

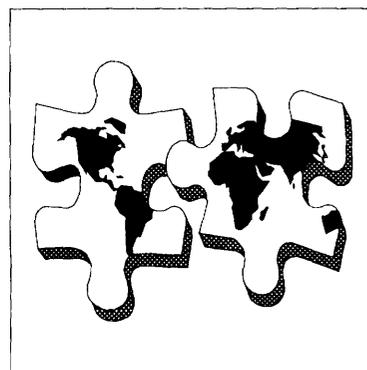
# Codes of Conduct and Voluntary Guidelines for Pharmaceutical Information

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**T**his chapter examines the potential for improving the quality of drug labeling in developing countries through means other than strengthening national drug regulation directly. Every country has laws governing at least some aspects of pharmaceutical registration and labeling, and a designated individual or agency to carry out those laws. In the United States and other industrialized countries, substantial resources are devoted to making sure the laws and regulations are upheld, even then with imperfect results. There is convincing evidence that in many, if not most, developing countries either the laws are too weak to ensure a safe and effective drug supply, or more commonly, the governments are unable to allocate sufficient resources to implement the laws fully.

Legitimate differences of opinion may exist about the extent of this problem, but both the OTA survey and a recent survey by Silverman, Lydecker, and Lee (212) confirm that pharmaceutical manufacturers are providing inadequate prescribing information for at least some of their products sold in developing countries. Silverman, Lydecker, and Lee make the important point that, overall, labeling by *domestic* companies in developing countries is worse than that of multinational corporations (MNCs), but both studies found significant problems with multinational labeling as well.

Alternatives to national regulation include codes of conduct and voluntary guidelines drawn up by international bodies (e.g., agencies of the United Nations). The main targets of codes and guidelines have been multinational corporations, which still leaves the problem of domestic companies to be solved. This study has focused only on U.S.-based multinationals; the mechanisms discussed in this chapter would apply to all multination-



als and in some cases, to domestic companies (e.g., when a code of conduct is adopted as law in a country).

There is no current international code of conduct for pharmaceutical labeling. The draft United Nations Code of Conduct for Transnational Corporations, which generally addresses labeling of all consumer goods by multinational corporations, comes closest, but it may never be ratified. A possible model for a pharmaceutical code is the World Health Organization (WHO) Code of Marketing of Breast-Milk Substitutes, which addresses the promotional practices of multinational corporations in developing countries. WHO has developed *guidelines*, which are of lesser standing than codes of conduct, for pharmaceutical promotion (“Ethical Criteria for Medicinal Drug Promotion”) (264).

Codes of conduct usually refer to voluntary actions of governments, but in the case of pharmaceuticals, the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) has adopted its own code of conduct for marketing and labeling. A discussion of the provisions of this code and its impacts are included in this chapter.

## **CODES OF CONDUCT AND GUIDELINES UNDER INTERNATIONAL LAW**

Since the 1970s, countries have become increasingly interested in the role MNCs play in national and global economics. A result of the increased attention has been the development of codes of conduct providing standards for national laws to regulate MNCs, and business Wides that MNCs may adopt as corporate policy. Codes of conduct have been formulated by both governmental and nongovernmental organizations, including the United Nations (U. N.) and its agencies, the International Labor Office (ILO), the Organization of Economic Co-operation and Development (OECD), the International Cham-

ber of Commerce, and regional organizations. The codes range from broad pronouncements of principle which multinationals should follow, such as the OECD Guidelines for Multinational Corporations, to codes aimed at corporate operations, such as the U.N. Conference on Trade and Development Code of Conduct on Restrictive Business Practices (98).

Codes of conduct function as formal pronouncements by nations on policy matters (48). They are not legally binding instruments unless adopted into the national law of a country or ratified as a treaty. Nonetheless, when a number of countries endorse a code of conduct, through a U.N. resolution or other legal instrument, it is likely to have an impact. Codes are “politically-agreed behavior which cannot be legally enforced directly, but cannot either be legitimately infringed” (125). Even the process of developing a code, through the pooling of information, opinions, and experiences, may facilitate regulation and increase cooperation.

Rather than becoming parties to a code of conduct, countries may instead endorse a resolution, stating general agreement with a set of principles, but assuming no obligation to take further action. Such instruments are usually called guidelines, and as the name implies, are meant to provide a framework for further action. Though not as strong a force as a code of conduct, guidelines may become the basis of national laws or be used to develop codes of conduct.

One might question the purpose of codes of conduct, given what seems to be rather weak means of enforcing them. It is important to remember, however, that all international law is, to some extent, voluntary because it is based on the consent of individual nations. There is no supranational organization with the power to enforce international laws, nor is there a legislative body in which the majority of nations can bind the minority (25 1). The main difference between inter-

national law<sup>1</sup> and voluntary codes of conduct is the degree to which a country agrees to be bound and the corresponding action that the international community will take in response to a breach of a country's obligations. If an obligation is established under international law, it might be acceptable for another country to take retaliatory action to enforce that obligation; for example, through a trade embargo. A country would not be justified in taking such extreme retaliatory action in response to infractions of a code of conduct by another country, but might respond by not abiding by the code with respect to that country.

A related question is why codes of conduct are not adopted as multilateral treaties, which have the strongest standing under international law. Codes represent a compromise that allows countries to come to agreement on certain policies, and to relieve tensions within the international community without giving up their sovereign right to regulate within their borders. Many countries perceive treaties that address domestic issues (e.g., the treatment of corporations operating within a country's borders) as unacceptable threats to sovereignty (125).

Codes serve a number of purposes. The principles embodied in a code maybe used as a model for national regulation; its widespread endorsement provides assurance that such legislation is acceptable to the international community and its enforcement is unlikely to create international tensions. Courts and other governmental agencies may also look to codes of conduct when interpreting relevant national laws or interpreting the reasonableness of private contractual provisions, However, some countries, including the United States, might disagree that codes of conduct should be used by courts or government

agencies. These "minimalist" countries emphasize the voluntary nature of codes of conduct and resist efforts to expand their significance beyond a statement of general principles if their provisions are not adopted in national legislation or other binding instruments (11).

A question with respect to MNCs is whether, and under what circumstances, they will comply with a code of conduct that has not been implemented in national laws. Even where codes have no formal legal standing, they create standards by which corporations' actions can be measured. Corporate behavior that is at variance with the code may result in adverse publicity or governmental action (125).

Although codes of conduct may be enforced only by the signatories, most codes establish an organization to monitor implementation and to provide interpretations of the code as needed. This organization is a locus for continued exchange of information and debate among signatories. It can also receive reports of violations and arbitrate complaints. Although these organizations usually have authority to clarify the meaning of provisions that apply in a particular dispute, in most cases they may not make a finding on the merits of the dispute, but they do provide a public forum for debate and may serve as triggers for further political intervention (125).

In sum, codes of conduct are political instruments that are likely to influence corporate and governmental behavior, but because they are voluntary, their influence may be limited. Industrialized countries have not been willing to agree to binding international agreements to govern the operations of MNCs, so codes of conduct provide an alternative means of affecting MNC behavior (125).

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<sup>1</sup>The Statute of the International Court of Justice identifies three sources of international law in order of importance: 1) international conventions or treaties, 2) customary international law, and 3) general principles of law recognized by civilized nations. Customary international law is derived from the practice of states. A practice rises to the level of customary international law when the practice is adopted by most states and the states conform with the practice out of a "recognition that a rule of law or legal obligation is involved" (105).

### The United Nations Code of Conduct for Transnational Corporations

Work on the U.N. Code of Conduct for Transnational Corporations (the “Transnational Code”) began in 1977 and a draft was completed in 1982. While agreement was reached quickly on roughly 80 percent of its provisions (225), the code has not been, and may never be, adopted in full. As drafted, however, the Transnational Code is more comprehensive than any international voluntary code now in existence. It attempts to create a single framework for the rights and responsibilities of MNCs and governments with respect to foreign investment by providing guidelines on how MNCs, both privately and government owned,<sup>2</sup> should operate in host countries,<sup>3</sup> and how the host countries should treat MNCs operating within their borders (224). Most of the provisions on which there is agreement address the role of the MNC in the host country. These include requirements that MNCs observe national laws, respect fundamental human rights, adhere to sociocultural objectives, support consumer and environmental protection, comply with the fiscal policies of host countries, and observe fair labor standards (225).

The Code also contains general guidelines for consumer protection, although this is not its central focus. The current draft requires that all MNCs obey the consumer laws of the countries in which they market products (this includes all types of consumer products, not only pharmaceuticals) and provide consumers with “all appropriate information on the contents and, to the extent known, on possible hazardous effects of products, . . . by means of proper labeling, informative and accurate advertising or other appropriate methods” (227). MNCs would also be called on to cooperate with international organizations in

developing and promoting national and international health and safety standards (227). Both of these provisions *could* require an MNC to go beyond the requirements of national laws. However, no more specific guidance is given on what is meant by phrases like “appropriate information” or “possible hazardous effects,” or on acceptable means of conveying the information. MNCs would retain a great deal of discretion in deciding the appropriate content of labeling if the Transnational Code were ratified as it now stands.

The Code calls for national laws and bilateral, regional, and multinational agreements to implement it (227). The Commission on Transnational Corporations, which drafted the Code, is the international body designated to assist with its implementation. The Commission is expected to:

1. facilitate dialogue among governments, trade unions, consumer groups, and other relevant groups;
2. develop procedures for providing clarification of the Code;
3. help negotiate Code-related agreements between governments or transnational corporations; and
4. act as an information clearinghouse on issues related to the Code.

Some commentators question the need for the Code, believing that it reflects outdated political concerns about the nature of foreign direct investment and the role of MNCs in developing countries, based on the experiences of the 1960s and 1970s (22,226). The U.N. Centre on Transnational Corporations concedes that developing countries have become more sophisticated in regulating MNCs and that tensions between industrialized and developing countries have eased

<sup>2</sup> There is no practical distinction between transnational corporations and MNCs, except that some commentators use **MNC** to refer to privately owned companies, while the term transnational **corporation**, as used in the U.N. **Transnational Code**, refers also to government owned companies.

<sup>3</sup> A **host country** is the country in which an **MNC** has a foreign subsidiary. The **home country** is the country in which the **MNC** has its headquarters.

since they began drafting the Code. However, supporters still believe that the Code can make a contribution, even in the changed investment environment (225). As of early 1993, negotiations are being conducted at a higher level, being chaired by the President of the U.N. General Assembly.

### International Code of Marketing of Breast-Milk Substitutes

The WHO International Code of Marketing of Breast-Milk Substitutes (Breast-Milk Substitutes Code) is not directed at pharmaceuticals, but is of relevance because it was developed in response to specific marketing practices of MNCs and, at the time of drafting, was seen as a possible precedent for a pharmaceutical marketing code.

For a number of years, MNCs advertised aggressively, and successfully promoted the use of breast-milk substitutes (infant formula) in developing countries. The marketing programs included direct promotion to the public through radio, television, posters, handouts, and through the use of "milk nurses" —sales representatives dressed as nurses who marketed infant formula to new mothers in maternity wards (180). The companies marketed formula directly to health providers as well, giving free samples, calendars, booklets, and "lavish assistance" in the form of "social entertainment at conferences, travel and fellowships, and of funds for research" (120).

Consumer groups and physicians began to criticize these marketing practices because companies ignored the health implications of their successful marketing. Many mothers in developing countries did not understand the difficulty they would have using infant formula once they left the hospital. The lack of clean water and the high cost of the formula made it impossible for many of them to use formula correctly. Once they became aware of these problems, however, most mothers could no longer return to breast feeding because lactation had ceased after they began to use formula. The contaminated or diluted bottles

of formula mothers were forced to use led to an increase in malnutrition and diarrhea, and in some cases, the infant's death.

A public campaign was instituted against these marketing practices, including the initiation in 1977 of an international boycott against Nestle Corp., one of the leading manufacturers of breast-milk substitutes. The boycott was organized by a U.S. group called the Interfaith Center on Corporate Responsibility, but was soon taken over by the International Baby Food Action Network (IBFAN), an organization devoted solely to carrying out this campaign (180). In 1981, after considerable international debate (including congressional hearings in the United States), WHO member countries adopted a voluntary International Code of Marketing of Breast-Milk



PHOTO CREDIT: J. LITTLEWOOD, WHO

*The WHO Code of Marketing of Breast-Milk Substitutes encourages breast feeding infants.*

Substitutes (268,269). The Code was adopted by 118 countries; the United States was the only WHO member country to vote against it.

The Code instructs manufacturers to refrain from certain promotional practices, including direct advertising to the public and distribution of free samples. Samples may be distributed to health professionals only if necessary for professional evaluation or research at an institutional

level. In addition, financial or material inducements are not to be used to promote products, and bonuses based on volume of sales are prohibited (269).

The Code also contains detailed instructions for proper labeling. Article IX requires that all containers of infant formula include a “clear, conspicuous, and easily readable and understandable message” informing the consumer that breast feeding is superior. The label should not contain pictures or text that idealize the use of infant formula, for example, by describing formula as being “humanized,” or “maternalized,” and should not include pictures of infants, except if necessary for graphic illustration of instructions. The label should also state that the product should be used only on the advice of a health worker and should provide instructions for use and carry warnings about the health risks associated with inappropriate preparation. Labels should also include a list of the ingredients, instructions on proper storage conditions, a batch number, and the expiration date.

### IMPLEMENTATION OF THE CODE

The Resolution adopting the Breast-Milk Substitutes Code instructed the Director General of WHO to “give all possible support to Member States” for its implementation and in particular, in the preparation of national legislation and other measures related to the promotion of breast feeding (268). To assist in this effort, each country is required to make an annual report to WHO on the actions it has taken toward implementation, information that is compiled in a biannual report. According to the 1990 report, over the previous 9 years, more than 150 countries and territories had taken some action to implement the Code, but as of 1988, only 6 developing countries had adopted the Code in its entirety (21). Other steps taken by developing countries include (281):

- education of health officials on the Breast-Milk Substitutes Code;
- adoption of country-specific codes of conduct based on the principles of the Breast-Milk Substitutes Code, often with a mechanism to monitor and enforce compliance;
- adoption of legislation implementing certain provisions of the Code, or revisions of existing legislation to implement the Code;
- government control of all imports and distribution of infant formula; and
- public education on the benefits of breast feeding.

Consumer organizations have played an active role in promoting the Code. IBFAN, which has more than 100 affiliates working in over 60 countries, supports research, education, and other efforts to implement the Code (281). The International Organization of Consumers Unions (IOCU) has published a guide for health care workers that explains the Code. The guide is available in eight languages and more than 25,000 copies are in circulation. Consumer groups also have helped educate and train health workers in countries with limited resources (28 1).

Industry has also responded to the Code. The International Association of Infant Food Manufacturers, an industry group with 35 member companies in 15 countries, has instituted a complaint mechanism and is developing an arbitration mechanism to address violations of the Code that cannot be dealt with by direct negotiations between the company and the complainant (281). Nestle Corp. created the Nestle Infant Formula Audit Commission (NIFAC), an independent nine-person commission that reviews allegations that Nestle’s advertisements, promotional activities, or corporate policies violate the Code.<sup>4</sup> As of 1984, NIFAC had reviewed 80 complaints, with the number of complaints declining over the years (180).

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<sup>4</sup> NIFAC was headed originally by former U.S. Senator and Secretary of State (during the Carter Administration) Edmund Muskie (180).

Despite widespread support for the Code, several countries report that manufacturers continue to distribute free samples of infant formula in hospitals and clinics (188,281). However, the more aggressive marketing practices, such as the use of milk nurses, have stopped (180). The requirement that countries report their progress under the Code, as well as the actions of public interest groups and industry with respect to violations, has kept the issue of breast-milk substitutes on the international agenda.

### A Code of Marketing of Pharmaceuticals

At the same time the Breast-Milk Substitutes Code was being drafted, WHO also debated developing a code of conduct for the marketing of pharmaceuticals (270). The pharmaceutical industry opposed the idea and in 1981, when the move for a pharmaceutical code was strongest, the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) developed its own industry code for marketing practices (see below) (145,251). WHO reportedly decided to refrain from promoting its code until it could evaluate the impact of the IFPMA Code (223). The debate remained alive, however. Heated discussions took place at the Sixth Session of the U.N. Council for Trade and Development in 1983 (174), as public interest groups continued to press for a WHO code. WHO's rejection of the idea was made clear in 1986 when the Director General stated that there is no place for "supranational regulation by WHO of drug promotion" (103,263).

In addition to industry opposition to a WHO pharmaceutical code, the U.S. executive branch has, in the past, expressed opposition to WHO formulating codes directed at specific industries. The United States, under the Reagan Administration, voted against the Code on Breast-Milk Substitutes for this reason (48, 183). The response

to a pharmaceutical code, however, could be different depending on the political climate.

U.S. governmental support for a code of conduct could be spurred by public support. A major impetus behind the Breast-Milk Substitutes Code was public outcry against the marketing practices of infant formula companies, generated by intense publicity by consumer advocates. There is currently no strong, vocal public support for a pharmaceutical code, and it may be difficult to generate interest for one. Unlike the Breast-Milk Substitutes Code, which addressed easily understood marketing practices, a pharmaceutical code must address a range of pharmaceutical products and complex national standards for safety, efficacy, and labeling. Given the statements of WHO, the strong industry opposition, and the lack of clear public support, a WHO code on pharmaceutical marketing is unlikely to materialize in the foreseeable future.

### The Ethical Criteria for Medicinal Drug Promotion

In 1968, WHO adopted *Ethical and Scientific Criteria for Pharmaceutical Advertising* (267). This document was revised and expanded in 1988 to cover a broad range of "informational and persuasive activities by manufacturers and distributors" (273). The revisions were based on results of a 1986 survey of governments and private parties that posed questions about the role of scientific data sheets, symposia, free samples, medical representatives, package inserts for patients, packaging and labeling, advertising, and promotion of pharmaceuticals to health professionals and the general public. The survey also asked about what information was included with pharmaceutical products exported from the responding countries.<sup>5</sup>

The revised document, now called the *Ethical Criteria for Medicinal Drug Promotion*, (Ethical

<sup>5</sup> Respondents included 17 (of 24) governments (11 industrialized, 6 developing) and 14 (of 18) associations, representing the drug industry, pharmacists, consumers, and medical specialties (273).

Criteria) focuses on various aspects of pharmaceutical promotion, including the content of drug advertising to medical professionals and the public, the use of medical representatives, the provision of free samples to the public, post-marketing surveillance, dissemination of information, drug packaging and labeling, patient information, and package inserts and booklets. The Ethical Criteria do not specify criteria for labeling and packaging. They instruct companies to comply with national laws, and if there are no national laws or if the laws are rudimentary, the company is expected to provide information consistent with that required by another reliable drug authority. In addition, the Ethical Criteria state that all text and illustrations on the drug package and label should provide only reliable, truthful, informative, and current information supported by scientific data. Companies are instructed not to use information that is likely to induce medically unjustifiable drug use or give rise to undue risks (264).

The Ethical Criteria give more specific standards for advertisements than for labeling. They state that advertisements should usually contain:

1. the names of active ingredients, using either the international non-proprietary names (INN)<sup>6</sup> or generic names;
2. the brand name;
3. the content of active ingredients per dosage form or regimen;
4. the name of other ingredients known to cause problems;
5. approved therapeutic use;
6. dosage form or regimen;
7. side-effects and major adverse drug reactions;
8. precautions, contraindications, warnings;
9. major interactions;

10. name and address of manufacturer or distributor; and
11. references to scientific literature as appropriate.

These categories of information are derived from WHO's drug information sheet, which is suggested as a guideline for labeling (271).

The Ethical Criteria are not as strong a pronouncement of public policy as a code of conduct would be. The preface to the Ethical Criteria "urges Member States to take into account the Ethical Criteria in developing their own appropriate measures" and "appeals to pharmaceutical manufacturers and distributors" to use these criteria (264). The document also states that the Ethical Criteria:

. . . constitute general principles that could be adapted by governments. . . as appropriate to their political, economic, cultural, social, educational, scientific and technical situation, their national laws and regulations.

The Ethical Criteria do not constitute legal obligations, and do not necessarily represent the consensus of all WHO member countries (264).

The Executive Director of the IFPMA, to which the U.S. Pharmaceutical Manufacturers Association belongs, has stated that its members have not adopted the Ethical Criteria because their Code of Conduct (discussed in detail below) is binding on its membership and with respect to prescription drugs, is fully congruent with the Ethical Criteria, even though the two documents differ in the amount of detail each contains (285). Consumer groups, however, are very concerned with many of the details. For example, whereas both the Ethical Criteria and the IFPMA code permit abbreviated information with reminder advertising, the Ethical Criteria limit the defini-

<sup>6</sup>Since 1950, WHO has coordinated the development of International Non-Proprietary Names (INNs) for **pharmaceuticals**, and as of 1989, WHO had selected over 5,000 INNs for **pharmaceutical** substances (257). WHO recently published its 60th list of proposed international non-proprietary names (194).

tion of reminder advertisements to printed advertisements that do not make claims for the drugs (i.e., promote them for a specific indication) while the IFPMA Code has no such restriction and leaves the definition of a reminder advertisement to the companies (196).

WHO's recent evaluation of the Ethical Criteria notes that "effective oversight and control of promotion is possible only when a comprehensive drug licensing [registration] system is in effect" (285). Control of promotional material requires specific standards for individual drugs, which means the country must have reviewed the scientific evidence for the individual drug and determined the proper labeling. Even countries with strong registration systems may not regulate advertisements effectively (285). Few countries screen advertisements before they appear. This is the case in the United States, where a recent study found that a large percentage of pharmaceuticals ads did not meet FDA regulatory standards (262).

The World Health Assembly, the legislative body of WHO, recently asked member states to intensify efforts to implement the Ethical Criteria by involving government authorities, pharmaceutical manufacturers, firms engaged in promotion of pharmaceuticals, health personnel responsible for prescribing, dispensing, supply and distribution of drugs, universities and other teaching institutions, professional organizations, professional and general media (e.g., medical and other journals), and consumer groups. The Director General of WHO was directed to convene a meeting of the Council for International Organizations

of Medical Sciences (CIOMS)<sup>7</sup> and other interested parties to discuss new approaches to implementing the Ethical Criteria (265).

## IFPMA CODE OF PHARMACEUTICAL MARKETING PRACTICES

The International Federation of Pharmaceutical Manufacturers Associations (IFPMA), formed in 1968, is an association of associations. It comprises about 50 associations of pharmaceutical manufacturers (e. g., the U.S. Pharmaceutical Manufacturers' Association) from 51 countries (108). The member companies of the IFPMA manufacture close to 80 percent of the world's prescription pharmaceuticals (excluding those manufactured in China and the former Warsaw Pact countries) (91). IFPMA registered as a non-governmental organization with WHO in 1971, stating its intent to collaborate in the following areas: technical and scientific assistance, economic assistance, and medical assistance.

In 1981, after widely publicized criticism of some pharmaceutical companies practices in developing countries, IFPMA adopted "A Code of Pharmaceutical Marketing Practices" (IFPMA Code) as industry's statement on what constitutes proper promotional practice for prescription drugs.<sup>8</sup> The IFPMA Code is a model that can be used by companies belonging to IFPMA's member associations in setting corporate policies for promotion and advertising. The IFPMA Code applies primarily to advertising, not labeling, but it reflects industry's philosophy on the type of information that should be provided with its products.

<sup>7</sup>In order to facilitate international adverse drug reaction reporting, representatives from regulatory authorities and manufacturers formed CIOMS with the objective of developing an appropriate, internationally acceptable form for reporting adverse drug reactions. CIOMS is also involved in a collaborative project between pharmaceutical manufacturers, representative bodies of medical specialties, and national drug regulatory authorities, that will involve updating the classification and definition of adverse drug effects, an essential requirement for post-marketing surveillance (285).

<sup>8</sup>The IFPMA Code is directed at promotion and advertising of pharmaceutical products directed to the health care professions, but advertising of self-medication products to the general public is excluded from the scope of the Code, as is advertising to pharmacists where this is intended to support advertising to the public of such products (1 11).

Section I of the Code outlines general principles that should govern all printed advertising. It states that industry has an obligation to provide “scientific information with objectivity and good taste, with scrupulous regard for truth and with clear statements with respect to indications, contraindications, tolerance and toxicity” (111). In addition, a product should be promoted only for those indications supported by current scientific evidence, and no product should be promoted as being safe and effective for an indication until it is approved for that use. Pharmaceutical companies are also expected to provide essential information on the safety, contraindications, side-effects, and toxic hazards of their products, subject to the legal, regulatory, and medical practices of the country.

Section IV of the Code expands on these requirements with respect to printed promotional material and recommends that all advertisements include: the name of the drug (usually the brand name); a list of active ingredients, using the International Non-proprietary Name (INN), if possible; at least one approved indication for use, with dosage and method of use; and a succinct statement of side-effects, precautions, and contraindications. Exceptions are made for short advertisements, known as “reminders,” provided the reminder states that further information is available on request. Finally, the word “safe” is not to be used without qualification in any advertisement (111).

The remaining sections of the Code cover other promotional practices, such as the use of medical representatives, symposia, medical congresses, and other means of verbal communication. The Code confirms the importance of these promotional practices for the dissemination of information, but stresses that scientific objectives should be their main focus. The Code requires that medical representatives be “adequately trained and possess sufficient medical and technical knowledge to present information on their company product in an accurate and responsible manner” (111). This stops short of WHO’s

Ethical Criteria, which require that medical representatives refrain from providing inducements to prescribers and dispensers and that the main part of medical representatives’ remuneration should not be directly related to their sales volume (264). The IFPMA Code also stipulates that supplies of samples should be limited to the amounts necessary for a health professional to become familiar with the drug. The Ethical Criteria state that free samples of prescription drugs should be provided only in modest quantities and generally only on request (264). The IFPMA Code also responds to criticisms that pharmaceutical companies sometimes make medical promotional material look scientific. The Code states that promotional material, such as a mailing or medical journal advertisement, must “not be designed to disguise its real nature” (111).

### Implementation Mechanisms

The original Code did not contain provisions for monitoring or enforcement. In 1982, apparently in response to criticism from consumer groups, the IFPMA established a complaint procedure for reporting alleged violations (90). Not all complaints go directly to the IFPMA because all member associations have adopted the Code, or more detailed codes, and some national organizations have their own adjudicating committees to address complaints (285). If the complaint is made directly to the IFPMA, the IFPMA contacts the appropriate member association in the country of the company’s headquarters and, if applicable, the member association in the country in which the violation occurred. (In cases involving nonmember companies, IFPMA makes informal contact, whenever possible, encouraging them to follow the IFPMA Code.) (109) The member association refers the matter to the company concerned, and the company’s response is sent back to IFPMA through the member association.

The response is reviewed by the IFPMA “President’s Committee,” consisting of the presi-

dent, two vice-presidents, and an executive vice-president. The Code also notes that the committee is counseled by three independent reviewers (1 11); however, the *Ten Year Report on the IFPMA Code* (1 10) makes no mention of the independent reviewers and the executive director of the IFPMA has stated it is not feasible to have outsiders review the complaints (187). When the President Committee has reviewed a case, a formal reply is sent to the complainant. The IFPMA states that no member company or member association has failed to take corrective action when found to be in violation of the Code (1 10).

Because the Code is voluntary, IFPMA relies on adverse publicity as a “stick” to keep members in compliance. Status reports on the Code (the list of all complaints made, the companies involved, and the actions taken) are public and can be obtained from IFPMA, though they are not distributed widely. Code-related activities are also summarized (by number and type of complaint, and by action taken) in the IFPMA newsletter, *Health Horizons*, and certain international pharmaceutical publications also report on complaints brought under the IFPMA Code (e.g., *SCRIP World Pharmaceutical News*).

### Reporting and Resolution of IFPMA Code Violations

The IFPMA complaint procedure has been used by consumer groups, WHO, and by individuals. Between 1982 and 1991, the IFPMA received 72 complaints, comprising 926 separate cases. Forty percent of the complaints (accounting for 86 percent of the cases) were brought by consumer groups, with WHO accounting for another 35 complaints (involving 100 cases) (1 10). In 1987, 13 complaints involving 509 separate instances were filed. The majority of these complaints were filed by the Medical Lobby for Appropriate Marketing (MaLAM), an international doctors lobbying network (See ch. 7.) (130). Most of their complaints referred to advertisements in prescribing guides (1 10).

Approximately 56 percent of complaints (535 citations) concern Section IV of the IFPMA Code. In particular, these complaints have focused on the lack of full disclosure of active ingredients, the nature of indications and the disclosure of side effects, precautions, and contraindications. Many of the complaints have focused on reminder advertisements, which need not carry complete information unless the pharmaceutical’s use entails specific precautionary measures (1 10). MaLAM, one of the groups whose complaints have focused on reminder advertisements, claims that the IRMA has refused to clarify the exact definition of a reminder or the phrase “specific precautionary measures.” According to MaLAM, IFPMA has permitted relatively long advertisements (more than 200 words) to be classified as reminders, exempting them from the more inclusive requirements for full advertisements. MaLAM also cited examples of reminders that, as required, state “further information is available on request,” but either fail to provide an address, or refer readers to information available only if the drug is purchased (130,196).

From August 1989 through August 1990, over half of the 34 breaches of the Code (out of 74 cases resolved) were for failure to adequately support claims for a product with scientific evidence, or for making claims not in accordance with “needs of public health.” Six advertisements were cited for using the word “safe” without proper qualification. Twelve other advertisements failed to include all the information required by the Code (109). U.S. pharmaceutical companies were responsible for six of the 34 breaches: one for failing to use the non-proprietary name, three for failing to include complete information in advertisements, one for including advertising claims that were stronger than justified, and one for using the word “safe” in an unqualified manner (109).

Not all complaints are found by the President’s Committee to violate the Code. Of the 926 cases resolved between 1982 and 1991, approximately

56 percent were declared by the IFPMA to be breaches; 21 percent were not breaches; 10 percent were declared invalid because the complaint was based on false or out-of-date information, or was a repeat complaint about the same advertisement; and 13 percent did not involve member association companies.<sup>9</sup>

### Criticisms of the Code

The IFPMA Code has been criticized by both pharmaceutical associations and health activists because its requirements lack specificity and are prone to subjective interpretation (103,196,223). The Code requires, for instance, that information on products conform to “ethical standards and standards of good taste” (111), without further explanation. On another point, the Code states that a product should not be promoted as safe and effective for a particular indication before it has been approved officially for that indication, but also states that the scientific community and the public have a right to be “fully informed” of the results of investigational studies (111). So while the Code does not permit a company to market a drug for indications not approved by a regulatory authority, the company may disseminate the results of studies that support unapproved indications.

With respect to pharmaceutical sales representatives, the Code does not define what constitutes “sufficient training” or the type of information sales representatives must provide, and it does not provide guidance on what might be a reasonable amount of free samples. According to one activist, the only provision that is not ambiguous is the requirement that the word “safe” be qualified (103).

IFPMA has also been criticized for the amount of time it takes to make a determination on alleged infractions; MaLAM has claimed that the delays permit companies to continue running

advertisements that violate the Code (130). MaLAM filed 208 complaints in January 1987, and the IFPMA responded with an interim report on 165 of them 7 months later. This interim report listed 89 infractions, and 28 “invalid complaints.” The remaining 43 complaints were not acted on because the companies involved were not members of IFPMA associations.

In April 1987, MaLAM filed another 254 complaints, and the IFPMA responded to 111 of them almost a year later, in March 1988, leaving 143 complaints unresolved. This response included findings of 44 new breaches and 42 repeat advertisements from the first submission by MaLAM (130). IFPMA classified these 42 repeat submissions as invalid complaints, rather than continued infractions, as MaLAM contended they were (130). One activist, who filed 259 complaints between November 1985 and April 1988, reported that the average time taken to resolve 222 of his complaints was about 7 months (195).

IFPMA explains that the large number of complaints received in 1987 could be interpreted as an attempt to “break the system,” as many of them did not include documentation, making resolution of those cases more difficult (110). IFPMA also points out that a delay in issuing a decision does not necessarily delay remedy of a breach. IFPMA claims that companies often take remedial action soon after being informed of a complaint, before the IFPMA decision is made.

Perhaps the most controversial aspect of the Code is IFPMA’s interpretation of provisions requiring deference to national laws. IFPMA acknowledges that it would be desirable for labeling, packaging, leaflets, and data sheets used in developing countries to be consistent with the ones used in industrialized countries. However, it recognizes that a company ultimately must follow the regulations of the country in which the drug is marketed. According to IFPMA, regulato-

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<sup>9</sup> Although the IFPMA may contact the member association in the country where the company is located, the complaint is not a breach unless the company is part of a member association of the IFPMA (110).

ry requirements differ among countries for good reasons (11 1):

... [t]he decision of a national authority with regard to the permitted indications and precautionary information to be provided about the product must take precedence.

Furthermore, when a product has been evaluated and registered by an established regulatory authority, the approval by itself is accepted as adequate evidence of the product's efficacy. IFPMA does not challenge the decisions or judgments of national regulatory agencies in any country (9).

MaLAM asserts that the IFPMA position is flawed, noting that the Code recognizes that "Third World countries are not aware of the indications, contra-indications, side-effects, etc. of individual drugs that have been adopted in developed countries" (11 1), yet IFPMA advocates deferring to regulatory bodies of developing countries on those issues. MaLAM contends that the point of self-regulation is to develop a voluntary standard that is compatible with, but different from, the government standard. According to MaLAM, industry standards should meet or exceed those of the government, especially when the government agency has limited resources for drug regulation (139).

Despite the criticisms of the Code, it remains one of the few formal mechanisms for challenging specific advertisements. The complaint procedure has been responsible for at least some improvements in pharmaceutical promotion. In the past 2 years, IFPMA has received only 17 complaints involving 34 different instances (1 10).

Consumer groups, however, still report violations of the Code and continue to push for stronger mechanisms for controlling promotion of pharmaceutical products (39).

## SUMMARY

Codes of conduct offer a possible means of setting international standards for drug labeling without compromising the sovereignty of individual countries. However, even though the codes are voluntary, they are not necessarily easy to develop, as the Translational Code demonstrates. While not binding legally, they are formal pronouncements and will not be endorsed by governments that do not agree with their provisions. The most relevant precedent for a pharmaceutical labeling code is the Breast-Milk Substitutes Code. That Code was devised at a time of public outrage at the behavior of certain MNCs, however, and addressed a less complex issue than that of drug labeling.

Codes of conduct provide general guidance and principles for behavior. A code of conduct for pharmaceutical labeling might define the categories of information that should be on a label and create some uniformity in labeling format. It could also address the type of information that should be presented to a developing country regulatory body with an application for registration. A code would not, however, define the content or wording of the label for each individual product. The overall impact of such a code would depend to a great extent on how it was implemented and monitored over the long term.