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REPORT ON THE WHO SURVEY ON
"ETHICAL CRITERIA FOR DRUG PROMOTION"



The Director-General acknowledges with much appreciation the outstanding contribution to the preparation of this document of Professor J.J. Boddewyn, Professor of International Business, Baruch College, City University of New York.

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ANNEXES¹

1. Respondents' answers and comments (tables). (Document DGO/ETHCDP/87.3, Annex 1)
2. Extracts from a study by Professor J. J. Boddewyn on "Medicine Advertising Regulation and Self-regulation in 54 countries" published by International Advertising Association Inc., New York (1985). (Document DGO/ETHCDP/87.3, Annex 2)
3. The 1968 WHO Ethical and Scientific Criteria for Pharmaceutical Advertising. (Document DGO/ETHCDP/87.3, Annex 3)

¹ In order to avoid having too bulky a document, these annexes have been printed separately from the main part of the report.

1. PURPOSE OF THE WHO SURVEY

1.1 In May 1986, the Thirty-ninth World Health Assembly endorsed WHO's revised drug strategy which includes, among other components, the establishment of ethical criteria for drug promotion, based on the updating and extension of the criteria established in 1968 by the Twenty-first World Health Assembly in the form of a resolution (see Annex 3).

1.2 The new ethical criteria will cover the promotion of such drugs, including their advertising which was the only subject of the 1968 resolution. That is, they will cover a broad range of informational and persuasive activities by manufacturers and distributors, whose purpose is to induce the prescription, supply, purchase and/or use of drugs. These activities include the provision of scientific information for the medical and related health professions, information to patients, and advertising to the medical and related professions as well as to the general public.

1.3 The criteria will constitute general principles and specific guidelines which could be adapted by governments to national circumstances and used by them and by the pharmaceutical industry. They will not constitute legal obligations for pharmaceutical firms and Member States. It was agreed during the Conference of Experts on the Rational Use of Drugs, held in Nairobi in 1985, and confirmed by the Thirty-ninth World Health Assembly, that there is no place for supranational regulation of drug promotion by WHO.

2. THE QUESTIONNAIRES AND THE RESPONDENTS

2.1 The office of the Director-General of the World Health Organization prepared two questionnaires during July-October 1986. Questionnaire No. 1 was sent to a number of organizations representing the pharmaceutical industry (manufacturers and distributors), the health professions (physicians, pharmacists, nurses and students), consumer groups (namely, the International Organization of Consumers Unions), and patients (mainly associations of retired persons). It included 147 questions dealing with scientific data sheets, symposia, free samples, medical representatives, package inserts for patients, packaging and labelling, advertising to both health professionals and the general public, and the promotion of exported drugs.

2.2 The respondents were asked to rate (0 = not important or not needed, 1 = desirable, and 2 = essential) their answers relating to both prescription (= RX) and over-the-counter (= OTC) drugs in terms of whether or not certain types of information should be provided, certain promotion practices should be allowed, certain groups of patients (namely, children) should be targeted, etc.

2.3 Questionnaire No. 2 was addressed to a government health authority in a sample of 24 countries to ascertain what is in fact the situation in these nations so that respondents were asked to answer "Yes" or "No" to a similar set of questions. However, advertising to health professionals and the general public was not covered in this questionnaire (which included only 88 questions) because a 1985 survey by the International Advertising Association had already collected most of that information.¹

2.4 Respondents to both questionnaires were invited to suggest additional criteria and to comment on their answers - as many of them did, either briefly or at greater length (see comments appended to the tables in Annex 1, and quoted in this report).

¹ J.J. Boddewyn, Medicine Advertising Regulation and Self-regulation in 54 countries (New York: International Advertising Association, April 1985). The relevant section is contained in document DGO/ETHCDP/87.3, Annex 2.

2.5 Out of 24 governments contacted by WHO, 17 answered by May 1987. The 17 responding countries (with the abbreviations used in the tables) were:

AUSL - Australia	NETH - Netherlands
BRA - Brazil	NOR - Norway
CAN - Canada	PHIL - Philippines
FRA - France	SWED - Sweden
ITA - Italy	SWIZ - Switzerland
JAP - Japan	THAI - Thailand
KEN - Kenya	UK - United Kingdom
MAL - Malaysia	USA - United States of America
MEX - Mexico	

2.6 From the government survey it was hoped to obtain answers from 12 "developed" and 12 "developing" countries, but answers were returned by only 11 and 6 of them, respectively.

2.7 Eighteen associations were contacted, with 14 of them returning the questionnaire. The 14 respondents (with their initials used in the tables) were:

AARP - American Association of Retired Persons (really part of the International Federation of Aged People's Associations (FIAPA), but its answer was received separately)

CPA - Commonwealth Pharmaceutical Association (London, UK)

ICN - International Council of Nurses (Geneva, Switzerland)

IFPMA - International Federation of Pharmaceutical Manufacturers Associations (Geneva, Switzerland)

IFPW - International Federation of Pharmaceutical Wholesalers (Alexandria, VA, USA)

IOCU - International Organization of Consumers Unions (answer provided by OXFAM's Public Affairs Unit, Oxford, UK)

IPA - International Pediatric Association (Paris, France)

IPF - International Pharmaceutical Federation (The Hague, Netherlands)

IPSF - International Pharmaceutical Students' Federation (answer received from Lisbon, Portugal)

ISA - International Sociological Association (answer received from Farmington, CT, USA)

MWIA - Medical Women's International Association (Cologne, Federal Republic of Germany)

WFPMM - World Federation of Proprietary Medicine Manufacturers (Bonn, Federal Republic of Germany)

WONCA - World Organization of National Colleges, Academies and Associations of General Practitioners/Family Physicians (12 separate answers were received from Canada, France, Hong Kong, Japan, Norway, New Zealand, Portugal, South Africa, Sweden, Thailand, the United Kingdom and Zimbabwe)

2.8 In the tables appearing in Annex 1, averages are usually given for the 12 WONCA and seven FIAPA answers (see numbers in parentheses).

3. THE QUALITY OF THE RESPONSES

3.1 The tables in Annex 1 as well as the following section which analyses response patterns may give the impression that clear-cut answers and definite views were obtained from all the respondents. Some governments and quite a few associations did, in fact, provide thoughtful answers and detailed comments on the questionnaire itself and in appended letters. However, some problems shared by all mail surveys or specific to this one, must be kept in mind when interpreting the tables and subsequent parts of this report.

3.2 Most respondents appeared to be familiar with the topics covered in this survey but a few were not - as evidenced by missing answers or perfunctory ones. Government answers came from a health ministry or agency but, in some countries, it is an economic agency that controls the promotion of OTC drugs (see, for example, the respective roles of the Food and Drug Administration and the Federal Trade Commission in the United States). It is not clear if government respondents checked with other regulatory bodies also involved in drug-promotion control.

3.3 The representativeness of the respondents is somewhat problematic. Some associations consulted their members or, at least, a sample of them, while in other cases a single individual responded for the entire association. In particular, the answers from the national "patients" associations belonging to FIAPA were provided by physicians associated with these bodies, so that no real "patient/customer" voices were directly heard. Thus, it is interesting to observe that the AARP and FIAPA answers were not very much in support of the use of lay language in inserts, labels, etc. - something one would have expected from a "patients" group.

3.4 The questionnaires forced the respondents to choose between YES and NO, or among 0, 1 and 2. However, various comments on the questionnaire or in appended letters revealed that various meanings were given to these alternative answers:

- "YES" was intended to mean "practised or required in fact" as far as government regulations are concerned, but that answer often implied "usually" or "in most cases" because certain drugs are more tightly controlled than others (e.g., narcotics).
- "0" was intended to mean "not important, not needed" but it was also used to signify "No, it should not be required", "not appropriate" or "not applicable".
- "1" stood for "desirable" but was also used in the sense of "it depends" or "maybe".
- "2" was equated with "essential" in the questionnaire instructions but it also conveyed the meaning of "Yes, it should be required by all means". On the other hand, the IFPW stressed that its answers were not based on what should be, but expressed views on items that should be reviewed in formulating government policy.

3.5 Some responses lacked discrimination, as the same responses were mechanically given to all subparts of a question and for both prescription (RX) and proprietary (OTC) drugs.

3.6 Association answers often revealed clear ideological inclinations for or against private enterprise, the promotion of medicines, regulation, etc. This was to be expected, and some of these biases were explicitly articulated and justified by additional comments. However, there were more subtle biases reflecting not only the occupation and affiliation of the respondents but also their location. Thus, a pharmacist responding from a country where pharmacies have a monopoly on the distribution of medicines, and are prevented by various legal and professional rules from advertising, will normally answer negatively about

advertisements aimed at the general public. Similarly, one pharmacy association wanted medical representatives to have a diploma in pharmacy; the pharmacy students association was not opposed to companies giving them medical textbooks; aged-people associations liked price advertising, and so on.

3.7 The questionnaire instructions asked for a single answer from a particular association; and most of them complied with this requirement. However, there were 12 answers from national WONCA associations of general practitioners/family physicians, and seven answers from national "aged-people" associations (FIAPA), plus the US AARP answer. The tables in Annex 1 give the average score for their multiple answers which, while not in accordance with the questionnaire instructions, offer an interesting glimpse of the variety of "national answers" - compared to the single "worldwide" answers provided by the other associations.

4. RESPONSE PATTERNS

4.1 This section highlights the pattern of responses to the various categories of questions (scientific data sheets, symposia, free samples, medical representatives, package inserts, packaging and labelling, promotion of exported drugs, advertising to health professionals and the general public, and promotion of exported drugs). The tables in Annex 1 include "comments" which state the basic philosophy of the responding associations, present detailed qualifications to their responses, and/or offer additional recommendations.

4.2 There do not appear to be systematic differences between the responses from the governments of "developed" (11) and "less-developed" (6) countries - except regarding the use of lay language in package inserts and on package/labels, which was reported as less common in developing countries (Questions V.4 and VI.3), and except regarding greater tolerance of free samples given to physicians in developing countries (Question III).

1. Scientific data sheets for physicians and other health-related professionals

1.1 These are made available in practically all countries for RX drugs but less so for OTCs. This situation is largely endorsed by association respondents, except when industry bodies (IFPW and WFPMM) oppose this requirement for OTCs because the necessary information for proper use is provided with each product through labels, package inserts, etc.

1.2 (a) and (b). Scientific data sheets (SDSs) are approved by most governments, but rarely by an industry self-regulatory body. A distinction has to be made between: (1) the registration data that have to be submitted to government authorities and approved by them, and (2) the scientific data sheets for distribution to health professionals. The Japanese Government, for example, does not require advance approval of SDSs but routinely checks their conformity with the registration data, and demands corrections if necessary. The IFPMA takes a similar position, namely, that it is the companies' responsibility to draft SDSs in conformity with the registration data, and to keep them up to date.

Recording OTCs, the US Government approves only drug ingredients rather than the final product; and industry (IFPW and WFPMM) is opposed to scientific data sheets for such products, whether to be approved by government or a self-regulatory body, emphasizing instead the label or package.

1.3 What does or should appear on scientific data sheets? Answers can be classified as follows:

Early General Agreement
Names of active ingredients (INN)
Content of active ingredients per dose
Accepted therapeutical uses
Dosage for adults and children

Form of administration
Side effects
Precautions and contra-indications
Interactions
Treatment in case of overdosage
Name and address of manufacturer
Much Less Agreement
Auxiliary pharmaceutical substances
Suggested therapeutical uses
Experimental pharmacological and toxicological data
 on active ingredients.
Mechanism of action
References to scientific literature

However, important qualifications were provided by some respondents (see table footnotes). In addition, several comments were made, here and in later questions, that the relevant name and address are not always those of the manufacturer but of the product licence-holder and/or the distributor.

II. Symposia sponsored by pharmaceutical companies

The questions in this section may have been difficult to answer for government respondents: "NO" answers could mean either that laws and regulations do not include a particular requirement, or that the practice in question is not common.

Few requirements were mentioned except for (1) companies having to disclose their sponsorship of a symposium (just as an advertisement cannot masquerade as an editorial); (2) putting some limits on expenditures, and (3) some limitation on the distribution of free samples (largely in accordance with the answers to Question III below).

Business associations oppose strict restrictions but stress, instead, "reasonable" publicity, transparency, expenditures, free sampling, etc. in accordance with self-regulatory rules. Other association respondents tend to be more suspicious, and they favour restrictions although their recommendations vary considerably (see table footnotes).

III. Free samples

Governments tend to require that samples be sent only on request, and industry (IFPMA, IFPW and WFPMM) considers such a restriction to be "desirable". A few countries add other restrictions - for example, only samples of new drugs may be supplied (see table footnotes). However, there is much less agreement about restricting samples to "trial use". (See the IAA 1985 survey, pp. 27-28 (Annex 2, pp. 19-20) for further details regarding this practice).

IV. Medical representatives

While practices vary among responding countries, most non-industry respondents strongly recommend that medical representatives always leave (or mail) a scientific data sheet for each RX product discussed with health professionals, in order to provide the latter with complete and unbiased information; while industry (IFPMA and IFPW) acknowledge that this would be "desirable". However, such a requirement is challenged in the case of OTCs by the IFPW and WFPMM since they do not consider SDSs as essential for these drugs.

The special training of medical representatives is overwhelmingly provided by the companies themselves - sometimes in connection with a national industry association in the case of RX products. Non-industry respondents tend to urge stricter requirements and even certification by a public or mixed body. There seems to be some consensus toward combining company and external (industry or independent body) training.

Practically all government and association respondents agreed that a company should be held responsible for the statements of its representatives as far as RX products are concerned. (OTC products are seldom discussed in scientific terms with the distributors).

V. Package inserts for patients

V.1 There are major national variations regarding the inclusion of a package insert when drugs are sold to consumers in their original package (see table footnotes). Whether by law or tradition, such inserts are not provided by physicians in some countries (e.g., the United States) when a RX drug is sold; while, in the case of OTCs, some products may be sold in small units (e.g., aspirin) or without an outside package so that no insert can readily be included in the container.

While non-industry respondents strongly favour the inclusion of an insert, industry and the pharmacist association IPF oppose such a requirement. In particular, the IFPMA and WFPMM emphasize a "system" approach, namely, that the necessary information be provided to customers through some combination of instructions by the prescribing physician, on the package itself, on the label, in an insert (if provided) and even in a separate leaflet provided by pharmacists and other distributors.

V.2 A majority of governments approve package inserts where used, with industry self-regulatory bodies playing a minor role in this respect. Non-industry respondents definitely favour such government approval, while industry reiterates its position that inserts should only conform (within certain limits) to the registration data, the scientific data sheets, or any other basic patient information required by government - without any prior government approval of the inserts themselves.

V.3 and 4 What do or should package inserts (where used or required) include in the way of information? And what about the use of lay language in inserts? The government and association answers often concur (but see table footnotes for various qualifications and recommendations):

Early General Agreement

- Names of active ingredients (INN)
- Content of active ingredients per dose
- Precise instructions for dosage
- Form of administration
- Major side effects
- Major precautions and contra-indications
- Major interactions
- What to do in case of side effects or overdosage
- Storage conditions (at least when special)
- Name and address of manufacturer or licence-holder,
or distributor)
- Wording in lay language

Much Less Agreement

- Names of all auxiliary pharmaceutical substances
- Description of all accepted and suggested therapeutical uses.

The OTC association's (WFPMM) negative answers reflect its opposition to the mandated use of inserts in the light of its "information system" approach previously mentioned. The retired-persons associations (AARP and FIAPA) were opposed or lukewarm to the use of lay language in inserts (their answers were however provided by physicians rather than by lay people).

V5 and 6 What kinds of information are or should be provided to patients when drugs are not sold in their original package? Several governments did not answer, presumably because drugs must be dispensed in their original package in those countries. However, answers converged to

the extent that respondents agreed that some minimal/crucial information should be conveyed through other means such as the external package, the label, separate leaflets, physician and pharmacist verbal instructions, etc.

VI. Packaging and labelling

VI.1 When drugs are sold in their original package (something which is not done in every country as far as RX drugs are concerned), the text on the external package and label are almost always approved by a government body. As with Question 1 on scientific data sheets, the Japanese Government and industry associations (IFPMA, IFPW and WFPMM) do not favour such prior government approval but stress the company's responsibility to prepare package and label materials in conformity with the registration data or official marketing approval. There is little evidence or support for prior approval by an industry self-regulatory body.

VI.2 What do or should the outside package and label include in the way of information? While the tables' comments report some important qualifications and variations, there was consensus among governments and associations about most of the subquestions:

Fairly General Agreement

Brand name
 Generic name
 Names of active ingredients (INN)
 Content of active ingredients per dose (among governments only)
 Major indications for use (among governments only, for OTCs)
 Form of administration
 Expiration date
 Storage conditions (if special)
 Name and address of manufacturer (or licence-holder or distributor)

Much Less Agreement

Content of active ingredients per dose (among associations only)
 Major indications for use (for RX drugs, by both governments and associations for OTCs, among associations only)
 Major precautions and contra-indications (the IFPMA and IFPW, on the industry side, and the IPF, on the pharmacy side, are opposed)

VI.3 and 4 Wording in lay language on the outside package is more practised and received more support in the case of OTCs than for RX drugs. For that matter, the IFPMA and the IPF (pharmacists) associations did not support the use of lay language regarding RX drugs (see table comments for further qualifications).

VII. Promotion of exported drugs (This is Question C in Questionnaire No. 1 to associations)

This section pertains only to drugs that can be legally exported, and to the contents of the information - not to the use of the local language(s). It is worth noting that several government respondents were unsure about the requirements of importing countries so that they did not know how to answer; others (as well as the IFPMA and WFPMM) referred to the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in the International Commerce which mentions the status of the drug in the exporting country. The table comments provide various details and qualifications.

VII.1 Government responses (when provided) varied considerably regarding conformity with either the demands of the exporting country or of the importing country - or of both. Industry associations (IFPMA, IFPW and WFPMM), but also the pharmacists association (IPF), generally favour the requirements of the importing country and the use of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce, while non-industry associations stress conformity with the requirements of both the importing and exporting countries or "whichever is the higher standard" (IOCU).

VII.2 In answer to the question as to whether the same information is or should be provided about exported drugs as about those consumed domestically, there was much division among governments and, particularly, among associations from their answers to Question VII.1. Industry associations (IFPMA, IFPW and WFPMM) practically always answered "0" (not important, not needed) while non-industry associations overwhelmingly answered "2" (essential) or "1" (desirable). This question pertained to: (a) scientific information; (b) package-insert wording; (c) outside-package wording; (d) label wording; (e) advertisements to physicians and health professionals, and (f) advertisements to the general public. Answers to (f) were less positive in view of some opposition to the advertising of drugs - a topic covered in Section B on advertising.

B.1 Advertising to physicians and health professionals¹

There is unanimity that governments should approve both RX and OTC drugs for registration before they can be advertised (BI.1), but there is a wide division of opinion about the advance approval of advertisements by a government or self-regulatory body (BI.2). The 1985 IAA survey (pp. 15-16) (Annex 2, pp. 7-8) revealed that 27 out of 54 governments required prior approval of advertisements - sometimes on an exceptional basis (UK and USA) or only for radio and television OTC advertisements (Canada); while self-regulatory bodies provided prior approval in Canada, Finland, Ireland, the Netherlands and the United Kingdom.

There is also unanimity of opinion that the advertising of prescription drugs should be restricted to physicians and other health professionals (BI.3) - as was also revealed by the 1985 IAA survey. Most respondents consider the direct mailing of advertisements and pamphlets to these professionals as "desirable" or "essential" (BI.4). It is worth noting, however, that the US Food and Drug Administration authorizes RX-drug advertising to the general public, provided that the advertisements include a "brief summary" of the risks and precautions in terms of side-effects and contra-indications.

There is fairly general agreement among responding associations about what should be included in advertisements to professionals (but see table comments for qualifications):

Fairly General Agreement

Brand name
Generic name
Names of active ingredients (INN)
Content of active ingredients per dose
Description of therapeutical uses
Dosage for adults and children
Form of administration
Side effects
Precautions and contra-indications
Name and address of manufacturer (or licence-holder, or manufacturer)

Much Less Agreement

Full designation of auxiliary pharmaceutical substances (IFPMA, IFPW, WFPMM and the pharmacists (IPF) are opposed)
Scientific references (broader opposition)
Use of lay language (Question BI.6)

On the other hand, the 1985 IAA survey (pp. 18-24) (Annex 2, pp.10-16) in 54 countries revealed a lack of uniform national requirements concerning what must be included in RX and OTC advertisements.

¹ Only associations were asked questions about advertising because the 1985 IAA questionnaire had already covered the regulatory situation. However, governments were provided with a copy of the IAA survey responses in order to check their accuracy (a few corrections were provided by France and Mexico).

B.II Advertising to the general public

Many questions were not answered regarding RX drugs on the grounds that these drugs should not be advertised to the general public. However, it has already been mentioned that the US Food and Drug Administration allows RX advertising to the public under certain conditions; and the International Pediatric Association endorsed such a practice "if approved in advance by the government" because it may prove beneficial to the public, while associations of retired persons (FIAPA) considered such RX advertising as "desirable".

Apart from governments approving drugs for registration before they can be advertised, opinions were very much divided about drug advertising to the general public - even OTCs. Industry associations (IFPW and WFPMM) generally took the position that, once a drug had been approved by the government, its advertising should remain free of prior approval and further restrictions, provided that the advertisements comply with the registration specifications. The 1985 IAA survey (pp. 18-24) (Annex 2, pp. 10-16) also revealed major national differences on topics related to questions BII.1 to 6.

Regarding the general question of whether OTC advertising to the general public should be allowed in the mass media (BII.7), only the IOCU answered negatively, while industry associations considered it as "essential" and the other non-industry associations as "desirable". Question BII.8 about restricting OTC drug advertising to fairly general statements (the company has OTC drugs appropriate for certain diseases or has a new OTC drug for those purposes; only mentioning the price of the OTC drug in the advertisement; the advertisement should mention that patients should discuss the OTC drug with their physicians) may have been misunderstood by some respondents, but the WFPMM was strongly opposed to such restrictions.

Question BII.9 asked whether an OTC drug advertisement could claim "cure, prevention and/or relief" of an ailment or disease if such claims can be scientifically substantiated. Only "relief" claims received general support, although industry associations (IFPW and WFPMM) were not alone in considering all three types of claims as "essential". Of course, there are conditions for which no cure can be claimed (See 1985 IAA Report (pp. 29-30) (Annex 2, pp. 21-22)).

Only industry associations (IFPW and WFPMM) strongly supported OTC advertising through the radio, television, outdoor and direct-mail media although some other associations (e.g., of retired persons) considered it "desirable" (BII.10 a to d). In the 1985 IAA survey (pp. 31-32) (Annex 2, pp. 23-24), relatively few government restrictions on the use of these media (where available) were discovered.

OTC drug testimonials by health professionals, by actors portraying health professionals, and by consumers received only a few "desirable" or "essential" mentions (BII.10 e to g) although it is worth noting that testimonials by health professional encountered less outright opposition. The 1985 UAA survey (pp. 31-34) (Annex 2, pp. 23-26) revealed many regulatory and self-regulatory restrictions on the first two types of testimonial but fewer (one-third) in the case of consumer testimonials.

All respondents opposed the advertising of OTC drugs to children (B.II.11).

Question BII.12 inquired about what should be included in drug advertisements through the media (mostly of OTC drugs since there is opposition to RX advertising to the general public). There was no opposition to the use of the brand name (subquestion a), but agreement stopped there. Industry associations (IFPW and WFPMM) generally opposed the inclusion of: (b) the generic name; (c) the names of active ingredients (INN); (d) major indications for use; (e) form of administration; (f) major precautions and contra-indications; and - to a lesser extent - (g) the name and address of the manufacturer. The WFPMM (see table comments) stressed that it is the role of labels to provide these kinds of information, but industry is generally opposed to "cluttering" and "overloading" advertisements with too much

information.¹ The 1985 IAA survey (pp. 22-24) (Annex 2, pp. 14-16) also revealed many national differences regarding such requirements.

There were no questions about the use of lay language in advertisements to the public but it can be assumed that such a use is imperative - at least as far as OTC drugs are concerned (see the 1985 IAA report (Annex 2) for further discussion of this issue).

Whether pharmacies and other stores should be allowed to advertise drugs in terms of efficacy, availability in store, and price (BII.13 and 14) received mixed responses - as was also found in the 1985 IAA survey (p. 25) (Annex 2, p.17). The ambiguity of the answers partly reflects the special rules pertaining to RX drug advertising to the general public (which is generally banned) and those deontological codes applying to pharmacists who are usually constrained as far as advertising is concerned.

The following sections discuss some key issues related to the answers and comments provided by respondents.

5. MAJOR UNDERLYING ISSUES FOR CONSIDERATION

5.1 The following comments were suggested by the analysis of the survey responses as well as by the comments appended by some respondents to the WHO questionnaire. Various WHO and UN documents, industry and consumerists reports as well as academic studies provided other sources for the following issues which, however, defy any simple definition, discussion and resolution.²

The objective of the WHO project

5.2 The questionnaires' instructions stressed that:

"The criteria will constitute general principles and specific guidelines for ethical criteria, which could be adapted by governments to national circumstances and used by them and by the pharmaceutical industry. They will not constitute legal obligations for pharmaceutical firms and Member States. It was agreed during the Conference of Experts on the Rational Use of Drugs, held in Nairobi in 1985, and confirmed by the 39th World Health Assembly, that there is no place for supranational regulation of drug promotion by WHO."

¹ The proceedings of the 1986 WFPMM conference (see reference below) revealed industry preferences for "general" warnings (e.g, "if you are under the care of a doctor or are pregnant, consult him before taking this product") over "specific" ones for every problematic health condition.

² Major sources used include: J.J. Boddewyn, Medicine Advertising Regulation and Self-Regulation in 54 countries (New York: International Advertising Association, 1985) - particularly at pp. 43-58 dealing with issues; the Food and Drug Law Institute's Seminar on "Prescription Drug Advertising: A Modern Primer" (Washington, DC: 18 September 1986); various issues of Consumer Affairs and of the Journal of Public Policy and Marketing; United Nations Centre on Transnational Corporations, Transnational Corporations in the Pharmaceutical Industry of Developing Countries (New York: 1984); World Health Organization: "Report of the Conference of Experts on the Rational Use of Drugs held in Nairobi, 25-29 November 1985, WHO, Geneva, Summary of the Debate, Part 2; and World Federation of Proprietary Medicine Manufacturers, "Self-Medication - Making It Work Better for More People"; Proceedings of the 8th General Assembly (Washington, DC: 21-23 September 1986).

5.3 This objective was not understood by all associations respondents. In fact, one of them recommended that a WHO panel of experts be involved in the approval of promotional materials. On the other hand, an industry respondent mentioned that: "The response to the questionnaire is not based on what 'should be' as suggested in the introduction of the questionnaire. Rather, the response was prepared as if a sovereign nation requested IPPW's views on items that should be reviewed in formulating policy with regards to the promotion of drug products."

5.4 As is discussed in the next section ("Terminology"), the final list of WHO "ethical criteria" is intended to assist governments and the pharmaceutical industry in maintaining ethical practices.

5.5 The ethical criteria - while very important - cannot by themselves guarantee the essential drug component of "Health for All by the Year 2000" which depends much more on the delivery to and rational use of essential drugs by the billions of people who need them desperately but do not have access to them. As one commentator put it: "The goal is 'health for all' - not regulation for all". The 1981 WHO Report of a Consultation on Basic Elements of Drug Legislation and Regulatory Control for Developing Countries also mentioned that: "During the deliberations, it was underlined that drug legislation is no panacea for all the problems arising out of the indiscriminate or improper utilization of drugs. Consumers have to be encouraged, through health education or drug-abuse preventive education programmes, regarding the proper use of drugs under appropriate guidance or supervision (document DAP/81.3, p. 2)." However, there is obvious room for improved knowledge and communication flows about drugs, as emphasized in resolution WHA37.33 (May 1984).

5.6 Finally, the WHO ethical criteria have to be appropriate for all countries, including those with adequate numbers of qualified health personnel and a well educated public and those with inadequate numbers of qualified personnel and low literacy rate, as well as a shortage of foreign currencies.

Terminology

5.7 Are the terms "Ethical Criteria for Drug Promotion" the most appropriate ones? The Commonwealth Pharmaceutical Association objected to the use of the word "drug" in this project:

"We are anxious to promote the description "medicine" or "medicinal product" in relation to formulated medicinal preparations, in order to emphasize that the 'drug' is normally the active ingredient of a medicine and that the therapeutic activity of a particular drug can vary, depending upon the formulation used."

Moreover, the word "drug" has become negatively associated with "illegal" and "habit-forming" medicinal substances (the same negative connotation applies to the French word "drogue"). In the French version of the WHO questionnaires, the word "medicament" was used, which is closer to the English term "medicine" or "medicinal product" also used by industry associations (e.g., the World Federation of Proprietary Medicine Manufacturers). Moreover, it is not clear if the word "drug" covers "herbal preparations" and "traditional medicines". Finally, the word "pharmaceutical" rather than "drug" was used in the 1968 WHO resolution on "Ethical and Scientific Criteria for Pharmaceutical Advertising."¹

¹ The questionnaire instructions stated that: "The definitions of drugs, medicines, pharmaceutical products and medicinal products vary from country to country. However, the terms usually mean substances and/or products for preventive, diagnostic and curative purposes, including substances of synthetic or natural origin, biological substances, vaccines and serums".

5.8 On the other hand, "drug" is a short and simple word which has long been used by some well-known regulatory bodies (e.g., the US Food and Drug Administration), and which can readily be qualified by the addition of the words "prescription (RX)" and "over-the-counter (OTC)".

5.9 Some industry representatives were more concerned about the word "ethical" - a term used in the 1968 WHO resolution on "Ethical and Scientific Criteria for Pharmaceutical Advertising". First, the term seems to be more appropriate for industry self-regulation than for government regulation, although the WHO criteria will constitute general principles and specific guidelines for both. In other words, it seems strange to them to associate "ethical" with "regulatory", which are two very different concepts.

5.10 Moreover, these industry representatives are concerned about loose charges of "unethical" behaviour if some WHO "ethical" criterion were to be violated, even though the pharmaceutical companies were following national requirements. They maintain that, while the WHO criteria are intended to be used as a basis for the subsequent development or refinement of regulation and self-regulation (see above), it will prove impossible to restrict their use to that purpose. It is one thing to be charged with "illegal" behaviour because the charges can be answered before some tribunal or judge. However, where does one defend oneself against charges of "unethical" behaviour, based on the WHO criteria, since the World Health Assembly agreed that "there is no place for supranational regulation of drug promotion by WHO"?

5.11 Therefore, these industry representatives expressed their preference for a more neutral expression in lieu of "ethical criteria" - for example, "norms" or "standards" which have a similar meaning and can be readily applied to both regulation and self-regulation, and are used in many languages. Actually, a WHO paper prepared for the Conference of Experts on the Rational Use of Drugs (Nairobi, 25-29 November 1985) repeatedly used the words "norms" and "standards" instead of "criteria". These words were subsequently avoided because of their somewhat regulatory connotation, whereas the word "criteria" appeared to be less stringent, being a principle by which something is judged.

Extent and specificity of the ethical criteria

5.12 The Introduction to the questionnaires mentions that "the criteria will constitute [both] general principles and specific guidelines". The inclusion of up to 147 questions in the questionnaires suggests, however, an emphasis on specific and fairly detailed guidelines, although not all of them may finally be retained.

5.13 Most non-industry respondents appeared to favour such an extensive list of criteria. On the other hand, several industry responses suggested an emphasis on "general principles" - as in their advocacy of a "system approach", which is discussed in a subsequent section.

"Maximum" versus "minimum" criteria

5.14 Many non-industry respondents were inclined to support most of the ethical criteria as well as government pre-approval of all promotional activities because of the importance of health, which justifies maximum safeguards and requirements in terms of disclosures about the safety and efficacy of drugs and about their use.¹ On the other hand, industry associations were most cautious, for a variety of explicit and implicit reasons.

5.15 For one thing, they stated, most of the economic and moral burden of regulatory and self-regulatory norms is borne by business. Besides, they added, the final list of ethical criteria will not be adopted by all governments - at least, not in the foreseeable future - so that the industry may face an increasing variety of national requirements which will complicate its compliance task. Furthermore, some requirements may be justified "in principle" but prove unworkable or ineffective "in practice".

¹ These views are discussed in the Report of the Conference of Experts on the Rational Use of Drugs.

5.16 For example, they asked whether warnings and contra-indications should be mentioned in OTC radio and television advertisements to the general public. This requirement may be justified in terms of advertising having to be informative and not misleading, and some patients paying attention only to advertisements on radio and television - either because they are illiterate or because they do not bother to read labels and package inserts, or as a way of multiplying the diffusion of important warnings and contra-indications. On the other hand, many reputable studies of how advertising actually works have concluded that readers and viewers of advertisements can and will absorb and understand only some of the information given to them,¹ and that "over-loading" advertisements with messages reduces their effectiveness. In other words, some communication problems do not lie with the advertisements themselves but with the audience which may miscomprehend even absolutely truthful messages. (Similarly, patients may not follow absolutely correct instructions provided on packages, labels and inserts.)

From "Advertising" to Promotion"

5.17 The 1968 WHO Ethical and Scientific Criteria dealt only with "advertising" while the present project extends them to "promotion" by including "a broad range of informational and persuasive activities by manufacturers and distributors, whose purpose is to induce the prescription, supply, purchase and/or use of drugs" (Introduction to the questionnaires). Therefore, it covers not only advertising to health professionals and the general public (the latter received less attention in the 1968 criteria) but also scientific data sheets, symposia, free samples, medical representatives, package inserts for patients, packaging and labelling, and the promotion of exported drugs. (Actually, some forms of promotion such as point-of-sale advertising were not covered by this survey.)

5.18 The rationale for this extension is that information and persuasion are conveyed not only through advertising in the narrow sense of the term (see below) but also through other forms of communication with prescribers, dispensers, buyers and users. Also, some of the criticisms addressed to the industry have ranged well beyond advertising; and the code of the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) deals with marketing practices and covers most of the topics included in the WHO survey. The proposed Health Action International's International Code on Pharmaceuticals (1983) also dealt with many more topics than just advertising. (HAI is associated with the International Organization of Consumers Unions.) On the other hand, this extension from "advertising" to "promotion" has to be considered in the light of the differences between advertising and other forms of promotion.

5.19 There is no official professional definition of advertising, while governments use many different definitions - broad or narrow - in their regulations. Still, advertising practitioners tend to limit it to paid communications through the mass and specialized media.² The key word here is media because it indicates that an advertiser cannot reach an audience without the agreement of a newspaper, magazine, radio or television station, poster or billboard (hoarding) company, etc. Even direct-mail advertising depends on the post office or a home-delivery company. This means that advertisements are usually checked by someone else (including advertising agencies, when they are used) while other forms of communication (talks by company salesmen and medical representatives, speeches by company officials, etc.) are not, or are checked in other ways (e.g., labels and package inserts are often checked by regulatory agencies).

¹ See, for example: L.A. Morris et al., "Miscromprehension Rates for Prescription Drug Advertisements", Current Issues and Research in Advertising 1986, Vol.9, No. 1-2, pp. 93-117. This study was commissioned by the US Food and Drug Administration in connection with the advertising of prescription drugs to the general public.

² In fact, governments also differ in their definitions of labelling, with the US Food and Drug Administration giving it a very extensive meaning since virtually all written information disseminated by, or directly on behalf of, a pharmaceutical company is considered to be "labelling".

5.20 Another important difference between advertising and other forms of promotion is that most advertisements are short and simple - particularly on radio and television. Otherwise, they lose effectiveness as people do not pay attention to long messages, forget them, get distracted, confused or bored, etc. Advertising is generally associated with low involvement on the part of the audience in that it commands only casual attention from readers, listeners or viewers who are surrounded by activities and materials (for example, the main editorial texts and broadcast programmes) that compete for their attention. Consequently, most advertisements limit themselves to stating, for example, that Company A has a well-known branded analgesic, a new analgesic, a better analgesic, an analgesic widely used or prescribed, an analgesic particularly suitable for certain patients or conditions, etc. In other words, advertising can "carry" all sorts of information but it can only "reach" people if its technical limitations are understood and accepted.

5.21 Obviously, when such advertising is permitted, this necessary brevity creates problems because important information, qualifications, warnings, etc. may be left out, even though the shortness and simplicity of most advertisements to the general public is not necessarily a deliberate attempt to deceive or mislead the reader, listener or viewer. Unless one is ready to prohibit all drug advertisements because they cannot be sufficiently complete on account of their brevity, one has to accept that they cannot realistically convey as much information as a scientific data sheet, a package, a label or a package insert.

5.22 In this context, a recent International Advertising Association document¹ stresses the proper role of advertising vis-à-vis labelling and, by extension, other forms of promotion and communication:

- (a) The purpose of advertising is to attract attention, offer choices, and provide limited general information to mass audiences of consumers. It must stimulate the interest of prospective buyers in a branded product, inform them of what it may do for them, persuade them to investigate it, and encourage them to purchase and/or repurchase it. Therefore, advertising should not be overloaded with information to the point that the individual prospective buyer may fail to comprehend it or may even ignore it.
- (b) The purpose of labelling is to establish clearly the brand of the product, and it should include all relevant information that the individual purchaser must have to make proper use of it. The information, supplied at the time of purchase, may be given not only on the outer package, but also on or with the inner package, including instructions and directions for use. Labelling is a "high-involvement medium" and tends to carry a heavier load of product information for the consumer than does advertising. Most readers of labels are motivated to concentrate on them, to comprehend them, to follow directions, and to take the indicated precautions. However, what is important is not the extent to which consumers actually read each and every label, but that they know that the labels contain detailed information about product use so that they can consult them on questions of usage and safety.

Advertising and labelling are two essential and interrelated methods of conveying brand identity and other information to the consumer. And while they serve different functions, have different purposes, do basically different jobs, and are treated differently, they are inseparable and, indeed, complementary.

Perhaps because of the very persuasiveness and effectiveness of commercial advertising in mass media, a few critical questions about its proper role are often asked, such as whether or not advertising is providing enough truthful

¹ International Advertising Association, "Labelling and Advertising: Their Functions in Consumer Information" (New York: June 1987), excerpts.

information. Labelling, on the other hand, is generally less visible to the public at large. Consequently, advertising tends to be asked to undertake certain responsibilities for which it is not suited - even responsibilities related to proper and safe use of products, that are better addressed by labelling.

- (c) For the consumer, too much information in advertising leads to information "overload" resulting in confusion and inadequate understanding. This is especially true of some types of product warnings which might needlessly scare people who are not at risk, or give a false or inadequate sense of security to those who are. Some relevant information, such as warnings, apply only to a small percentage of the mass audience. They are neither a substitute for general education nor complete enough to inform persons at risk. What advertisers can reasonably do in these cases is include brief general warnings such as "use only as directed" or call attention to the labels for specific or complete information. Finally, it is physically impossible to include all product information in advertising, due to limitations on the size of print advertisements and length of commercials.

This advertising-industry statement will probably not satisfy its critics; and it leaves unanswered the question of what exactly should be included in drug advertisements. Still, this industry view is important to understand the "system approach" advocated by some of its respondents.

The System Approach

5.23 Most of the questions in the WHO survey dealt with information to be included in/on scientific data sheets, packages, package inserts, labels, advertisements, etc. Asking such questions one after another can make one lose sight of the "big picture", namely, that important and approved information about drug safety, efficacy, form of administration, precautions, etc. has to be provided somewhere and somehow to the relevant participants in the "health chain" - from manufacturer/distributor to prescriber (if there is one), to dispenser/retailer, and to customer/patient - both before and after the acquisition of the drug.

5.24 Actually, the extended focus on "promotion" leaves out additional forms of "communication" such as health education in schools, health columns in print media, health books, radio and television programmes, word-of-mouth exchanges among professionals and among people in general, health-agency pronouncements, company press releases, scientific publications and conferences, etc. which also constitute part of the "health-information chain". Some of these communications are much less controlled by governments, associations and companies because they are often protected under the principle of "freedom of speech" or "freedom of expression".

5.25 The preceding discussion of the complementary roles of advertising and labelling has already introduced some elements of the "system view" in that they constitute complementary sources of information. While most association respondents looked at each question separately and more or less agreed that each form of communication (label, insert, advertisement, etc.) should contain a lot of information, others considered both "the trees and the forest" by stressing that such redundancy is not necessary if the right information reaches the right people at the right time.

5.26 Such a system approach was repeatedly emphasized by the association of OTC-drug manufacturers (WFPNM): "The package, the label and any leaflet that may be included should be looked upon as an information system which should be applied in a flexible manner due to the differences between products as well as the varying physical characteristics and forms of packaging . . . The role of self-medication advertising is to inform the consumer about product availability and the conditions for which it may be suitable. It is the role of labelling to provide the consumer with the appropriate information required to use the medicine properly."

5.27 Obviously, the system approach requires different national applications because some elements of the health-information chain are missing in those countries where patients do not receive the prescription drug in its original container and/or with the package insert. As far as OTC drugs are concerned, some are dispensed or sold in small or even single units (e.g., aspirin) which preclude the distribution of much or even any information. Furthermore, some health information may be so important as to justify repeating the same information. Finally, the Thirty-ninth World Health Assembly recognized the responsibilities of a long list of parties concerned with the rational use of drugs (resolution WHA39.27, operative paragraph 3). No single party can completely control the communication of information throughout the "health chain". Still, it is worth viewing health information as a "total package" that needs to be delivered in various forms with as little unnecessary overlapping as possible.

Regulation, self-regulation and self-discipline

5.28 A few questions in the WHO survey dealt with the role of industry associations in approving scientific data sheets, package inserts and advertisements, and in certifying medical representatives. Actually, these associations play such a role in Canada, Finland, Ireland, the Netherlands and the United Kingdom as far as advertising is concerned.¹

5.29 The association responses revealed mixed feelings as well as strange agreements about the role of self-regulation by industry. For example, industry respondents (IFPMA, IFPW and WFPMM) usually rated pre-approval by such associations as "not important, not needed" - but so did the IOCU. Other non-industry associations gave it ratings of 1 or 2, but there was also a fairly high rate of non-response.

5.30 Since few comments were offered on the questions on the role of self-regulatory bodies, one has to guess about this response pattern. First, there seems to be some lack of knowledge about the role of self-regulatory bodies in the pharmaceutical and advertising industries - what they do and can do. Second, the industry responses of "0" can be interpreted in the light of their view that companies rather than associations should assume various responsibilities (see below) without, however, minimizing the role of self-regulation in improving industry behaviour and in handling complaints from consumers, consumers organizations, governments, competitors, etc.

5.31 Third, the IOCU's negative stand probably reflects its greater overall trust of government regulation and control by health agencies than of voluntary regulation and control by the pharmaceutical industry. Finally, other non-industry associations may have thought that it would be "nice" to have a supplementary check beside the controls that should be provided by government agencies whose prior approval often received a "2" rating ("essential"). Still, the interaction between government regulation, industry-level self-regulation and company level self-discipline was emphasized in several responses.² This view is well represented in the Japanese Government's response, which repeatedly mentioned that pharmaceutical companies are responsible for preparing their scientific data sheets, package inserts, packaging and labelling materials (and, presumably, their advertisements) in conformity with the items approved by the drug regulatory authority. In other words, the Japanese Government must approve certain key items (trade name, ingredients and composition, manufacturing method, dosage and administration form, indications or efficacy, storage instructions and expiration date, specifications and test methods) but it

¹ The role of self-regulatory bodies in drug advertising was studied at greater length in the 1985 IAA survey already mentioned.

² For details about these concepts, see: J. J. Boddewyn, Advertising Self-Regulation: 16 Advanced Systems (New York: International Advertising Association, 1986).

does not require that scientific data sheets, inserts, packages and labels be approved in advance by the health agency, whose role is limited to routine governmental inspections and to requiring corrections if found necessary. Thereby, the government sets the parameters, rather than getting involved in approving each link in the health-information chain.

5.32 The IFPMA took a similar position:

"As a general comment, it appears that the WHO questionnaire addresses issues which are more of a regulatory or medical practice nature and have little to do with ethical practices. We believe that more emphasis should be placed on the responsibility of the pharmaceutical industry for the products which it develops and markets. The industry has the prime responsibility for the information generated for the registration of products, for providing information to doctors, pharmacists and health care workers and, where appropriate, to the patient. We see the scientific data sheet (drafted in conformity with the registration data submitted to the regulatory authorities, and kept up to date) as the key document, in this respect, and believe that this should be reflected in the report. We do not believe the questionnaire reflects adequately the need for industry to be responsible for the information it provides on the products which it makes."

5.33 While the IFPMA (RX drugs) emphasized the registration data, the WFPMM (OTC drugs) association stressed that "advertising of self-medication medicines to the general public in the mass media should be allowed as long as the claims are made in compliance with the required marketing approval (which also governs labelling)".

5.34 Thus, the industry argues that the government should specify what approved information should appear in/on scientific data sheets, packages, inserts, labels and advertisements and then make industry responsible for providing it, without requiring governmental pre-approval of each one of these documents but with government agencies checking company compliance with these requirements.

5.35 The President of the Société Française de Médecine Générale (a WONCA affiliate) also emphasized a multiple-level approach in a letter he appended to the WHO questionnaire. In essence, he advocates: (1) registration data, as approved by the health authorities, to serve as the basis for later controls and complaints, and to be made widely available to enforcement authorities, health professionals and even the general public through drug-description manuals; (2) a possible self-regulatory role for industry associations, and (3) a tripartite complaint-handling body made up of government, health-professionals and industry representatives in order to minimize recourse to the penal system, yet able to obtain the necessary corrections from companies. Here again, the burden of control is not exclusively put on the government but involves all or most interested parties.

Attitudes toward drug promotion

5.36 Obviously, industry respondents believe in drug promotion within a regulatory, self-regulatory (e.g., the IFPMA and proprietary-medicine codes) and self-disciplinary ("company responsibility") context. The only major exceptions relate to: (1) industry opposition to advertising RX drugs to the general public (although it is practised to some extent in the United States), and (2) advertising to children.

5.37 Non-industry respondents are more divided and often less favourably inclined toward drug promotion by pharmaceutical companies. They know, suspect or believe it to be biased, uninformative, misleading, fostering a "drug culture" and overconsumption, pushing worthless or marginal products, overemphasizing brands and duplicative products over generics, wasteful, increasing the price of drugs, etc. Governments are also concerned, particularly when they finance health-care expenditure or its reimbursement, lack hard currencies to pay for imports or licensing fees, support a local pharmaceutical industry against foreign companies, etc. At the limit, some non-industry respondents came out strongly against all advertising to the public, symposia organized by pharmaceutical companies, and free samples - among other promotional activities.

Professional versus lay views

5.38 It has already been mentioned that the questionnaires were not answered by "ordinary people" but by government officials, association executives and health professionals - even in the case of retired persons' associations since the questions were "too technical" for consumers to answer, according to the FIAPA cover letter. Even industry respondents, at least on the RX side, appear to question people's ability to understand package inserts if not labels.

5.39 This "professional" view may be explained by the multiplication and growing complexity of drugs (and combinations thereof) which prescribers have to tailor closely to the patient's condition. Besides, companies are concerned about their legal and financial liability, should drugs be misused. Problems associated with low literacy in many countries also reinforced their view that most information on prescription drugs should be communicated first and even only to health professionals, who in turn, will "translate" it for the users in order to reserve the "physician-patient" or "pharmacist-patient" personal relationships traditionally associated with the practice of health care.

5.40 Some consumer organizations, however, emphasize greater patient information (and education) concerning the selection and use of drugs.

5.41 Yet, this "professional" view is being challenged from various quarters. The letter of the French WONCA respondent has already been mentioned, and it is interesting to observe his plea for a broad diffusion of officially approved medical knowledge to all concerned, including the general public. The OTC industry is, of course, wedded to the notion of self-medication without medical supervision for the relief (and even cure) of certain symptoms and conditions.¹

5.42 Moreover, in both developed and developing countries, there have been increasing expressions in favour of self-medication by lay people or of medication by "low-tech" health professionals in view of the growth of world population, the shortage of "high-tech" health professionals, the savings that can be achieved, etc.

5.43 Moreover, however incomplete and uneven this development may be, there is no gainsaying that in many countries people are more informed than were previous generations - both in general and about health matters - through school curricula, health columns in periodicals, health books, and general-public education programmes. The consumer and feminist movements have not only contributed to improved lay knowledge about health matters but have also opposed a certain elitist and/or paternalistic tendency to distrust the capacity of ordinary people to understand health information and to make some of the decisions about health matters if they were sufficiently informed.

5.44 The issue of using "lay language" in communicating with the general public is obviously related to the above discussion.

RX versus OTC drugs

5.45 The WHO questionnaires did not define "prescription" and "over-the-counter" drugs - partly because there are important national distinctions related to how governments classify drugs, to whether they are reimbursed or not under health-insurance schemes, to their availability in pharmacies versus other types of stores, etc.² However, the respondents

¹ OTC products already represent some 20-25% of the worldwide market for drugs in market economies although sales in many developing countries may amount to less than US \$1 a year per capita (WFPM 1986 General Assembly's Proceedings, p.14).

² For example, the Mexican Government's answer mentioned that, if a drug has a regulated expiry date, it cannot be sold "over the counter"; codeine is treated as an OTC drug in Canada but not in the United States; some OTC drugs are not promoted to the general public, etc.

probably understood that "RX drugs" normally involve prior medical consultation as well as dispensing by a pharmacist on the basis of a physician's prescription, even though in many developing countries no physician intervenes, and the dispensing occurs under the control of a pharmacist or other health-professional. (Speaking for the RX-drug industry, the IFPMA defined a prescription drug as one "promoted and advertised to the medical profession rather than directly to the lay public").

5.46 Conversely, "OTC drug" was defined by the World Federation of Proprietary Medicine Manufacturers (WFPMM) as "a self-medication medicine which is intended by the manufacturer to be obtained by the consumer without prescription and used without medical supervision, according to label indications consistent with the required marketing approval".

5.47 A third category of "traditional/herbal medicines"¹ was not specifically covered in this survey. It straddles both RX and OTC drugs since some of them are available only through health practitioners although most of them are readily available for self-medication. Some are "promoted" and even reimbursable under medical insurance schemes, but it is not clear how the WHO Ethical Criteria for Drug Promotion will cover these traditional medicines, since they are often not registered with the national regulatory authorities. The industry associations for RX and OTC drugs (IFPMA and WFPMM) clearly differentiated the two kinds of drugs by declining to answer questions about the other kind. On the other hand, many non-industry respondents gave the same answer for both types of drugs. Several interpretations can be offered for these strikingly different response patterns.

5.48 Prescription drug companies appear anxious to maintain their traditional direct relationships with health professionals - particularly physicians - in order to induce the trial and prescription of their new (but also old) branded drugs, under medical supervision. Their position is related to the debate that is still going on in some quarters over "restricted lists" of drugs and the use of generics, issues that appear to challenge a number of RX-drug manufacturers. As such, they resist the "banalization" of their branded products, and they prefer to distance themselves from the general public.

5.49 The OTC-drug industry, on the other hand, is riding a different horse. By emphasizing "self-medication without medical supervision or instruction", OTC manufacturers are capitalizing on several developments. First, the drug approval process by a number of drug regulatory authorities is progressively weeding out useless ingredients and worthless claims, so that many remaining OTC drugs and new OTC drugs are claimed to be increasingly safe and efficacious for their approved uses (relief, treatment and even cure in some cases). The OTC industry is thus acquiring a more scientific and responsible image.

5.50 Secondly, the OTC industry is capitalizing on the growing if sometimes grudging recognition that delivering generalized health care to the world's population cannot exclusively or even mainly depend on prescribed drugs and licensed health professionals because of higher cost and relative shortage considerations - even in developed countries. Higher "medical literacy" on the part of growing segments of the general public is facilitating this transition, although it appears that the role of self-medication is not sufficiently understood or accepted by health professionals nor well taught in schools of medicine, pharmacy, nursing and health administration.

5.51 Thirdly, in certain countries some drug ingredients are being switched from RX to OTC states (e.g., hydrocortisone, antihistamines, ibuprofen) once their safety, under proper instructions, has been established. Clearly, the OTC industry prides itself on its new and

¹ One definition currently used by WHO considers traditional medicine as comprising those medical practices based on beliefs that were in existence, often for hundreds of years, before the development and spread of modern scientific medicine, and which are still in use today.

better products, while its critics emphasize that too much is spent on "unnecessary" or "non-essential" vitamins, cough syrups, tonics, etc. on account of overpromoted self-medication.

5.52 These developments may help to explain: (1) why the OTC-industry response acknowledged the need for the marketing approval process by regulatory authorities even though it is burdensome, and (2) why many non-industry association respondents were as demanding regarding information requirements for OTC drugs as for RX drugs, since some of the former now require detailed instructions, warnings, contra-indications, etc. for the general public to use them without medical supervision. In other words, there seems to be some convergence between the two types of drugs as far as registration and information requirements are concerned - with obvious implications for the development of the WHO Ethical Criteria for Drug Promotion.¹ For example, proper labelling assumes greater importance when drugs are switched from RX to OTC status.

5.53 It is worth noting that the WHO Revised Drug Strategy does not clearly identify a role for self-medication, except to state that governments should establish lists of drugs permitted for OTC sale. (However, there have been several WHO studies and reports about self-medication.)

National differences

5.54 The Introduction to the WHO questionnaires stressed that "there is no place for supranational regulation of drug promotion by WHO", and stated that "the criteria will constitute general principles and specific guidelines . . . which could be adapted by governments to national circumstances". Still, the WHO exercise implied that at least some universal "principles" could be developed; while respondents often took different positions regarding the possibility of and/or necessity for universal standards.

5.55 The industry responses made several references to important national regulatory and even self-regulatory differences which are a fact of life, as is evident from the government responses. Thus, the IFPMA stated in its cover letter:

"The facts remain that most of the areas included in the questionnaire are already covered by national regulation and codes of practice in many countries (both developed and developing), and that practices vary widely from country to country for very valid reasons. No one system is necessarily desirable for the whole world or even for all countries at a similar stage of economic or health development."

5.56 Similarly, the WFPMM stressed in a separate letter that:

"Nonprescription products are often indigenous to the country in which they are sold, having been developed by native manufacturers from long-used ingredients often herbal or animal rather than synthetic chemical origin. Advertising and promotion are not directed to medical practitioners, who tend to have a common global level of education and sophistication, but are directed to the general public which differs greatly in culture, education, traditions, medical customs, and health-care practices from country to country and indeed within countries. Therefore, general international guidelines must be interpreted, adapted and extended to achieve the objective of a nationally applicable code of practice specific to the realities of each country, with practical credible methods for the handling of complaints of violations and their satisfactory resolution at the local level . . . with our industry, our real existence is at the national level, where we promote directly to the local consumer, and consequently only our national codes can be the measure of our commitment to supplementing government controls, which we expect and welcome for our industry, with responsible self-regulation."

¹ As was argued at the 1986 WFPMM General Assembly: "There are not two sciences of pharmacology and clinical therapeutics" (Proceedings, p.10).

5.57 The drug industry fears being caught in a "no-win" situation where, on the one hand, they have to satisfy national requirements which are unlikely to become standardized in the foreseeable future; while on the other hand they would be held by their critics to higher WHO "ethical criteria", thus leaving them open to the criticism of hiding behind national differences and playing "double games" to suit their own interests.

5.58 Yet, the drug industry itself is moving toward uniform standards through the IFPMA Code of Pharmaceutical Marketing Practices and the WFPMM Guidelines for the Production of Voluntary Codes of Advertising Practice, among others, although these represent voluntary exercises in self-regulation rather than mandatory legal requirements. Actually, the Introduction to the WHO questionnaires suggested that the revised ethical criteria could serve for the development and improvement of such industry and company codes of practice as well. On the other hand, many non-industry association respondents favour "universal" requirements because it seems obvious to them that the same basic information should be provided everywhere - at least for drugs that are used everywhere - and that the industry should be held to the "highest standards", as is particularly evident in some of the comments elicited by the questions related to the promotion of exported drugs.

5.59 Furthermore, many non-industry respondents tend to visualize the drug industry as being dominated by multinational companies (MNCs) - irrespective of the fact that there are strong local companies in many countries (particularly in the case of OTC drugs), that MNCs often have to take local partners or licence local firms, and that drug piracy multiplies the sources of supply outside the control of MNCs, etc. Some of their critics stress that MNCs play nasty games by dumping inferior or dangerous drugs, by using different countries, and by leaving out some crucial information (warnings, contra-indications, instructions for use, etc.) in some countries with lower standards. In this perspective, uniform standards would help eradicate such detrimental contradictory practices.

5.60 Furthermore, the development of extended WHO Ethical Criteria for Drug Promotion may be viewed as a way of raising standards around the world through the reach of multinational corporations (perceived as omnipresent) even if national regulations remain different. In other words, if MNCs are as ubiquitous and powerful as their critics see them, why can they not be influenced to apply "ethical criteria" everywhere, thereby short-circuiting the tedious process of upgrading and homogenizing national regulations? For that matter, the pharmaceutical industry claims that it is moving in that direction through its control of foreign subsidiaries and licencees (when possible) and through the development of international (IFPMA) and national (e.g., WFPMM) codes.

Alternative Remedies

5.61 While most of the questions in the WHO survey dealt with the information provided to health professionals and/or the general public through scientific data sheets, inserts, labels and advertisements, other topics were also covered: symposia, medical representatives, free samples, etc. Even if these practices can be improved through the application of WHO ethical criteria, they can also be dealt with by regulatory and self-regulatory approaches such as fiscal treatment (deductibility) of promotion expenditures, the limitation of such expenditures, the control of prices,¹ the certification of medical representatives by industry associations, the non-reimbursement of certain drug expenditures, private or mixed complaint-handling systems, and the like.

¹ A couple of respondents objected to pricing being left out of the WHO survey although this is not a "promotion" topic. The issue of different prices being charged for the same drug in different countries may have motivated these comments.

Developing new WHO criteria

5.62 Novel problems, growing pressures and some emerging consensus may all influence the elaboration of new WHO ethical criteria - to be developed by an international group of experts, to be reviewed by an Ad Hoc Committee of the Executive Board on Drug Policies and the Executive Board, and to be approved as a resolution by the 1988 World Health Assembly. A few final comments may be useful in this context.

5.63 As the tables listing the responses indicate, there is some uniformity of practice and consensus of opinion about certain promotional methods that should not be allowed (e.g., advertising drugs to children) and about information that should be provided to health professionals and/or the general public. There should not be any major problems in developing new criteria regarding them.

5.64 It has already been mentioned that there is some convergence between RX and OTC drugs not only in terms of efficacy but also in terms of necessary instructions, warnings, etc. This raises the question of whether these two types of drugs (and possibly "traditional medicines") should share some common standards without, however, making them too detailed and burdensome.

5.65 Where there are major differences in national requirements and among responding associations' options - often but not exclusively between industry and non-industry associations - and consensus cannot be reached at the meeting of the international group of experts mentioned above, several options are possible. One is to present two or more options to the Executive Board Ad Hoc Committee on Drug Policies.

5.66 Another possible approach to resolving major differences is to distinguish between the "essential" and the "desirable" - as was done in Questionnaire No. 1. In other words, there could be two sets of WHO criteria, with the appropriate titles, implying the selection of a range between minimum and maximum.

5.67 A third approach would be to suggest to the World Health Assembly that it adopt either a rather short resolution with a very extensive appendix or a resolution spelling out the principles underlying the criteria, with detailed criteria in appendix form.¹

5.68 A fourth approach related to the previous ones would consist of surmounting the dissension, which is often related to specific requirements, by stressing objectives rather than means, for example, that promotional materials must conform to the original drug registration or marketing approval granted by the authorities; and that important/crucial information must be given to patients, whether through the package itself, the package insert, the label, other pamphlets, advertisements, or some combination thereof.

5.69 The above comments suggest, however, the danger that "general principles" may be considered as toothless, amenable to multiple interpretation, easily avoidable, and ultimately pointless. Conversely, over-detailed criteria may encourage over-regulation and foster rigidity over flexibility of application.

¹ Thus, the Report of the Conference of Experts on the Rational Use of Drugs mentions that: "It appears that international norms for drug labelling are hardly possible. Rather, it was suggested, guidelines should be prepared on good labelling practices within countries and for drugs moving in international commerce ("Rational Use of Drugs", WHO, Geneva, 1987, page 9, paragraph 22).



WORLD HEALTH ORGANIZATION
 ORGANISATION MONDIALE DE LA SANTÉ

DGO/ETHCDP/87.3
Annex 2

ORIGINAL: ENGLISH

INTERNATIONAL GROUP OF EXPERTS
 ON ETHICAL CRITERIA FOR DRUG
 PROMOTION

Geneva, 9-13 November 1987

REPORT ON THE WHO SURVEY ON
 "ETHICAL CRITERIA FOR DRUG PROMOTION

Annex 2

Selected extracts from a study on



MEDICINE ADVERTISING REGULATION AND SELF-REGULATION IN 54 COUNTRIES

by J.J. BODDEWYN

APRIL 1985



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Contents

- Executive Summary (pages 8 and 9 of the publication)
- Survey findings (pages 12 to 35 of the publication)

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IV. EXECUTIVE SUMMARY OF SURVEY FINDINGS

1. Only one third of the 54 countries in this survey have a list of diseases and clinical conditions for which OTC medicines should not be advertised to the public.
2. A majority of countries require that RX and OTC medicine advertisements be approved in advance by a government authority.
3. Only in Finland, Ireland, the Netherlands and the United Kingdom does a pharmaceutical-industry body also preclear OTC ads (it does it for RX drugs in Canada). In Greece and the Philippines, an advertising-industry organization screens OTC ads in advance; a media body plays such a role in Australia, Canada, Taiwan and the United Kingdom.
4. Only claims and indications-for-use approved for labeling can be used in RX and OTC ads in about half the countries. The requirement that only specified wording approved for labeling be used in ads is much less common, however.
5. Mentioning the major active ingredients in ads - particularly in the case of OTC drugs - is not commonly required.
6. About half of the countries mandate various types of warnings and contra-indications in ads although less frequently for OTC drugs.
7. Only Greece, India, Kenya and Singapore reported problems with the tax-deductibility of drug-advertising expenditures. France taxes and the United Kingdom restricts such expenditures for RX drugs.
8. The advertising of drugs and of their prices by pharmacies and other stores is rather uncommon.
9. Only the United States allows some forms of RX-drug advertising to the general public, but this practice remains controversial and will not be liberalized.

10. While promotional materials about RX drugs can readily be sent to health professionals, free RX samples are restricted in 14 countries.
11. There are relatively few restrictions on the use of various media for OTC-drug advertising.
12. Claims that an OTC drug can cure or prevent an ailment are acceptable in a slight majority of countries, but such claims must be capable of substantiation.
13. Testimonials by health professionals are more restricted than those by actors portraying them in the case of OTC ads. Consumer endorsements are acceptable in about two-thirds of the responding countries.
14. From one half to two thirds of the 54 nations prohibit the use of premiums, gifts, competitions, sweepstakes and contests with OTC drugs. Industry self-regulation typically discourages such practices.
15. Various new restrictions or taxes are anticipated in half of the countries.
16. While some international organizations (WHO, UNCTAD, ECOSOC, Council of Europe, EEC Commission and European Parliament) have discussed pharmaceutical codes - usually at the prompting of a few activist groups - respondents from only 12 countries referred to such developments or expressed concern about them.
17. Similarly, few references were made to new industry code developments.
18. Many national pharmaceutical and advertising associations have developed and are enforcing codes and guidelines of good advertising behavior as far as medicines are concerned. There are similar initiatives at the international level for both RX and OTC drug advertising.
19. The above findings are related to such old and new issues as miraculous cures, claim substantiation, the need for warnings and understandable wording, drug acculturation, advertising to children and the economic usefulness of medicine ads.

VI. SURVEY FINDINGSA. QUESTIONS 1-21: CURRENT GOVERNMENT REGULATIONS AND INDUSTRY GUIDELINES

QUESTION 1: DOES GOVERNMENT HAVE TO APPROVE DRUGS BEFORE THEY CAN BE MARKETED/ADVERTISED?

FINDINGS:

The answer is overwhelmingly YES for both RX and OTC drugs. Only Costa Rica, F.R. Germany, Ireland, Malaysia and Singapore answered NO but their answers must be qualified. In Germany, for example, the industry has long policed itself although the Federal Health Office's control is increasing. In the United States, only OTC drug ingredients have to be approved under the FDA OTC-review process, but not medicine products in finished form.

QUESTION 2: IS THERE A GOVERNMENT LIST OF DRUGS FOR WHICH ADVERTISING IS SPECIFICALLY APPROVED?

FINDINGS:

Here, the pattern of answers is reversed: most countries answered NO, except for the following:

"YES" FOR RX DRUGS

- Jamaica
- Kenya
- Paraguay
- South Africa
- Thailand
- Venezuela

"YES" FOR OTC DRUGS

- Australia
- Brazil
- India
- Jamaica
- Kenya
- Malaysia
- Netherlands
- Paraguay
- Portugal
- Spain
- Switzerland (but not for
- all OTCs)
- Thailand

This largely negative response can be explained by the fact that the focus of regulation and self-regulation is on: (1) diseases (e.g., cancer) for which self-treatment should not be advertised to the public, and (2) appropriate standards for advertising medicines rather than on a list of drugs for which advertising is allowed. Besides, this question may have been misunderstood by some respondents.

QUESTION 3: IS THERE A GOVERNMENT LIST OF DISEASES AND CLINICAL CONDITIONS FOR WHICH DRUGS SHOULD NOT BE ADVERTISED TO THE PUBLIC?

FINDINGS:

Here again, most countries answered NO although such lists exist in a number of them (see Figure 1 for a Canadian example). For the countries answering YES for OTC drugs, such conditions as cancer, tuberculosis, baldness, venereal diseases, diabetes, polio, arthritis, hypertension, cardiovascular diseases, gastric ulcer, lung-kidney-heart diseases, cholera and asthma were typically mentioned.

COUNTRIES ANSWERING "YES" FOR OTC DRUGS

- o Australia
- o Belgium
- o Canada
- o Hong Kong
- o Indonesia
- o Ireland
- o Jamaica
- o Japan
- o Korea
- o Malaysia
- o Netherlands
- o New Zealand
- o Nigeria
- o Singapore
- o Taiwan
- o Trinidad and Tobago
- o United Kingdom
- o Zimbabwe

FIGURE 1

DISEASES AND CONDITIONS THAT CANNOT BE ADVERTISED TO THE GENERAL PUBLIC
(CANADIAN FOOD AND DRUG ACT, SCHEDULE A)

Alcoholism	Hypotension
Alopecia	Impetigo
Anxiety state	Influenza
Appendicitis	Kidney disease
Arteriosclerosis	Leukemia
Arthritis	Liver disease
Bladder disease	Nausea and vomiting of pregnancy
Cancer	Obesity
Convulsions	Pleurisy
Depression	Pneumonia
Diabetes	Poliomyelitis
Disease of the prostate	Rheumatic fever
Disorder of menstrual flow	Scabies
Dysentery	Septicemia
Edematous state	Sexual impotence
Epilepsy	Tetanus
Gallbladder disease	Thrombotic and embolic disorders
Gangrene	Thyroid disease
Glaucoma	Tuberculosis
Gout	Tumor
Heart disease	Ulcer of the gastrointestinal tract
Hernia	Vaginitis
Hypertension	Venereal disease

QUESTION 4: MUST EACH DRUG ADVERTISEMENT BE APPROVED IN ADVANCE?FINDINGS:

Four options were available: (1) preclearance by a government authority; (2) preclearance by a pharmaceutical industry self-regulatory body; (3) preclearance by an advertising industry self-regulatory body, and (4) preclearance by a media association.

1. Preclearance by a government authority. A majority of the countries answered YES - typically by a Ministry or Board of Health.

COUNTRIES WHERE GOVERNMENT PRECLEARANCE IS REQUIRED FOR:

<u>RX DRUGS</u>	<u>OTC DRUGS</u>
Argentina	Argentina
Austria	Australia (radio-TV commercials only)
Canada	Austria
Chile	Canada (radio-TV commercials only)
Colombia	Chile
Denmark	Colombia
Ecuador	Denmark
France	El Salvador
Greece	France
Hong Kong	Guatemala
Indonesia	Greece
Italy	Hong Kong (radio-TV commercials only)
Jamaica	Indonesia
Kenya	Italy
Lebanon	Jamaica
Mexico	Kenya
Nigeria	Lebanon
Norway	Malaysia
Paraguay	Mexico
Peru	Nicaragua
Portugal	Nigeria
Singapore	Norway
Spain	Panama
Syria	Paraguay
Taiwan	Peru
Thailand	Singapore
Venezuela	Spain
	Switzerland (for some OTC drugs only)
	Taiwan
	Thailand
	Venezuela

NOTE: In both the United Kingdom (DHSS) and the United States (FDA), the government can require preclearance but uses this power only in exceptional cases (e.g., the U.S. Food and Drug Administration has recently required the preclearance of ads for RX asthma drugs). In the United States, RX ads must adhere to the FDA-approved labeling, however.

In Canada, OTC-drug radio and TV commercials must be previewed and cleared by the Department of Health and Welfare to ensure that they do not contravene the Food and Drug Act and Regulations. This is required under Section 11 of the Broadcasting Regulations administered by the Canadian Radio-Television and Telecommunications Commission (CRTC) which provides each acceptable script with a CRTC registration number. However, OTC advertisements appearing in newspapers, magazines and direct-mail pieces are not subject to preclearance even though they must conform to the same rules as broadcast commercials.

When governments own broadcasting stations or even have a broadcasting monopoly (e.g., France and Sweden), this may amount to an indirect form of governmental preclearance of all commercials - not just those for medicines.

2. Preclearance by a pharmaceutical industry self-regulatory body. For RX drugs, Canada is the only country that answered YES. The Pharmaceutical Advertising Advisory Board is a non-governmental board with representation from the Proprietary Association of Canada, the Pharmaceutical Manufacturers Association of Canada, the Canadian Cosmetic, Toiletries and Fragrance Association and the Canadian Pharmaceutical Association - with the Health Protection Branch of the Department of National Health and Welfare serving in an advisory capacity but retaining ultimate veto power.

For OTC drugs, Finland has a tripartite Drug Advertising Supervisory Commission for the preclearance of TV drug commercials, which involves the pharmaceutical and advertising industries as well as government and medical experts. The Federation of Irish Chemical Industries, the Dutch KOAG and the Proprietary Association of Great Britain also provide preclearance for all types of OTC advertisements.

3. Preclearance by an advertising self-regulatory body. This does not seem to exist - except perhaps in Greece and the Philippines (where the Philippine Board of Advertising has been delegated significant regulatory power by the government, and preclears all OTC advertisements).

4. Preclearance by a media association. Most newspapers, magazines, broadcasting stations and networks (some of them government monopolies as in France) have their own acceptance rules for advertisements, but it is rare to find a media association involved in preclearance.

In Australia, however, drug commercials are screened by both the Therapeutic Goods Branch of the Department of Health and the Federation of Australian Commercial Television Stations (FACTS) and the Federation of Australian Radio Broadcasters (FARB). Materials intended for use in publications which are members of the Media Council of Australia are screened by the Australian Publishers Bureau.

In Taiwan, the Taipei Newspaper Industry New Review Committee appears to play a similar role. In Canada, the Telecaster Committee (TC) is a self-regulatory organization of television stations and networks that rules on the acceptance of all commercials in accordance with its guidelines, although only TC members are bound by its decisions.

In the United Kingdom, the Independent Broadcasting Authority (IBA) is a statutory body responsible to government, which has the duty to apply appropriate controls to broadcast commercials. In practice, the IBA Code of Advertising Practice (which includes specific clauses dealing with medicine advertising) is administered by the Independent Television Companies' Association (ITCA). Commercials must be approved by ITCA; and in the case of

medicine advertisements, they are subject to comment from the IBA Medical Advisory Panel. This procedure is in addition to the pre-publication clearance mandated by the Proprietary Association of Great Britain (see Appendix).

QUESTION 5: MAY ONLY CLAIMS AND INDICATIONS FOR USE APPROVED FOR LABELING BE USED IN ADS?

FINDINGS:

As Figure 2 indicates, more countries answered YES (27) than NO (17) for RX drugs while the situation is somewhat reversed for OTC medicines (23 vs. 29).⁶ Of course, advertisers are normally not allowed to make unsubstantiated claims by either law or self-regulation.

[FIGURE 2 INCLUDES THE ANSWERS TO QUESTIONS 5 TO 9]

6. Some answers are missing for some of the questions so that their total does not always equal 54 (countries).

F I G U R E 2 (cont.)

FINDINGS:	Question 5 LABELLING CLAIMS IN ADS		Question 6 LABELLING WORDS IN ADS		Question 7 ACTIVE INGREDIENTS IN ADS		Question 8 WARNINGS IN ADS		Question 9 CONTRA-INDICATIONS IN ADS	
	RX	OTC	RX	OTC	RX	OTC	RX	OTC	RX	OTC
FINLAND	yes	yes	no	no	yes	no	yes	yes	yes	yes
FRANCE	no	no	no	no	no	no	yes	yes	yes	yes
F. R. GERMANY	no	no	no	no	yes	no	yes	yes	yes	yes
GUATEMALA		no		no		no		no		no
GREECE	no	no	no	no	no	no	no	no	no	no
HONDURAS		no		no		no		no		no
HONG KONG	no	no	yes	yes	no	no	no	no	no	no
INDIA		no		no		no		no		no
INDONESIA	yes	yes	no	no	yes	yes	yes	yes	yes	yes
IRELAND	no	yes	no	no	no	no	no	yes	yes	yes
ITALY	no	no	no	no	no	no	yes	yes	no	no
JAMAICA	no	no	no	no	no	no	yes	yes	yes	no
JAPAN	yes	yes	no	no	no	no	yes	yes	no	no
KENYA	yes	no	yes	no	no	no	yes	yes	no	no
KOREA	no	no	no	no	no	no	no	no	no	no
LEBANON							no	no		
MALAYSIA	yes	yes	no	no	yes	yes	yes	yes	no	no
MEXICO	no	no	no	no	no	no	yes	yes	no	no
NETHERLANDS	yes	yes	no	no	yes	no	yes	yes	yes	yes
NEW ZEALAND	yes	yes	no	no	yes	no	no	no	no	no
NICARAGUA		no		no		no				no

QUESTION 6: MAY ONLY SPECIFIED WORDS APPROVED FOR LABELING BE USED IN
ADVERTISEMENTS?

FINDINGS:

A major issue in medicine advertising has been: "Should an ad read like a label or package insert?" - with the latter often constituting the government-approved statement about the drug's effectiveness, side effects and contra-indications which must be specifically included on the label, package insert or equivalent product accompaniment, and in the promotional literature.

The answers to Question 6 are predominantly negative: 36 NO for RX drugs and 46 NO for OTC drugs (see Figure 2). Industry has largely succeeded in defending its position that the language used in advertising to the public should not necessarily be the same as the scientific or technical terminology used by government reviewers in approving the indications for use of the drug (see Section VII.E below for a discussion of this "exclusivity" issue).

QUESTION 7: MUST THE MAJOR ACTIVE INGREDIENTS INCLUDED IN THE DRUG BE
MENTIONED IN THE AD?

FINDINGS:

This requirement is found in less than half of the responding countries as far as RX drugs are concerned: 21 YES vs. 24 NO answers, but it is much less common for OTCs: 7 YES vs. 46 NO answers (see Figure 2). Switzerland requires it only in OTC advertisements to health professionals - a requirement probably found in many countries.

QUESTION 8: MUST ADVERTISEMENTS INCLUDE APPROPRIATE WARNINGS (E.G., "ALWAYS READ THE LABEL," "USE ONLY AS DIRECTED," "MAY CAUSE DROWSINESS" OR "CONSULT A DOCTOR IF THE SYMPTOMS PERSIST")?

FINDINGS:

A distinction must be made between (1) general warnings or cautions such as "Consult your doctor" (required by the Mexican government for all labels and advertisements) and "As with all medicines, keep out of the reach of children" (a voluntary practice in the United States), and (2) specific cautionary statements applicable to particular products or ingredients (e.g., "May cause drowsiness. Do not drive or operate machinery after taking") which are more likely to appear on the label. Various OTC warnings have originated with the industry rather than with government - for example in Australia and the United States. Unfortunately, this survey did not sufficiently differentiate between these two types of warnings.

Half of the countries have such a requirement (see Figure 2), revealing that the problem of overloading ads with warnings defies a simple solution. In the case of RX drugs, the NO answers must be interpreted in terms of the simple "reminder" advertisements which are used to promote them to health professionals. Such simplified ads without warnings are allowed in a number of countries, provided full information is readily available to them elsewhere (e.g., in data sheets, promotional literature and medical reference books).

QUESTIONS 9: MUST ADVERTISEMENTS INCLUDE APPROPRIATE CONTRA-INDICATIONS (E.G., "NOT FOR PEOPLE ON A LOW-SODIUM DIET")?

FINDINGS:

Such a requirement is more common for RX drugs (27) than for OTCs (16 YES

vs. 38 NO), and it is less common than mandating warnings (Question 8) as far as OTCs are concerned (see Figure 2).

QUESTION 10: ARE REASONABLE ADVERTISING EXPENDITURES FULLY TAX-DEDUCTIBLE?

FINDINGS:

Only four countries answered NO: Greece, India (20 percent of such expenditures are not tax-deductible), Kenya and Singapore.⁷

o In France, there is a special 5 percent tax on RX-drug promotion expenditures, which is not tax-deductible; and there are limits on how much firms can spend on promotion per unit sold. This measure is designed to reduce the cost of reimbursable prescriptions but works to the detriment of smaller pharmaceutical firms which thus dispose of a smaller tax-deductible advertising budget.

o In the United Kingdom, the government has restricted the amount of money pharmaceutical companies can spend on advertising RX drugs to doctors in order to curtail the spiraling costs of medical care provided by the National Health System. Under a recent agreement with the government, U.K. prescription-drug manufacturers are now limited to spending only 10 percent of their annual drug sales on advertising and other forms of promotion. If expenditures go over this "voluntary" limit, the companies will be forced to pay a penalty equal to the excess spending.⁸ In 1985, this upper limit goes down to 9 percent.

7. For a fuller treatment of this subject, see: J.J. Boddewyn, Advertising Taxation in 39 Countries (New York: International Advertising Association, 1983).

8. "Britain Orders Drug Ad Cuts," Advertising Age (23 January 1984), p. 46.

QUESTIONS 11 & 12: CAN PHARMACIES AND OTHER STORES ADVERTISE THROUGH THE MASS MEDIA?

FINDINGS:

The answer is NO for RX drugs since they cannot, as a general rule, be advertised to the general public. However, in the United States, RX advertising by pharmacies is permitted but limited to name and price.

Regarding OTC medicines, most countries say YES but some add: "It is not done." The explanation is that in nations like Belgium, Chile, Finland, France and Norway, pharmacies have a monopoly on the sale of both RX and OTC drugs. This monopolistic situation, together with legal or professional restrictions, makes it unnecessary or impossible for pharmacies to advertise - a task then left to manufacturers and importers. Countries where such factors prevent pharmacies and other stores from advertising OTC drugs include: Austria, Belgium, France, Indonesia, Ireland and Italy - among others.

QUESTION 13: CAN THE PRICE OF DRUGS BE ADVERTISED?

FINDINGS:

Most countries answer YES but a number of them point out that "it is not done" - again, because pharmacies do not or cannot advertise at all. In Australia, price advertising is legal but contrary to the Proprietary Association of Australia's Code of Ethics; in Finland and Norway, prices must be mentioned in the advertisement. In Finland, in the case of ads in health-care professional journals, the average cost of treatment must be given when its calculation is possible. In the United States, a 1976 Supreme Court decision (Virginia State Board of Pharmacy) resulted in the relaxation of state bans on price advertising for drugs.

[NOTE: THE FOLLOWING QUESTIONS 14-18 APPLY ONLY TO RX-DRUG ADVERTISING]

QUESTION 14 & 15 CAN PRESCRIPTION DRUGS BE ADVERTISED TO PHYSICIANS,
PHARMACISTS AND OTHER HEALTH-RELATED PROFESSIONALS - AND
ONLY TO THEM?

FINDINGS:

All responding countries answered YES to these questions although there are some restrictions about certain categories of health professionals (midwives, nurses, etc.). The United States presents a special case discussed in the following section.

QUESTION 16: ARE THERE PROPOSALS IN YOUR COUNTRY TO ALLOW THE ADVERTISING OF
PRESCRIPTION DRUGS TO THE GENERAL PUBLIC?

FINDINGS:

The United States stands alone in this regard. It has no legal restrictions on advertising RX drugs to the public, provided detailed side-effect information is presented. Some companies introduced a few ads of this type in 1981-1982, but the Food and Drug Administration instituted a legally questionable moratorium in September 1983. Various reviews and surveys were conducted and analyzed in order to determine if consumers can properly understand such unusual advertisements, but no liberalization seems likely. However, RX ads to the general public concerning only prices as well as institutional ads focussing on diseases and their appropriate treatment, without naming any specific drugs, can still be run.

Besides, the Cable Health Network (now Lifetime Network) already carries RX advertisements complying with FDA regulations.⁹ Although directed at

9. The U.S. Food, Drug and Cosmetic Act requires that a "brief summary" of a drug's risks and precautions be included in advertisements promoting the uses of the product. The purpose of the brief summary is to communicate a fair balance of benefits and risks to health-care professionals. The "brief summary" requirement is met in medical-journal advertisements by reprinting all the cautionary (risk) information from the package insert.

health professionals, this cable network can also be viewed by the general public. Some U.S. consumers, therefore, are already exposed to such advertisements through this network as well as through medical reference books and professional journals - but not through the mass media.

QUESTION 17: IS THE DIRECT MAILING OF PROMOTIONAL MATERIALS (COPIES OF ADS, PAMPHLETS, MANUALS, ETC.) TO PHYSICIANS, PHARMACISTS AND HEALTH-RELATED PROFESSIONALS ALLOWED?

FINDINGS:

All countries answered YES. In France, however, prior permission of the Health Ministry is usually needed.

QUESTION 18: CAN FREE SAMPLES OF DRUGS BE SENT TO PHYSICIANS, PHARMACISTS AND OTHER HEALTH-RELATED PROFESSIONALS EVEN IF THEY HAVE NOT BEEN EXPRESSLY REQUESTED BY THEM (THAT IS, CAN YOU SEND THEM A FREE SAMPLE WITHOUT THEIR REQUESTING IT)?

FINDINGS:

Fourteen countries answered NO:

- | | |
|---|---|
| <input type="checkbox"/> Austria | <input type="checkbox"/> Ireland |
| <input type="checkbox"/> Belgium | <input type="checkbox"/> Korea |
| <input type="checkbox"/> Canada | <input type="checkbox"/> Mexico |
| <input type="checkbox"/> Denmark (unless permission is granted) | <input type="checkbox"/> Norway |
| <input type="checkbox"/> Finland | <input type="checkbox"/> Singapore |
| <input type="checkbox"/> France | <input type="checkbox"/> Sweden |
| <input type="checkbox"/> Germany | <input type="checkbox"/> United Kingdom |

Physicians in these countries must request such samples in writing (this is also the case in some U.S. states as far as controlled substances are concerned). Only physicians and dentists may usually receive such samples, compared to the larger number of health professionals who may be given free

literature and other promotional materials. One rationale for this restriction is the reduction of promotional expenses which impact the cost of government-provided services.

There are also time limitations applying to free samples: in Belgium, they may only be distributed during the 6-month period following registration of the new drug; in France and the Netherlands, for 2 years; and in Norway for one year, and only the smallest unit available may be sampled.

[NOTE: THE FOLLOWING QUESTIONS 19-21 APPLY ONLY TO OTC DRUG ADVERTISING.]

QUESTION 19: CAN OTC DRUGS BE ADVERTISED TO THE GENERAL PUBLIC THROUGH THE MASS MEDIA?

FINDINGS:

All countries, except Syria and Turkey, answered YES. However, this freedom is sometimes limited:

- o In Australia, only "unscheduled" OTCs and certain types of "scheduled" OTCs (i.e., pharmacy-restricted) can be advertised to the general public.
- o In Canada, advertising is allowed only for specific conditions and limited dosages.
- o In Chile, not for laxatives, anti-flu medicines, and those that may be habit-forming.
- o In Finland, there are size restrictions for ads in newspapers (1/4 page) and periodicals (1 page) per issue.
- o In Japan, not more than 1/3 page in newspapers.
- o In Switzerland, analgesics are excluded (on the basis of a pharmaceutical industry gentlemen's agreement) as well as other drugs which may only be sold in pharmacies.

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- o In Thailand, in the case of medicines containing certain ingredients such as antihistamines in cough syrup.
- o In Turkey, drug advertising in the mass media is in principle not allowed, with the exception of announcing the availability of drugs in the press. However, pharmaceutical companies try to overcome this barrier by point-of-purchase displays and materials in pharmacies, and by other means.
- o In Zimbabwe, there are some exceptions (e.g., codeine-based products).

QUESTION 20: MAY OTC ADS CLAIM THAT AN OTC DRUG CAN CURE OR PREVENT AN AILMENT OR DISEASE?

FINDINGS:

As the following list indicates, a majority of countries (33) said YES but there were 21 NO answers - sometimes with the qualification: "YES if scientifically proven," which refers to the substantiation issue discussed below.

A few countries restrict such claims to prevention or relief only, and do not accept claims for cure: Guatemala, Spain and Sweden. The codes administered by the Australian Media Council state that: "An advertisement relating to goods for therapeutic use which contains reference to the following conditions shall not refer to such a condition in its chronic, recurrent or persistent form but it may contain a claim to relieve the sufferers or alleviate acute forms of conditions: acidity of stomach . . . [many other conditions are listed]."

Clearly, there are medical conditions (e.g., cancer - see Figure 1) for which no cure or prevention claims may be made at all. On the other hand, a

"cure" claim is legitimate for some OTCs - for example, for typical cases of dandruff and athlete's foot. Thus, the U.S. Proprietary Association has recently revised its definition as follows: "OTC medicines are appropriate for the prevention, treatment, symptomatic relief or cure of diseases, injuries or other conditions - acute or chronic - which the consumer can identify and manage alone or with professional diagnosis or supervision."

QUESTION 20

"YES" COUNTRIES

- Australia
- Austria
- Belgium
- Brazil
- Canada
- Chile
- Denmark
- Finland
- France
- Germany
- Greece
- Guatamala (prevent, only)
- Hong Kong
- India
- Indonesia
- Italy
- Japan
- Kenya
- Korea
- Malaysia
- Mexico
- Netherlands
- Paraguay
- Peru
- South Africa (prevent, mostly)
- Spain (prevent, mostly)
- Sweden
- Switzerland
- Taiwan
- Thailand
- Trinidad and Tobago
- United Kingdom (prevent, only)
- United States (prevent, only)

"NO" COUNTRIES

- Argentina
- Colombia
- Costa Rica
- Educador
- El Salvador
- Honduras
- Ireland
- Jamaica
- Lebanon
- New Zealand
- Nicaragua
- Nigeria
- Norway
- Panama
- Philippines
- Portugal
- Singapore
- Syria
- Turkey
- Venezuela
- Zimbabwe

QUESTION 21: CAN DRUG ADVERTISING USE THE FOLLOWING MEDIA AND TECHNIQUES?FINDINGS:

Ten questions inquired about the permissibility of using television, outdoor and direct-mail advertising, testimonials, premiums, gifts, competitions and refunds. The results are presented in Figure 3.

C O M M E N T A R Y

211. Use Television: Disregarding Belgium, Denmark, Indonesia, Norway and Sweden where no commercials are broadcast at all, only Switzerland, Syria and Turkey answered NO.

212. Use Outdoor Advertising: Only Austria, Denmark, Finland, Syria and Turkey answered NO.

213. Use Direct Mail (to the general public): Only Argentina, Austria, Finland, Ireland and Turkey answered NO.

214-216. Use Testimonials:¹⁰ The largest incidence of NO answers pertains to "testimonials by physicians, pharmacists and other health-related professionals," followed by "testimonials by actors portraying physicians, pharmacists and other health-related professionals." In any case, such testimonials are generally not used and are discouraged by industry self-regulation today. On the other hand, "testimonials by consumers" are allowed in about two-thirds of the countries. In the United States, restrictions on actors portraying health professionals originated with broadcasters, not with the government.

10. See: J.J. Boddewyn, Endorsements/Testimonials: A 36-Country Survey (New York: International Advertising Association, 1981).

FIGURE 3

QUESTION 21 - COUNTRY-BY-COUNTRY FINDINGS

Q. 21 - Can OTC drug ads use the following:

	211 TELEVISION ADVERTISING	212 OUTDOOR ADVERTISING	213 DIRECT MAIL TO GENERAL PUBLIC	214 TESTIMONIALS BY PHYSICIANS	215 TESTIMONIALS BY ACTORS	216 TESTIMONIALS BY CUSTOMERS	217 PREMIUMS & COUPONS	218 FREE GIFTS	219 COMPETITIONS, CONTESTS, SWEEPSTAKES	220 REFUNDS
ARGENTINA	yes	yes	no	no	no	no	no	no	no	yes
AUSTRALIA	yes	yes	yes	no	no	yes	no	no	no	no
AUSTRIA	yes	no	no	no	no	no	no	no	no	no
BELGIUM	no(na)	yes	yes	no	no	no	no	no	no	no
BRAZIL	yes	yes	yes	no?	no	yes	no	no	no	no
CANADA	yes	yes	yes	no	no	yes	yes	yes	yes	yes
CHILE	yes	yes	yes	yes	yes	yes	no	yes	no	no
COLOMBIA	yes	yes	yes	no	no	no	no	no	no	yes
COSTA RICA	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
DENMARK	no(na)	no	yes	no	no	no	no	no	no	no
ECUADOR	yes	yes	yes	no	yes	no	yes	yes	yes	yes
EL SALVADOR	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
FINLAND	yes	no	no	no	no	no	no	no	no	no
FRANCE	yes	yes	yes	no	yes	no	no	no	no	no

F I G U R E 3 (cont.)

	211 TELEVISION ADVERTISING	212 OUTDOOR ADVERTISING	213 DIRECT MAIL TO GENERAL PUBLIC	214 TESTIMONIALS BY PHYSICIANS	215 TESTIMONIALS BY ACTORS	216 TESTIMONIALS BY CUSTOMERS	217 PREMIUMS & COUPONS	218 FREE GIFTS	219 COMPETITIONS CONTESTS, SWEEPSTAKES	220 REFUNDS
F. R. GERMANY	yes	yes	yes	no	no	no	no	yes	no	no
GUATEMALA	yes	yes	yes	no	no	yes	yes	yes	yes	yes
GREECE	yes	yes	yes	yes	yes	yes	no	yes	yes	no
HONDURAS	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
HONG KONG	yes	yes	yes	no	no	yes	yes	no	yes	no
INDIA	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
INDONESIA	no (na)	yes	yes	no	no	yes	no	no	no	no
IRELAND	yes	yes	no	yes	yes	yes	no	no	no	no
ITALY	yes	yes	yes	no	yes	yes	no	no	no	no
JAMAICA	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
JAPAN	yes	yes	yes	yes	no	yes	yes	yes	no	no
KENYA	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
KOREA	yes	yes	yes	no	yes	yes	no	no	no	no
LEBANON	yes	yes	yes	no	yes	yes	na	yes	yes	no
MALAYSIA	yes	yes	yes	no	no	yes	yes	yes	no	yes
MEXICO	yes	yes	yes	yes	yes	yes	no	yes	no	no
NETHERLANDS	yes	yes	yes	no	no	no	no	no	no	no
NEW ZEALAND	yes	yes	yes	no	no	no	yes	yes	yes	yes
MICARAGUA	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
NIGERIA	yes	yes	yes	no	yes	yes	yes?	yes	no	no
NORWAY	no (na)	yes	yes	no	no	no	no	no	no	no

F I G U R E 3 (cont.)

	211 TELEVISION ADVERTISING	212 OUTDOOR ADVERTISING	213 DIRECT MAIL TO GENERAL PUBLIC	214 TESTIMONIALS BY PHYSICIANS	215 TESTIMONIALS BY ACTORS	216 TESTIMONIALS BY CUSTOMERS	217 PREMIUMS & COUPONS	218 FREE GIFTS	219 COMPETITIONS, CONTESTS, SWEEPSTAKES	220 REFUNDS
PANAMA	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
PARAGUAY	yes	yes	yes	no	yes	yes	yes	yes	yes	no
PERU	yes	yes	yes	yes	yes	yes	no	no	no	no
PHILIPPINES	yes	yes	yes	no	no	no	no	no	no	no
PORTUGAL	yes	yes	yes	yes	yes	yes	yes	yes	yes	no
SINGAPORE	yes	yes	yes	no	no	yes	no	no	no	no
SOUTH AFRICA	yes	yes	yes	no	yes	yes	yes	no	no	no
SPAIN	yes	yes	yes	yes	no	yes	yes	yes	yes	no
SWEDEN	no {na}	yes	yes	no	no	no	no	yes	no	yes
SWITZERLAND	no	yes	yes	no	no	no	no	no	no	no
SYRIA	no	no	yes	no	no	no	no	no	no	no
TAIWAN	yes	yes	yes	yes	yes	no	yes	yes	yes	no
THAILAND	yes	yes	yes	no	no	yes	no	no	no	no
TRINIDAD	yes	yes	yes	no	no	yes	yes	yes	yes	yes
TURKEY	no	no	no	no	no	no	no	no	no	no
UNITED KINGDOM	yes	yes	yes	no	no	yes	no	yes	no	no
UNITED STATES	yes	yes	yes	no	no	yes	yes	yes	yes	yes
VENEZUELA	yes	yes	yes	yes	no	no	no	no	no	no
ZIMBABWE	yes	yes	yes	no	no	yes	yes	yes	yes	yes

NOTE: {na} means "not applicable" as these countries do not broadcast commercials at all.

217-219. Use Premiums, Coupons; Absolutely Free Gifts; Competitions, Contests, Sweepstakes (in consumer advertising): From half to two-thirds of the countries were negative on this score, reflecting opposition to such "distracting" practices in some nations, but also the discouragement of any incentive to the unnecessary use of drugs.¹¹ National industry codes usually oppose such practices even when the law does not (see the U.S. Proprietary Association's code in the Appendix for an example).

220. Offer Refunds If the Customer Is Not Satisfied: Here again, the NO answers predominated by far for the same reasons.



Geneva, 9-13 November 1987

REPORT ON THE WHO SURVEY ON
"ETHICAL CRITERIA FOR DRUG PROMOTION"

Annex 3

WHO's ethical and scientific criteria
for pharmaceutical advertising
(Resolution WHA21.41, May 1968)



WHA21.41 The Twenty-first World Health Assembly,

Having considered the Director-General's report on pharmaceutical advertising;

Having noted resolution EB41.R24 of the Executive Board on the matter;

Considering that, if it is not objective, pharmaceutical advertising in whatever form is detrimental to the health of the public; and

Holding that the adherence to certain fundamental principles for the advertising of pharmaceutical products is essential,

URGES Member States to enforce the application of the ethical and scientific criteria for pharmaceutical advertising as annexed to this resolution.

ANNEX

ETHICAL AND SCIENTIFIC CRITERIA
FOR PHARMACEUTICAL ADVERTISING

All advertising on a drug should be truthful and reliable. It must not contain incorrect statements, half-truths or unverifiable assertions about the contents, effects (therapeutic as well as toxic) or indications of the drug or pharmaceutical speciality concerned.

Advertising to the Medical and Related Professions

In describing the properties of a drug and its use, stress should be laid on rendering facts and data, whereas general statements should be avoided. Statements should be supported by adequate and acceptable scientific evidence. Ambiguity must be avoided. Promotional material should not be exaggerated or misleading.

A full description, based on current scientific knowledge, should include information on the producer and sponsor of the product advertised; full designation (using generic or non-proprietary names) of the nature and content of active ingredient(s) per dose; action and uses; dosage, form of administration, and mode of application; side-effects and adverse reactions; precautions and contra-indications; treatment in case of poisoning; and references to the scientific or professional literature.

A fair balance should be maintained in presenting information on effectiveness on the one hand and adverse reactions and contra-indications on the other.

Advertising to the Public

Advertisements to the public should not be permitted for prescription drugs, for the treatment of certain diseases and conditions which can be treated only by a doctor and of which certain countries have established lists, or in a form which brings about fear or distress, or which declares specific remedies to be infallible, or suggests that they are recommended by members of the medical profession.