in Australia and the United Kingdom.

An international perspective on self-regulatory codes

Recognition of violations of self-regulatory codes in industrialized countries, including Australia and the United Kingdom, is unanimously achieved through a complaints mechanism.¹¹ In addition, the Australian and UK codes make provision for monitoring of random samples of journal advertisements to ensure that they comply with technical requirements of the codes, such as legibility of prescribing information. Codes contain details for their administration, but the structure and composition of the administrative committees vary. The three members of the Prescription Medicines Code of Practice Authority of the Association of the British Pharmaceutical Industry operate independently of the association.^{12,13} The Australian Code of Conduct Subcommittee is chaired by a lawyer with trade practice experience and has a representative from a consumer's organization; in total 6 of its 10 members come from outside the industry, although 2 of these 6 (the chair and the deputy chair) are appointed by the Australian Pharmaceutical Manufacturers Association.¹⁴

The Australian subcommittee may impose one or more of the following sanctions: a written undertaking to discontinue or modify any practice that is determined to breach the code, the issuance of retraction statements, the issuance of a fine, with a maximum limit of \$20 000, and suspension or expulsion from the Australian Pharmaceutical Manufacturers Association.¹⁵ No company has ever been fined, suspended or excluded, and only 2 corrective letters were required in 1994–95 out of a total of 20 breaches.¹⁶ Sanctions in the UK code are similar to those in the Australian code except that there is no provision for the levying of fines. A significant addition to the UK code is the provision for an audit of a company's procedures in relation to the code.¹⁷

Reports on code violations in Australia contain only scanty information about breaches: the company's name, the product, the section of the code in breach and the sanction. They do not describe the nature of the complaint, the company's response or the details of the reasoning leading to the subcommittee's decision as to whether or not a breach has occurred.¹⁶ In contrast, the quarterly reports in the United Kingdom contain all this information.

Until October 1994 publication of information about complaints regarding the Australian code appeared regularly in summarized form in the *Medical Journal of Australia*. However, since then, publication seems to have ceased. Copies of the reports regarding the UK code go to the British Medicines Control Agency, the Office of Fair Trading, the British Medical Association, the Royal Pharmaceutical Society of Great Britain and the editors of the *British Medical Journal* and the *Pharmaceutical Journal*.

The Canadian experience

Canada is somewhat unique in that promotional material is regulated by 2 codes. Journal advertising as well as advertising and promotional messages conveyed via audio, visual, audiovisual, electronic and computer means of communication are subject to clearance by the Pharmaceutical Advertising Advisory Board (PAAB) before dissemination.¹⁸ All this material must be submitted to the PAAB before use, where it is reviewed by the commissioner and the commissioner's staff for compliance with the provisions of the PAAB's Code of Advertising Acceptance.¹⁸ The PAAB is independent of the industry and is governed by a board of directors that has representatives from the Pharmaceutical Manufacturers Association of Canada (PMAC), the generic drug manufacturers, the CMA, the Canadian Pharmaceutical Association, the Consumers' Association of Canada and professional advertising associations.

The other code in Canada is the Code of Marketing



Practices of the PMAC.¹⁹ The PMAC represents nearly all multinational subsidiaries active in Canada along with some Canadian-owned biotechnology companies. One of the provisions of the PMAC code is that all members of the organization agree to abide by the PAAB code along with the journal insert guidelines from the Association of Medical Media. The PMAC code covers 8 different forms of promotion: advertising and information dissemination (the provision of information about new products as well as the signing of promotional material by medical and scientific personnel), distribution of samples, sponsorship of continuing medical education (CME) events such as symposia and congresses, displays at conventions or clinical days, activities of pharmaceutical sales representatives, postmarketing clinical studies, service-oriented items (e.g., books and medical equipment) and "special promotions," and marketing research used to identify and define marketing opportunities and problems.

The PMAC code has the most in common with those in Australia and the United Kingdom in the sense that it is a self-regulatory industry-generated code. At the same time, the scope of the PMAC code is more limited than that of the Australian and UK codes, because elements of promotion that are governed by these codes fall under the purview of the PAAB code. Moreover, as previously mentioned, part of the PMAC code mandates compliance with the provisions of the PAAB code. Consequently, activities that the PAAB engages in, such as pre-clearance, are de facto part of the PMAC code and its operations. Similarly, other features of the PAAB code, such as sanctions for violations, and the type of information in the PAAB reports are also effectively endorsed by the PMAC code. Therefore, although I have focused the bulk of my analysis on the PMAC code, I will also refer to relevant aspects of the PAAB code.

Enforcement of the 2 codes

Violations of both the PMAC code and the PAAB code are initially identified through a complaints mechanism. The PMAC code makes no provision for any monitoring of promotional activities in any of the areas regulated, but the PAAB clears advertising material and also monitors journal advertisements to ensure that the advertisements are identical to the copy approved and that technical requirements such as minimum typesize are met. Complaints against the PMAC code are reviewed by the Marketing Practices Review Committee. In addition to 4 members from the industry, the committee has 1 member representing the PAAB and 2 appointed by the CMA. The committee is chaired by one of the industry representatives. I was unable to obtain any further information about the composition of this committee despite 2 at-

tempts to contact the PMAC official responsible for this area.

Sanctions for code violations are levied according to the number of violations a company commits in a given 12-month period. For the first violation the only sanction is publication of the infraction in *PMAC News*, an industry newsletter that is issued 10 times per year. The newsletter receives little distribution outside of industry circles. For the second, third and fourth violations there are fines of \$1000, \$5000 and \$10 000 respectively. In addition, after the fourth violation the matter is referred to the PMAC's board of directors. There is no mention in the PMAC code about what actions may be taken at this level, and there are no provisions for issuing corrections or for a review of a company's compliance with the code as there are in the United Kingdom.

The commissioner of the PAAB, who is independent of the pharmaceutical industry, adjudicates complaints about advertisements that fall within the scope of that organization's code. When complaints are upheld the usual penalty is the cost of revision of the offending advertisement. However, in cases of more serious or repeated violations the PAAB may require that the company involved send out letters of retraction or publish notices in the same medium in which the original offending advertisement appeared.

To assess the quantity and quality of information in reports about complaints and violations of the PMAC code, I reviewed reports in *PMAC News* and its predecessor, *PMAC Bulletin*, from Nov. 1, 1991, to Dec. 31, 1995. Reports usually appear quarterly and cover a 3-month period, but none was published for March–April 1994 or July–September 1995. Reports or summaries of code violations do not appear in any Canadian general or medical media.

Over the 45 months for which figures were available, there were 157 violations. The largest number, 55, took place in the period November 1991–October 1992 (Table 1). Violations were reported in 6 of 8 possible categories: advertising and information dissemination, sponsorship of CME events, displays at conventions, activities of pharmaceutical sales representatives, postmarketing clinical studies, and service-oriented items and special promotions. Over half the violations involved sponsorship of CME events. There were only 8 infractions in the combined categories of displays at conventions, activities of pharmaceutical sales representatives and postmarketing clinical studies.

Thirty-six companies had at least one code violation. The vast majority committed 5 or fewer. Marion Merrell Dow (Canada) Inc. and Hoechst Canada Inc. (now Hoechst Marion Roussel Canada Inc.) had by far the largest number (24 and 19 respectively), and 6 other companies had more than 5 infractions (Table 2).

There was no published information about the total number of complaints, who made the complaints, when the complaint was made, when the violation took place, the product involved, the exact nature of the offence or sanctions imposed or about alleged violations that were not upheld. The lack of any details about the nature of the infraction or the sanctions imposed makes it impossible to determine how serious the violations were and whether the guilty companies were disciplined appropriately. Similarly, if Marion Merrell Dow's 24 violations were all minor, it may actually have been more observant than a company with 2 or 3 serious violations.

The PAAB publishes an annual report that goes to the Drugs Directorate of the federal Health Protection Branch as well as to the PAAB board of directors and presumably thence to the member organizations. Distribution of the report to other parties is on an ad hoc basis. The report lists the total number of complaints handled during the year and the number of retraction letters that companies were required to send out. Otherwise, little in-

formation about the complaints is given: the companies involved are not identified, the complainant is not identified except to give the numbers of complaints made by pharmaceutical companies and by others, the nature of the violations is not described, the product involved is not named, the time the violation took place is not disclosed, and the reasons for the commissioner's decision are not given.

Some proposals for change

Clearly, enforcement of the PMAC code is deficient in all of the areas under consideration compared with procedures in Australia and the United Kingdom (Table 3). A complaints mechanism means that unreported violations avoid detection. There is evidence that many violations of marketing codes go unreported. According to one US report, although over 10% of statements from pharmaceutical sales representatives are inaccurate, physicians did not recognize these inaccuracies and therefore would not have

Table 1: Violations of the Pharmaceutical Manufacturers Association of Canada (PMAC) Code of Marketing Practices reported in *PMAC News* from Nov. 1, 1991, to Dec. 31, 1995

Category	Period; no. of violations				Total
	Nov. 1/91 to Oct. 31/92	Nov. 1/92 to Oct. 31/93	Nov. 1/93 to Oct. 31/94*	Nov. 1/94 to Dec. 31/95†	
Advertising and information dissemination	5	3	7	1	16
Continuing health education	31	28	16	14	89
Displays at conventions	3	1	0	0	4
Activities of pharmaceutical sales representatives	0	1	1	1	3
Postmarketing clinical studies	1	0	0	0	1
Service-oriented items and special promotions	15	15	11	3	44
Total	55	48	35	19	157

*No report for March–April 1994.

†No report for July–September 1995.

Table 2: Companies noted for more than 5 violations of the PMAC Code of Marketing Practices between Nov. 1, 1991, and Dec. 31, 1995

Company	Period; no. of violations				Total
	Nov. 1/91 to Oct. 31/92	Nov. 1/92 to Oct. 31/93	Nov. 1/93 to Oct. 31/94	Nov. 1/94 to Dec. 31/95	
Marion Merrell Dow (Canada) Inc.	16	7	1	0	24
Hoechst Canada Inc.	8	4	6	1	19
Hoffmann–La Roche Limited	1	1	3	5	10
Miles Canada Inc.	1	4	3	0	8
Cyanamid Canada Inc.	1	6	0	0	7
Glaxo Canada Inc.	1	4	2	0	7
Pfizer Canada Inc.	0	2	2	3	7
Rhône-Poulenc Rorer Canada Inc.	1	1	2	2	6



filed complaints.²⁰ Herxheimer and Collier²¹ speculated that a considerable number of violations of the UK code escaped detection because few health care professionals bothered to complain. Proactive ongoing monitoring of a random sample of all promotional activities governed by the PMAC code is needed. This step could be financed by a levy on PMAC member companies.

The committee that monitors the code needs to be reconstituted in a manner similar to the one in Australia. A majority of its members should come from outside the industry, and consumer representatives need to be included. The committee should have an independent chair with experience in trade practice areas.

Sanctions should have 2 main objectives. First, they should deter companies from misleading promotion. A wide range of escalating sanctions, up to and including

temporary or permanent suspension of all promotion for the product, need to be considered and implemented. Second, sanctions should aim to correct any false beliefs. When a prescriber has been misled, incorrect beliefs or actions will continue until that person receives effective alternative information.¹⁶ The current sanctions imposed under the PMAC code fall short on both accounts.

The quantity and quality of information contained in reports of PMAC code violations is unacceptable. As well, the lack of widespread publication of the reports needs correction. Public reporting on all aspects of complaints and violations is a critical issue for a number of reasons. First, this is an important accountability mechanism. Second, public reporting should be considered an integral part of any sanctions against companies. Companies have an incentive to maintain compliance with a code and

Table 3: Key characteristics of pharmaceutical codes in Australia, the United Kingdom and Canada*

Characteristic	Australia	United Kingdom	Canada	
			PMAC code	PAAB code
Enforcement mechanism	Complaints plus random audits of journal advertisements to check for compliance with technical provisions of code	Complaints plus random audits of journal advertisements to check for compliance with technical provisions of code	Complaints	Preclearance plus complaints plus random audits of journal advertisements to check for compliance with technical provisions of code
Committee membership	10 members: 6 not from industry (1 consumer representative; chair and deputy chair appointed by APMA) and 4 from industry	3 members: committee operates independently from ABPI	7 members: 4 from industry, 2 representatives from CMA, 1 from PAAB	Commissioner
Sanctions	One or more of: written undertaking to discontinue practice, issue of formal retraction, fine of up to \$20 000, suspension or expulsion from APMA	One or more of: published reprimand, audit of company's procedures in relation to code, publication of corrective statement, suspension or expulsion from ABPI	Escalating fines up to \$20 000, possible unspecified action taken by PMAC board of directors after 4th violation in a 1-year period	One or more of: withdrawal of advertisement, retraction letter, published notice in the same medium in which the offending advertisement appeared
Information in reports	Company name, product name, section of code in breach, sanction	Company name, product name, section of code in breach, sanction, nature of complaint, company's response, details of decision as to whether breach occurred	Company name, section of code in breach	Number of retraction letters sent out, number of complaints
Report distribution	Semiannual summary of all code breaches sent to medical journals	Quarterly summary of all code breaches sent to British Medicines Control Agency, editors of <i>BMJ</i> and <i>Pharmaceutical Journal</i> , British Medical Association, Royal Pharmaceutical Society of Great Britain and Office of Fair Trading	In <i>PMAC News</i> (distribution largely within industry)	In PAAB annual report sent to Health Protection Branch and member organizations

*PMAC = Pharmaceutical Manufacturers Association of Canada, PAAB = Pharmaceutical Advertising Advisory Board; APMA = Australian Pharmaceutical Manufacturers Association; ABPI = Association of British Pharmaceutical Industry.



avoid adverse publicity and possible deterioration of their public image. Third, public reporting is a good way to inform health care professionals about the existence of a code and its requirements. Above all, public reporting is essential for informing health care professionals about which misleading claims they have been exposed to.¹⁶ Reports on violations of the PMAC code should include all the information given out in the United Kingdom, and these reports should be distributed to medical, advertising and general media to ensure they receive widespread circulation.

In most respects enforcement of the PAAB code is much more consistent with the practices in Australia and the United Kingdom, and in the area of preclearance the PAAB code is superior. The exception is the quality and quantity of the information in the PAAB annual reports and their limited distribution. Reforms in these areas would help strengthen the credibility of the PAAB.

Promotion is here to stay. To help balance the inevitable conflicts between the commercial objectives and the ethical and scientific goals of promotion it is important that codes function as optimally as possible.

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