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THE INTERNATIONAL CODE OF MARKETING OF BREAST-MILK SUBSTITUTES: SURVEY OF NATIONAL LEGISLATION AND OTHER MEASURES ADOPTED (1981-1991)

by

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Since the adoption of the International Code of Marketing of Breast-milk Substitutes in 1981, Member States of the World Health Organization have responded in varying degree and manner in giving effect to it. WHO has prepared a comprehensive summary, organized on a country-by-country basis, of government action in this regard (document WHO/MCH/NUT/90.1). The present paper complements this summary, and increases its usefulness, by focusing on the Code's individual articles and describing how each has been given expression through national legislation or other measures. Their adoption is one aspect of the wider efforts Member States are making to address the health and nutritional problems of infants and young children, and the related aspects of the health and social status of women and families.

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INTRODUCTION

- 1. The adoption of the International Code of Marketing of Breast-milk Substitutes¹ on 21 May 1981 marked the culmination of several years of concern within the World Health Organization, and among its Member States and various groups and individuals, about the detrimental effects on infant and child health of the decline of breast-feeding in favour of artificial feeding practices.² Its genesis lay in the recognition that the marketing and distribution of breast-milk substitutes was one of a number of important factors that influence infant-feeding practices, and therefore infant health.³
- 2. The International Code was adopted by the World Health Assembly in the form of a recommendation, under Article 23 of WHO's Constitution. The intention was that Member States take action to give effect to its principles and aim by adopting legislation or other suitable measures that are appropriate to their social and legislative framework. The aim of the International Code is "to contribute to the provision of safe and adequate nutrition for infants, by the protection and promotion of breast-feeding, and by ensuring the proper use of breast-milk substitutes, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution". In furtherance of this aim, the International Code sets out detailed provisions on the appropriate dissemination of information and provision of education on infant feeding; on the marketing of breast-milk substitutes and related products to the general public and mothers; on measures to be taken in health care systems, and with regard to health workers and employees of manufacturers and distributors; on the labelling and quality of breast-milk substitutes and related products; and on the implementation and monitoring of the Code's provisions.
- 3. The ten years since the adoption of the International Code have seen Member States respond in varying degree and manner. WHO has prepared a comprehensive summary, organized on a country-by-country basis, of government action in line with, or otherwise giving effect to, the International Code (hereafter referred to as the "Synthesis Document").⁵ The present paper complements this summary, and increases its usefulness, by

¹ World Health Organization. *International Code of Marketing of Breast-milk Substitutes* (hereafter referred to as the "International Code"). Document WHA34/1981/REC/1, Annex 3, Geneva, 1981; and Annex 1 to the present document.

² For an overview of the events leading up to the adoption of the Code, see Shubber, S. "The International Code of Marketing of Breast-milk Substitutes". *International Digest of Health Legislation* (hereafter *IDHL*) 36(4): 879-880 (1985).

³ Sec, in particular, the preambular paragraphs of the resolutions of the Thirty-third and Thirty-fourth World Health Assemblies, which led to the development and adoption of the International Code, respectively resolution WHA33.32 (1980) and resolution WHA34.22 (1981), and the preamble to the Code itself.

⁴ International Code, op. cit., Article 1.

⁵ The International Code of Marketing of Breast-milk Substitutes: synthesis of reports on action taken (1981-1990) (document WHO/MCH/NUT/90.1; available in English, French and Spanish).

focusing on the Code's individual articles and describing how each has been given expression through national legislation and other measures.

4. At the outset, several points should be noted. First, the present text discusses general trends in the measures taken in each of the six WHO regions.¹ Specific national provisions or policies are described only in some cases, for purposes of illustration.² Second, since the information presented is based largely on reporting by Member States, it varies in detail and scope. Third, the International Code urges Member States "to translate [it] into legislation, regulations or other suitable measures" (emphasis added).³ Legislation or regulations are thus neither the only measures, nor necessarily the best measures, for achieving the aim of the International Code in every country. Which measures are most effective, practical and feasible depends on their context and mode of application. This paper should therefore not be seen as evaluating the success or failure of Member States in implementing the aim of the International Code on the basis of the form of the measures they have taken. Such an analysis would require the assessment of different factors, and indeed, is the subject of a separate study undertaken by a number of Member States themselves.⁴ Finally, the adoption of national legislation and other measures to give effect to the International Code is but one aspect of the wider efforts Member States are making to address the health and nutritional problems of infants and young children, and the related aspects of the health and social status of women and families.

ACTION GIVING EFFECT TO THE PRINCIPLES AND AIM OF THE INTERNATIONAL CODE

5. Articles 1-3 of the International Code are entitled, respectively, "Aim of the Code", "Scope of the Code" and "Definitions". These provisions, which serve as a framework within which the other provisions operate, are not addressed directly within this analysis.

Article 4 - Information and education

- 6. This provision urges governments to "ensure that objective and consistent information is provided on infant and young child feeding" to the public and to health workers. It sets out detailed recommendations as to the content and distribution of informational and educational materials, and discourages donations by manufacturers or distributors except on the basis of a written government request.
- 7. By and large, national governments have vested health authorities with the responsibility for implementing this provision. In some regions, however, private and volunteer interest groups play an active promotional role. Implementation is generally achieved through policy directives, guidelines or campaigns rather than legislation. Various modes of communication, including the mass media, video, printed materials, and educational curricula are used to disseminate information. In addition, several countries have conducted studies to gather objective information on current feeding practices and public attitudes. A few countries have devised detailed guidelines or strategies for public education.

¹ The six WHO regions are the African Region, the Region of the Americas, the South-East Asia Region, the European Region, the Eastern Mediterranean Region and the Western Pacific Region. See Annex 2.

² For a more detailed account of legislation and other measures, the reader may wish to refer to the numerous texts reproduced in the /DHL, cited in the present document where applicable; and to the summary within the Synthesis Document of individual reports of Member States submitted to the World Health Assembly in even years since the adoption of the Code, respectively documents WHA35/1982/REC/1, Annex 5; A36/7; WHA37/1984/REC/1, Annex 5, part II; WHA39/1986/REC/1, Annex 6, part 1; EB81/1988/REC/1, Annex 10; WHA43/1990/REC/1, Annex 1; and WHA45/1992/REC/1, Annex 9.

³ International Code, op. cit., Article 11.

⁴ In 1990-1991 the governments of Brazil, Egypt, Finland, Guatemala, the Islamic Republic of Iran, Kenya, the Netherlands, Nigeria, Papua New Guinea, the Philippines, Poland, Sweden, the United Kingdom of Great Britain and Northern Ireland, and Yemen undertook an in-depth review and evaluation of their own experiences in giving effect to the International Code. A summary of the results of this exercise served as the basis for discussion by representatives of the countries concerned at a technical meeting on the subject held in The Hague (30 September-2 October 1991). The report of the meeting, which includes the background document, is available in document WHO/MCH/NUT/91.2.

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- 8. In the African Region, the most prevalent means of implementing this provision has been through information circulars to health educators and health workers requesting that they ensure adequate information is disseminated to mothers. Only six of 34 countries for which information is available have instituted measures to promote the aim of the International Code through public information and education.\(^1\) Three of these have done so through radio and television campaigns,\(^2\) and in one country five-minute film messages on breast-feeding have been prepared for screening in public cinemas.\(^3\)
- 9. In the Region of the Americas five countries have established structured programmes for public education, sometimes in collaboration with national breast-feeding promotion associations, such as La Leche League.⁴ These programmes have variously involved workshops in health centres, schools and hospitals, mass media campaigns, and the expansion of health educational curricula. One country has incorporated into its legislation a set of standards for breast-feeding promotion.⁵ The standards set out a strategy, which includes defining and researching the groups targeted so that socioeconomic and cultural factors are taken into account, and designing a simple and clear message, which seeks to awaken interest, encourage acceptance and facilitate active participation in breast-feeding.
- 10. Little detail is available on specific measures taken in the area of information and education by countries in the South-East Asia Region. One country, however, has made an active effort to discourage the notion that bottle-feeding is a status symbol. This campaign also adopted the slogan "from breast to cup and spoon". In another country, money donated by manufacturers for educational purposes is channelled through the national medical association, to be disbursed as the association sees fit.
- 11. Five countries in the European Region report the provision of consistent and objective information through hospitals, clinics, the mass media and the scientific literature. A more common practice is to distribute circulars or booklets, usually to health workers, who are in turn encouraged to teach mothers appropriate feeding techniques (discussed under Article 7, below). One country has placed restrictions on contributions by manufacturers for meetings and the distribution of prizes, bursaries and study travel. The European Commission Directive on infant formulae and follow-on formulae (91/321/EEC) (hereafter referred

¹ Synthesis Document, op. cit., at paras. 16 (Burkina Faso), 26 (Kenya), 28 (Liberia), 38 (Sierra Leone) and 42 (United Republic of Tanzania). South Africa also has such measures.

² Ibid. at paras. 28 (Liberia), 38 (Sierra Leone) and 42 (United Republic of Tanzania).

³ Ibid. at para. 16 (Burkina Faso),

⁴ Ibid. at paras. 52 (Bolivia), 53 (Canada), and 74 (Saint Kitts and Nevis). Paraguay (ibid. at para. 72) also recently reported a National Programme for the Promotion of Breast-Feeding to be implemented in 1991-1992. Peru established its programme through legislation, prior to the adoption of the International Code: Ministerial Resolution No. 0041-80-SA/DS of 1 April 1980 [hereafter "Peru, Resolution No. 0041-80-SA/DS"], chap. II, Secs. 8-11. chap. III, Sec. 12. See also Peru, Legislative Decree No. 346 of 6 July 1985 promulgating the National Population Policy Law [hereafter, "Peru, Decree No. 346"], Sec. 32. For IDHL citation of this and all subsequent legislation referred to in this paper, see Annex 3.

⁵ Peru, Supreme Decree No. 20-82-SA of 10 September 1982 prescribing regulations on standards for infant feeding [hereafter "Peru, Supreme Decree No. 20-82-SA"], Chap. V.

⁶ Synthesis Document, op. cit., at para. 93 (Maldives).

⁷ Ibid. at para. 96 (Sri Lanka),

⁸ Ibid. at paras. 101 (Bulgaria), 102 (Czechoslovakia), 107 (France), 125 (Portugal: see Portugal, Code of Ethics for the Marketing of Breast-milk Substitutes, Feeding-bottles and Teats [hereafter "Portugal, Code"]) and 133 (former USSR).

[°] Ibid. at para. 119 (Malta).

¹⁰ Spain, Crown Decree No. 1424 of 18 June 1982 amending item 15 of Section 20 of Crown Decree No. 2685/1976 of 16 October 1976 approving Technical Health Regulations on the preparation and marketing of and trade in food preparations for special dictary uses [hereafter "Spain Crown Decree No. 1424"], item 15.1.5.

to as the "EEC Directive")1 requires that objective and consistent information be provided on infant and young child feeding for use by families and others concerned.2

- 12. Four of the seven countries that report implementing Article 4 in the Eastern Mediterranean Region have delegated the task to the Minister of Health, who relies on the mass media to conduct public education campaigns. One country has undertaken several studies on infant and child nutrition, with the purpose of raising awareness of the importance of breast-feeding among the general public and mothers, and is also setting up centres to teach mothers to prepare infant foods and encourage breast-feeding rather than the use of breast-milk substitutes.³
- 13. Countries in the Western Pacific Region have been particularly active in implementing Article 4. Nearly two-thirds of countries report the promotion of breast-feeding through such means as the mass media, video and other audiovisual aids, health education in school curricula, workshops, posters, and guidelines and booklets distributed directly to the public. In some cases, special committees have been established to conduct a promotional campaign.⁴ One campaign adopted the accessible theme that if breast-milk substitutes must be used, they should be fed with a cup and spoon.⁵ Another programme, which provides counselling and prenatal classes, has instituted an innovative promotional scheme in which breast-fed infants of mothers in the programme receive T-shirts that read "Mommy loves me I'm breast-fed".⁶

Article 5 - The general public and mothers

- 14. This provision discourages advertising and other forms of promotion to the general public. It discourages, in particular, the distribution of manufacturers' samples or gifts to pregnant women, mothers or their families, special sales inducements such as discount pricing, and direct contact between marketing personnel and potential consumers among the general public.
- 15. This Article has been implemented through such measures as legal prohibitions, non-legislative bans, voluntary suspensions, government requests, and the screening of the content of advertisements. Where measures do exist, their scope is typically limited to advertising in the mass media. Less commonly, measures extend to special sales promotions, the donation of samples, and the other items covered by Article 5.
- 16. Almost half the countries in the African Region report implementation of this provision in some form, for the most part by non-legislative government bans on advertising. Three countries have adopted policies or entered into voluntary agreements that essentially reflect the International Code.⁷ Another requires that promotional materials first obtain clearance from the Government.⁸
- 17. Countries in the Region of the Americas have been most active in implementing Article 5, with 16 of 35 countries reporting some type of action. Six countries have enacted legislation with effects including the virtual

¹ Official Journal of the European Communities, No. L 175, 4 July 1991, pp. 35-49. The directive deals solely with the internal Community market; a separate instrument is being drawn up concerning exports to countries outside the Community (see under Articles 9 and 10). The Member States of the European Community are Belgium, Denmark, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, and the United Kingdom of Great Britain and Northern Ireland.

² Ibid., Article 9.

³ Synthesis Document, op. cit., at para. 160 (Qatar).

⁴ Ibid. at paras. 184 (Guam), 198 (Philippines) and 201 (Singapore).

⁵ Ibid. at para. 202 (Solomon Islands).

⁶ Ibid. at para. 184 (Guam).

⁷ Ibid. at para. 15 (Botswana); Kenya Code for Marketing of Breast Milk Substitutes [hereafter "Kenya Code"], Article 10; Nigeria, Code of Ethics and Professional Standards for Marketing of Breastmilk Substitutes [hereafter "Nigeria, Code"], Articles 4, 5 and 7.

⁸ Ibid. at para. 43 (Zairc).

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adoption of the provisions of the International Code,¹ the regulated allowance of advertising,² and a prohibition only on donations of samples.³ Other countries report non-legislative measures, which ban,⁴ partially ban,⁵ or discourage⁶ advertising. Three countries rely on voluntary agreements by manufacturers and advertisers to refrain from promoting products within the scope of the International Code.⁷

- 18. In the South-East Asia Region, three countries have legislation prohibiting the advertising and promotion of breast-milk substitutes to the public, in one case modelled on the International Code.⁸ A non-legislative ban on advertising and distributing samples is also in place in one country.⁹ A fourth country has passed a resolution to adopt legislation to implement Article 5.¹⁰
- 19. No country in the European Region reports legislation prohibiting the marketing of breast-milk substitutes to the general public and mothers. However, in two countries, legislation encourages "responsibility" on the part of manufacturers, for example, by stipulating that infant foods "must not be offered for sale in such a way as to influence the feeding of the child and have an adverse effect on the child's health". In addition, nine countries report voluntary agreements or policies to prohibit advertising. In another country, the sole manufacturer of breast-milk substitutes, in cooperation with health workers, has prepared and distributed a booklet on proper feeding practices. The EEC Directive permits advertising of infant formula in

¹ Peru, Supreme Decree No. 20-82-SA of 10 September 1982 prescribing regulations on standards for infant feeding. Part II. Standards for the marketing of breast-milk substitutes and complementary infant foods [hereafter "Peru, Supreme Decree No. 20-82-SA Part II"], Standard IV, Secs. 17-18; Venezuela, Resolution No. 5 of 16 July 1982 of the Ministry of Health and Social Welfare on the requirements to be fulfilled by infant formulas as regards the relevant legal provisions in force and those to be issued in future by the Ministry [hereafter "Venezuela, Resolution No. 5"], Secs. 3, 7 and 8.

² Colombia, Decree No. 1220 of 23 May 1980 regulating the promotion, labelling, and packaging of breast-milk substitutes and supplements [hereafter "Colombia, Decree No. 1220"], Secs. 4 and 5 (this legislation was in place before the adoption of the International Code); Ecuador, Decree No. 2215 of 3 November 1983 promulgating Regulations on the marketing of formulas for infants and young children under one year of age [hereafter "Ecuador, Decree No. 2215"], Chap. V; Nicaragua, Decree No. 912 of 15 December 1981 promulgating the Law for the promotion of breast-feeding [hereafter "Nicaragua, Decree No. 912"], Sec. 3.

³ Guatemala, Decree-Law No. 66-83 of 6 June 1983 on the marketing of breast-milk substitutes [hereafter "Guatemala, Decree-Law No. 66-83"], Sec. 12 (provisions on donation of samples).

⁴ Synthesis Document, op. cit., at paras. 58 (Cuba), and 71 (Panama).

⁵ Ibid. at para. 85 (Uruguay).

⁶ Ibid. at para. 74 (Saint Kitts & Nevis).

⁷ Ibid. at paras. 53 (Canada) and 79 (United States of America). See also Trinidad and Tobago, The International Code of Marketing of Breast-milk Substitutes as applied to Trinidad and Tobago. Dated 1 February 1982 [hereafter "Trinidad and Tobago, Code"], Article 5.

⁸ Bangladesh, The Breast-Milk Substitutes (Regulation of Marketing) Ordinance, 1984 [hereafter "Bangladesh, Ordinance, 1984"], Secs. 3-4; Indonesia, Regulations No. 240/Men.Kes./Per/V/85 of 1 May 1985 of the Minister of Health of the Republic of Indonesia on breast-milk substitutes [hereafter "Indonesia, Regulations No. 240"], Sec. 10; Sri Lanka, Direction No. 44 under Section 6(1)(c) of the Consumer Protection Act, No. 1 of 1979. Dated 3 February 1983 [hereafter Sri Lanka, Direction No. 44"], Secs. 2-3 (modelled after the International Code). Note also that Thailand reports having a national code, but its text has not been made available.

⁹ Synthesis Document, op. cit., at para. 95 (Nepal).

¹⁰ India, Indian National Code for Protection and Promotion of Breast-feeding. Dated 19 December 1983 [hereafter "India, Code"], Article 5.

¹¹ Norway, Regulations No. 1251 of 8 July 1983 on the production and offer for sale, etc. of foods for infants and young children [hereafter "Norway, Regulations No. 1251"], Sec. 3. See also, Sweden, Regulations No. 21 of 2 May 1983 of the National Board of Health and Welfare for health care and nursing personnel, etc. on the implementation of the International Code of Marketing of Breast-milk Substitutes [hereafter "Sweden, Regulations No. 21"], under the rubric "Aim and Scope".

¹² Synthesis Document, op. cit., at paras. 101 (Bulgaria), 105-106 (Finland), 121-122 (Netherlands), 125 (Portugal), 131 (Switzerland), 133 (former USSR), 134-137 (United Kingdom) and 138-139 (Yugoslavia). Greece also has reported such a policy.

¹³ Ibid. at para, 139 (Yugoslavia),

"publications specializing in baby care". However, it also provides that "Member States may further restrict or prohibit such advertising".1

- 20. Two countries in the Eastern Mediterranean Region have adopted Article 5 as part of their legislation.² Six other countries prohibit advertising as a matter of public policy.³
- 21. There has been a widespread response to Article 5 in the Western Pacific Region by way of voluntary agreements or government policy initiatives. However, only about half of the countries with such agreements prohibit both advertising and samples, while the others prohibit only advertising or samples. Several countries have "vetting committees" made up of representatives of the government and other interested groups, which must approve all advertising before it can be used. One country has adopted Article 5 as legislation.

Article 6 - Health care systems

- 22. Article 6 sets out recommendations for public and private institutions, including health workers in private practice, involved in maternal and child health care. This provision vests such institutions with the responsibility to ensure that the appropriate information is disseminated to health workers and patients on the premises. This includes, not surprisingly, a prohibition on the marketing or display of products within the scope of the International Code. It also includes guidelines relating to employees, such as the requirement that the use of infant formulas be demonstrated only by health or community workers (accompanied by a warning as to the hazards of improper use), and a prohibition on the employment of persons paid by manufacturers or distributors. Finally, Article 6 sets out limitations on the use to be made of supplies and equipment donated by manufacturers or distributors: for example, these items are not to be accepted if designed to induce sales, nor if they bear the name of a product falling within the scope of the International Code.
- 23. The most prevalent response to this provision is a prohibition of the promotion or display of infant formulas in health institutions. Somewhat less common are prohibitions of donations of samples and equipment, employment restrictions, institution-run educational programmes for mothers and health workers, and policies to encourage "rooming-in" (accommodating mothers and infants in the same room). Other techniques devised for discouraging resort to breast-milk substitutes, which do not appear in the International Code, include making substitutes available only by prescription, and setting up breast-milk donor banks.
- 24. In the African Region, three countries have responded to Article 6 through voluntary agreements between government and the infant-food industry.9 Other countries have less formal policies to prohibit

¹ EEC Directive, op. cit., Article 8.

² Lebanon, Decree-Law No. 110 of 16 September 1983 on the marketing of breast-milk substitutes [hereafter "Lebanon, Decree-Law No. 110"]; Tunisia, Law No. 83-24 of 4 March 1983 on the quality control, marketing, and information concerning the use of breast-milk substitutes and related products [hereafter "Tunisia, Law No. 83-24"], Secs. 6-9.

³ Synthesis Document, op. cit., at paras. 152 (Egypt), 155 (Jordan), 156 (Kuwait), 161 (Saudi Arabia), 168 (United Arab Emirates) and 169 (Yemen).

⁴ Ibid. at paras. 181 (Cook Islands), 183 (French Polyncsia), 187 (Kiribati), 189 (Macao), 193-194 (New Zcaland) and 195 (Republic of Korea).

⁵ Ibid. at paras. 172 (American Samoa), 178 (Brunei Darussalam), 185 (Hong Kong), 186 (Japan), 190-191 (Malaysia) and 204-205 (Vanuatu).

⁶ Ibid. at paras. 200 (Samoa) and 203 (Tonga).

⁷ Ibid. at paras. 190-191 (Malaysia), 201 (Singapore) and 203 (Tonga). Sec. 12 of the Philippines Code also prescribes advance approval.

⁸ Philippines, Executive Order No. 51 adopting a National Code of Marketing of Breastmilk Substitutes, Breastmilk Supplements and Related Products, penalizing violations thereof, and for other purposes. Dated 20 October 1986 [hereafter "Philippines, Code"], Sec. 6.

⁹ Kenya Code, Articles 11.1-11.2; Nigeria, Code, Article 3; South Africa, Code of Ethics for Infant Food Manufacturers [hereafter "South Africa Code"], 1977, Secs. 9-10 (this Code was drafted prior to the adoption of the International Code).

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promotion by manufacturers and distributors of substitutes, or the donation of samples to health institutions.¹ Only one country has established a programme for educating health workers and instructors in health institutions on the principles of the International Code.² One country also restricts the availability of breast-milk substitutes to a prescription basis.³

- 25. Nearly half the countries in the Region of the Americas have responded to Article 6, largely by way of public policy rather than legislation. In general, the policies respond by restricting promotion,⁴ acceptance of donations,⁵ or both.⁶ Some address other parts of Article 6; one country has adopted it fully in the form of a voluntary agreement,⁷ while others provide education within health institutions⁸ or prohibit the employment of persons paid by manufacturers.⁹ Four countries have passed legislation, in two cases entirely adopting the International Code.¹⁰ Finally, health institutions in various countries practice rooming-in¹¹ or human milk-banking,¹² or require prescriptions for distribution of the products covered by the International Code.¹³
- 26. In the South-East Asia Region, one country has passed legislation which adopts Article 6 of the International Code. Another country has resolved to adopt legislation implementing the provision. Other countries' policy measures include creating mother's milk donor units in maternity hospitals and making breast-milk substitutes available on prescription only, and a prohibition against the display or distribution of breast-milk substitutes and related products in health institutions.
- 27. Two countries in the European Region have adopted Article 6 via national codes, one in the form of legislation, and the other as a voluntary agreement by manufacturers, traders and distributors of infant foods and related products. Approximately one-third of the countries in the Region have implemented policy

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¹ Synthesis Document, op. cit., at paras. 15 (Botswana), 21 (Ethiopia), 33 (Mozambique), and 39 (Swaziland).

² Ibid. at para. 42 (United Republic of Tanzania).

³ Ibid. at para. 25 (Guinca).

⁴ Ibid. at paras. 49 (Belize), 59 (Dominica), 63 (El Salvador), 64 (Grenada) and 69 (Montserrat).

⁵ Ibid. at paras. 53-54 (Canada), 56 (Colombia), 67 (Honduras, public institutions only), 71 (Panama) and 74 (Saint Kitts and Nevis).

⁶ Ibid. at paras. 51 (British Virgin Islands) and 85 (Uruguay).

⁷ Trinidad and Tobago, Code, Article 6.

⁸ Synthesis Document, op. cit., at paras. 63 (El Salvador), 74 (Saint Kitts and Nevis) and 75 (Saint Lucia).

⁹ Mexico Regulations of 4 January 1988 for the implementation of the General Law on health in the field of the health control of activities, establishments, products and services [hereafter "Mexico, Regulations of 4 January 1988"], Sec. 731.

¹⁰ Ecuador, Decree No. 2215, Chap. V, Secs. 26-29 (deals with promotion and donations only); Guatemala Decree-Law No. 66-83, Secs. 4, 6 and 12; Mexico, Regulations of 4 January 1988, Sec. 731; and Peru, Supreme Decree No. 20-82-SA, Standard XI, and Part II, Standard V.

¹¹ Synthesis Document, op. cit., at paras. 51 (British Virgin Islands), 61 (Dominican Republic), 64 (Grenada), 69