# HEALTH ACTION INTERNATIONAL ASIA-PACIFIC *at 40*

1981 - 2021

*A chronicle of health heroes, historic events and developments, challenges and victories*

## Volume 2
## Annexes

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Health Action International Asia Pacific

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# ANNEXES

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# Declaration of Alma-Ata

## International Conference on Primary Health Care, Alma-Ata, USSR, 6-12 September 1978

The International Conference on Primary Health Care, meeting in Alma-Ata this twelfth day of September in the year Nineteen hundred and seventy-eight, expressing the need for urgent action by all governments, all health and development workers, and the world community to protect and promote the health of all the people of the world, hereby makes the following

**Declaration:**

**I**
The Conference strongly reaffirms that health, which is a state of complete physical, mental and social wellbeing, and not merely the absence of disease or infirmity, is a fundamental human right and that the attainment of the highest possible level of health is a most important world-wide social goal whose realization requires the action of many other social and economic sectors in addition to the health sector.

**II**
The existing gross inequality in the health status of the people particularly between developed and developing countries as well as within countries is politically, socially and economically unacceptable and is, therefore, of common concern to all countries.

**III**
Economic and social development, based on a New International Economic Order, is of basic importance to the fullest attainment of health for all and to the reduction of the gap between the health status of the developing and developed countries. The promotion and protection of the health of the people is essential to sustained economic and social development and contributes to a better quality of life and to world peace.

**IV**
The people have the right and duty to participate individually and collectively in the planning and implementation of their health care.

**V**
Governments have a responsibility for the health of their people which can be fulfilled only by the provision of adequate health and social measures. A main social target of governments, international organizations and the whole world community in the coming decades should be the attainment by all peoples of the world by the year 2000 of a level of health that will permit them to lead a socially and economically productive life. Primary health care is the key to attaining this target as part of development in the spirit of social justice.

**VI**
Primary health care is essential health care based on practical, scientifically sound and socially acceptable methods and technology made universally accessible to individuals and families in the community through their full participation and at a cost that the community and country can afford to maintain at every stage of their development in the spirit of self-reliance and self-determination. It forms an integral part both of the country's health system, of which it is the central function and main focus, and of the overall social and economic development of the community. It is the first level of contact of individuals, the family and

community with the national health system bringing health care as close as possible to where people live and work, and constitutes the first element of a continuing health care process.

**VII**
Primary health care:

1. reflects and evolves from the economic conditions and sociocultural and political characteristics of the country and its communities and is based on the application of the relevant results of social, biomedical and health services research and public health experience;

2. addresses the main health problems in the community, providing promotive, preventive, curative and rehabilitative services accordingly;

3. includes at least: education concerning prevailing health problems and the methods of preventing and controlling them; promotion of food supply and proper nutrition; an adequate supply of safe water and basic sanitation; maternal and child health care, including family planning; immunization against the major infectious diseases; prevention and control of locally endemic diseases; appropriate treatment of common diseases and injuries; and provision of essential drugs;

4. involves, in addition to the health sector, all related sectors and aspects of national and community development, in particular agriculture, animal husbandry, food, industry, education, housing, public works, communications and other sectors; and demands the coordinated efforts of all those sectors;

5. requires and promotes maximum community and individual self-reliance and participation in the planning, organization, operation and control of primary health care, making fullest use of local, national and other available resources; and to this end develops through appropriate education the ability of communities to participate;

6. should be sustained by integrated, functional and mutually supportive referral systems, leading to the progressive improvement of comprehensive health care for all, and giving priority to those most in need;

7. relies, at local and referral levels, on health workers, including physicians, nurses, midwives, auxiliaries and community workers as applicable, as well as traditional practitioners as needed, suitably trained socially and technically to work as a health team and to respond to the expressed health needs of the community.

**VIII**
All governments should formulate national policies, strategies and plans of action to launch and sustain primary health care as part of a comprehensive national health system and in coordination with other sectors. To this end, it will be necessary to exercise political will, to mobilize the country's resources and to use available external resources rationally.

**IX**
All countries should cooperate in a spirit of partnership and service to ensure primary health care for all people since the attainment of health by people in any one country directly concerns and benefits every other country. In this context the joint WHO/UNICEF report on

primary health care constitutes a solid basis for the further development and operation of primary health care throughout the world.

**X**

An acceptable level of health for all the people of the world by the year 2000 can be attained through a fuller and better use of the world's resources, a considerable part of which is now spent on armaments and military conflicts. A genuine policy of independence, peace, détente and disarmament could and should release additional resources that could well be devoted to peaceful aims and in particular to the acceleration of social and economic development of which primary health care, as an essential part, should be allotted its proper share.

The International Conference on Primary Health Care calls for urgent and effective national and international action to develop and implement primary health care throughout the world and particularly in developing countries in a spirit of technical cooperation and in keeping with a New International Economic Order. It urges governments, WHO and UNICEF, and other international organizations, as well as multilateral and bilateral agencies, non-governmental organizations, funding agencies, all health workers and the whole world community to support national and international commitment to primary health care and to channel increased technical and financial support to it, particularly in developing countries. The Conference calls on all the aforementioned to collaborate in introducing, developing and maintaining primary health care in accordance with the spirit and content of this Declaration.

# *International Code of Marketing of Breast-milk Substitutes*

**World Health Organization**
**Geneva**
**1981**

# Introduction

THE WORLD HEALTH ORGANIZATION (WHO) and the United Nations Children's Fund (UNICEF) have for many years emphasized the importance of maintaining the practice of breast-feeding—and of reviving the practice where it is in decline—as a way to improve the health and nutrition of infants and young children. Efforts to promote breast-feeding and to overcome problems that might discourage it are a part of the overall nutrition and maternal and child health programmes of both organizations and are a key element of primary health care as a means of achieving health for all by the year 2000.

A variety of factors influence the prevalence and duration of breast-feeding. The Twenty-seventh World Health Assembly, in 1974, noted the general decline in breast-feeding in many parts of the world, related to sociocultural and other factors including the promotion of manufactured breast-milk substitutes, and urged "Member countries to review sales promotion activities on baby foods to introduce appropriate remedial measures, including advertisement codes and legislation where necessary".[1]

The issue was taken up again by the Thirty-first World Health Assembly in May 1978. Among its recommendations were that Member States should give priority to preventing malnutrition in infants and young children by, *inter alia*, supporting and promoting breast-feeding, taking legislative and social action to facilitate breast-feeding by working mothers, and "regulating inappropriate sales promotion of infant foods that can be used to replace breast milk".[2]

Interest in the problems connected with infant and young child feeding and emphasis on the importance of breast-feeding in helping to overcome them have, of course, extended well beyond WHO and UNICEF. Governments, nongovernmental organizations, professional associations, scientists, and manufacturers of infant foods have also called for action to be taken on a world scale as one step towards improving the health of infants and young children.

In the latter part of 1978,WHO and UNICEF announced their intention of organizing jointly a meeting on infant and young child feeding, within their existing programmes, to try to make the most effective use of this groundswell of opinion. After thorough consideration on how to ensure the fullest participation, the meeting was convened in Geneva from 9 to 12 October 1979 and was attended by some 150 representatives of governments, organizations of the United Nations system and other intergovernmental bodies, nongovernmental organizations, the infant-food industry, and experts in related disciplines. The discussions were organized on five main themes: the encouragement and support of breast-feeding; the promotion and support of appropriate and timely complementary feeding (weaning) practices with the use of

[1] Resolution WHA27.43 (Handbook of Resolutions and Decisions of the World Health Assembly and the Executive Board, Volume II, 4th ed., Geneva, 1981, p.58).

[2] Resolution WHA31.47 (Handbook of Resolutions and Decisions…. Volume II, 4th ed., p.62).

local food resources; the strengthening of education, training and information on infant and young child feeding; the promotion of the health and social status of women in relation to infant and young child health and feeding; and the appropriate marketing and distribution of breast-milk substitutes.

The Thirty-third World Health Assembly, in May 1980, endorsed in their entirety the statement and recommendations agreed by consensus at this joint WHO/UNICEF meeting and made particular mention of the recommendation that "there should be an international code of marketing of infant formula and other products used as breast-milk substitutes", requesting the Director-General to prepare such a code "in close consultation with Member States and with all other parties concerned".[3]

To develop an international code of marketing of breast-milk substitutes in accordance with the Health Assembly's request, numerous and lengthy consultations were held with all interested parties. Member States of the World Health Organization and groups and individuals who had been represented at the October 1979 meeting were requested to comment on successive drafts of the code, and further meetings were held in February and March and again in August and September in 1980. WHO and UNICEF placed themselves at the disposal of all groups in an effort to foster a continuing dialogue on both the form and the content of the draft code and to maintain as a basic minimum content those points which had been agreed upon by consensus at the meeting in October 1979.

In January 1981, the Executive Board of the World Health Organization at its sixty-seventh session, considered the fourth draft of the code, endorsed it, and unanimously recommended[4] to the Thirty-fourth World Health Assembly the text of a resolution by which it would adopt the code in the form of a recommendation rather than as a regulation.[5] In May 1981, the Health Assembly debated the issue after it had been introduced by the representative of the Executive Board.[6] It adopted the code, as proposed, on 21 May by 118 votes in favour to 1 against, with 3 abstentions.[7]

[3] See resolution WHA33.32, reproduced in Annex 2.

[4] See resolution EB67.R12, reproduced in Annex 1.

[5] The legal implications of the adoption of the code as a recommendation or as a regulation are discussed in a report on the code by the Director-General of WHO to the Thirty-fourth World Health Assembly; this report is contained in document WHA34/1981/REC/1, Annex 3.

[6] See Annex 3 for excerpts from the introductory statement by the representative of the Executive Board.

[7] See Annex 1 for the text of resolution WHA34.22, by which the code was adopted. For the verbatim record of the discussion at the fifteenth plenary meeting, on 21 May 1981, see document WHA34/1981/REC/2.

The Member States of the World Health Organization:

Affirming the right of every child and every pregnant and lactating woman to be adequately nourished, as a means of attaining and maintaining health;

Recognizing that infant malnutrition is part of the wider problems of lack of education, poverty, and social injustice;

Recognizing that the health of infants and young children cannot be isolated from the health and nutrition of women, their socioeconomic status and their roles as mothers;

Conscious that breast-feeding is an unequalled way of providing ideal food for the healthy growth and development of infants; that it forms a unique biological and emotional basis for the health of both mother and child; that the anti-infective properties of breast-milk help to protect infants against disease; and that there is an important relationship between breast-feeding and child-spacing;

Recognizing that the encouragement and protection of breast-feeding is an important part of the health, nutrition and other social measures required to promote healthy growth and development of infants and young children; and that breast-feeding is an important aspect of primary health care;

Considering that, when mothers do not breast-feed, or only do so partially, there is a legitimate market for infant formula and for suitable ingredients from which to prepare it; that all these products should accordingly be made accessible to those who need them through commercial or non-commercial distribution systems; and that they should not be marketed or distributed in ways that may interfere with the protection and promotion of breast-feeding;

Recognizing further that inappropriate feeding practices lead to infant malnutrition, morbidity and mortality in all countries, and that improper practices in the marketing of breast-milk substitutes and related products can contribute to these major public health problems;

Convinced that it is important for infants to receive appropriate complementary foods, usually when they reach four to six months of age, and that every effort should be made to use locally available foods; and convinced, nevertheless, that such complementary foods should not be used as breast-milk substitutes;

Appreciating that there are a number of social and economic factors affecting breast-feeding, and that, accordingly, governments should develop social support systems to protect, facilitate and encourage it, and that they should create an environment that fosters breast-feeding, provides appropriate family and community support, and protects mothers from factors that inhibit breast-feeding;

Affirming that health care systems, and the health professionals and other health workers serving in them, have an essential role to play in guiding infant

feeding practices, encouraging and facilitating breast-feeding, and providing objective and consistent advice to mothers and families about the superior value of breast-feeding, or, where needed, on the proper use of infant formula, whether manufactured industrially or home-prepared;

Affirming further that educational systems and other social services should be involved in the protection and promotion of breastfeeding, and in the appropriate use of complementary foods;

Aware that families, communities, women's organizations and other nongovernmental organizations have a special role to play in the protection and promotion of breast-feeding and in ensuring the support needed by pregnant women and mothers of infants and young children, whether breast-feeding or not;

Affirming the need for governments, organizations of the United Nations system, nongovernmental organizations, experts in various related disciplines, consumer groups and industry to cooperate in activities aimed at the improvement of maternal, infant and young child health and nutrition;

Recognizing that governments should undertake a variety of health, nutrition and other social measures to promote healthy growth and development of infants and young children, and that this Code concerns only one aspect of these measures;

Considering that manufacturers and distributors of breast-milk substitutes have an important and constructive role to play in relation to infant feeding, and in the promotion of the aim of this Code and its proper implementation;

Affirming that governments are called upon to take action appropriate to their social and legislative framework and their overall development objectives to give effect to the principles and aim of this Code, including the enactment of legislation, regulations or other suitable measures;

Believing that, in the light of the foregoing considerations, and in view of the vulnerability of infants in the early months of life and the risks involved in inappropriate feeding practices, including the unnecessary and improper use of breast-milk substitutes, the marketing of breast-milk substitutes requires special treatment, which makes usual marketing practices unsuitable for these products;

THEREFORE:

The Member States hereby agree the following articles which are recommended as a basis for action.

*Article 1. Aim of the Code*

The aim of this 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.

*Article 2. Scope of the Code*

The Code applies to the marketing, and practices related thereto, of the following products: breast-milk substitutes, including infant formula; other milk products, foods and beverages, including bottlefed complementary foods, when marketed or otherwise represented to be suitable, with or without modification, for use as a partial or total replacement of breast milk; feeding bottles and teasts. It also applies to their quality and availability, and to information concerning their use.

*Article 3. Definitions*

For the purposes of this Code:

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| "Breast-milk substitute" | means | any food being marketed or otherwise presented as a partial or total replacement for breast milk, whether or not suitable for that purpose. |
| "Complementary food" | means | any food whether manufactured or locally prepared, suitable as a complement to breast milk or to infant formula, when either become insufficient to satisfy the nutritional requirements of the infant. Such food is also commonly called "weaning food" or breast-milk supplement". |
| "Container" | means | any form of packaging of products for sale as a normal retail unit, including wrappers. |
| "Distributor" | means | a person, corporation or any other entity in the public or private sector engaged in the business (whether directly or indirectly) of marketing at the wholesale or retail level a product within the scope of this Code. A "primary distributor" is a manufacturer's sales agent, representative, national distributor or broker. |

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| "Health care system" | means | governmental, nongovernmental or private institutions or organizations engaged, directly or indirectly, in health care for mothers, infants and pregnant women; and nurseries or child-care institutions. It also includes health workers in private practice. For the purposes of this Code, the health care system does not include pharmacies or other established sales outlets. |
| "Health worker" | means | a person working in a component of such a health care system, whether professional or non-professional, including voluntary unpaid workers. |
| "Infant formula" | means | a breast-milk substitute formulated industrially in accordance with applicable Codex Alimentarius standards, to satisfy the normal nutritional requirements of infants up to between four and six months of age, and adapted to their physiological characteristics. Infant formula may also be prepared at home, in which case it is described as "home-prepared". |
| "Label" | means | any tag, brand, marks, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on, or attached to, a container (see above) of any products within the scope of this Code. |
| "Manufacturer" | means | a corporation of other entity in the public or private sector engaged in the business or function (whether directly or through an agent or through an entity controlled by or under contract with it) of manufacturing a product within the scope of this Code. |
| "Marketing" | means | product promotion, distribution, selling, advertising, product public relations, and information services. |
| "Marketing personnel" | means | any persons whose functions involve the marketing of a product or products coming within the scope of this Code. |

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| "Samples" | means | single or small quantities of a product provided without cost. |
| "Supplies" | means | quantities of a product provided for use over an extended period, free or at a low price, for social purposes, including those provided to families in need. |

*Article 4. Information and education*

4.1 Governments should have the responsibility to ensure that objective and consistent information is provided on infant and young child feeding for use by families and those involved in the field of infant and young child nutrition. This responsibility should cover either the planning, provision, design and dissemination of information, or their control.

4.2 Informational and educational materials, whether written, audio, or visual, dealing with the feeding of infants and intended to reach pregnant women and mothers of infants and young children, should include clear information on all the following points: (a) the benefits and superiority of breast-feeding; (b) maternal nutrition, and the preparation for and maintenance of breast-feeding; (c) the negative effect on breast-feeding of introducing partial bottle-feeding; (d) the difficulty of reversing the decision not to breast-feed; and (e) where needed, the proper use of infant formula, whether manufactured industrially or home-prepared. When such materials contain information about the use of infant formula, they should include the social and financial implications of its use; the health hazards of inappropriate foods or feeding methods; and, in particular, the health hazards of unnecessary or improper use of infant formula and other breast-milk substitutes. Such materials should not use any pictures or text which may idealize the use of breast-milk substitutes.

4.3 Donations of informational or educational equipment or materials by manufacturers or distributors should be made only at the request and with the written approval of the appropriate government authority or within guidelines given by governments for this purpose. Such equipment or materials may bear the donating company's name or logo, but should not refer to a proprietary product that is within the scope of this Code, and should be distributed only through the health care system.

*Article 5. The general public and mothers*

5.1 There should be no advertising or other form of promotion to the general public of products within the scope of this Code.

5.2 Manufacturers and distributors should not provide, directly or indirectly, to pregnant women, mothers or members of their families, samples of products within the scope of this Code.

5.3 In conformity with paragraphs 1 and 2 of this Article, there should be no point-of-sale advertising, giving of samples, or any other promotion device to induce sales directly to the consumer at the retail level, such as special displays, discount coupons, premiums, special sales, loss-leaders and tie-in sales, for products within the scope of this Code. This provision should not restrict the establishment of pricing policies and practices intended to provide products at lower prices on a long-term basis.

5.4 Manufacturers and distributors should not distribute to pregnant women or mothers or infants and young children any gifts of articles or utensils which may promote the use of breast-milk substitutes or bottle-feeding.

5.5 Marketing personnel, in their business capacity, should not seek direct or indirect contact of any kind with pregnant women or with mothers of infants and young children.

*Article 6. Health care systems*

6.1 The health authorities in Member States should take appropriate measures to encourage and protect breast-feeding and promote the principles of this Code, and should give appropriate information and advice to health workers in regard to their responsibilities, including the information specified in Article 4.2.

6.2 No facility of a health care system should be used for the purpose of promoting infant formula or other products within the scope of this Code. This Code does not, however, preclude the dissemination of information to health professionals as provided in Article 7.2.

6.3 Facilities of health care systems should not be used for the display of products within the scope of this Code, for placards or posters concerning such products, or for the distribution of material provided by a manufacturer or distributor other than that specific it Article 4.3.

6.4 The use by the health care system of "professional service representatives", "mothercraft nurses" or similar personnel, provided or paid for by manufacturers or distributors, should not be permitted.

6.5 Feeding with infant formula, whether manufactured or home-prepared, should be demonstrated only by health workers, or other community workers if necessary; and only to the mothers or family members who need to use it; and the information given should include a clear explanation of the hazards of improper use.

6.6 Donations or low-price sales to institutions or organizations of supplies of infant formula or other products within the scope of this Code, whether for use in the institutions or for distribution outside them, may be made. Such supplies should only be used or distributed for infants who have to be fed on breast-milk substitutes. If these supplies are distributed for use outside the institutions, this should be done only by the institutions or organizations concerned. Such donations or low-price sales should not be used by manufacturers or distributors as a sales inducement.

6.7 Where donated supplies of infant formula or other products within the scope of this Code are distributed outside an institution, the institution or organization should take steps to ensure that supplies can be continued as long as the infants concerned need them. Donors, as well as institutions or organizations concerned, should bear in mind this responsibility.

6.8 Equipment and materials, in addition to those referred to in Article 4.3, donated to a health care system may bear a company's name or logo, but should not refer to any proprietary product within the scope of this Code.

### *Article 7. Health workers*

7.1 Health workers should encourage and protect breast-feeding; and those who are concerned in particular with maternal and infant nutrition should make themselves familiar with their responsibilities under this Code, including the information specified in Article 4.2.

7.2 Information provided by manufacturers and distributors to health professionals regarding products within the scope of this Code should be restricted to scientific and factual matters, and such information should not imply or create a belief that bottle-feeding is equivalent or superior to breast-feeding. It should also include the information specified in Article 4.2.

7.3. No financial or material inducements to promote products within the scope of this Code should be offered by manufacturers or distributors to health workers or members of their families, nor should these be accepted by health workers or members of their families.

7.4 Samples of infant formula or other products within the scope of this Code, or of equipment or utensils for their preparation or use, should not be provided to health workers except when necessary for the purpose of professional evaluation or research at the institutional level. Health workers should not give samples of infant formula to pregnant women, mothers of infants and young children, or members of their families.

7.5 Manufacturers and distributors of products within the scope of this Code should disclose to the institution to which a recipient health worker is affiliated any contribution made to him or on his behalf for fellowships, study tours, research grants, attendance at professional conferences, or the like. Similar disclosures should be made by the recipient.

### *Article 8. Persons employed by manufacturers and distributors*

8.1 In systems of sales incentives for marketing personnel, the volume of sales of products within the scope of this Code should not be included in the calculation of bonuses, nor should quotas be set specifically for sales of these products. This should

not be understood to prevent the payment of bonuses based on the overall sales by a company of other products marketed by it.

8.2 Personnel employed in marketing products within the scope of this Code should not, as part of their job responsibilities, perform educational functions in relation to pregnant women or mothers of infants and young children. This should not be understood as preventing such personnel from being used for other functions by the health care system at the request and with the written approval of the appropriate authority of the government concerned.

*Article 9. Labelling*

9.1 Labels should be designed to provide the necessary information about the appropriate use of the product, and so as not to discourage breast-feeding.

9.2 Manufacturers and distributors of infant formula should ensure that each container as a clear, conspicuous, and easily readable and understandable message printed on it, or on a label which cannot readily become separated from it, in an appropriate language, which includes all the following points: (a) the words "Important Notice" or their equivalent; (b) a statement of the superiority of breast-feeding; (c) a statement that the product should be used only on the advice of a health worker as to the need for its use and the proper method of use; (d) instructions for appropriate preparation, and a warning against the health hazards of inappropriate preparation. Neither the container nor the label should have pictures of infants, nor should they have other pictures or text which may idealize the use of infant formula. They may, however, have graphics for easy identification of the product as a breast-milk substitute and for illustrating methods of preparation. The terms "humanized", "materialized" or similar terms should not be used. Inserts giving additional information about the product and its proper use, subject to the above conditions, may be included in the package or retail unit. When labels give instructions for modifying a product into infant formula, the above should apply.

9.3 Food products within the scope of this Code, marketed for infant feeding, which do not meet all the requirements of an infant formula, but which can be modified to do so, should carry on the label a warning that the unmodified product should not be the sole source of nourishment of an infant. Since sweetened condensed milk is not suitable for infant feeding, nor for use as a main ingredient of infant formula, its label should not contain purported instructions on how to modify it for that purpose.

9.4 The label of food products within the scope of this Code should also state all the following points: (a) the ingredients used; (b) the composition/analysis of the product; (c) the storage conditions required; and (d) the batch number and the date before which the product is to be consumed, taking into account the climatic and storage conditions of the country concerned.

*Article 10. Quality*

10.1 The quality of products is an essential element for the protection of the health of infants and therefore should be of a high recognized standard.

10.2 Food products within the scope of this Code should, when sold or otherwise distributed, meet applicable standards recommended by the Codex Alimentarius Commission and also the Codex Code of Hygienic Practice for Foods for Infants and Children.

*Article 11. Implementation and monitoring*

11.1 Governments should take action to give effect to the principles and aim of this Code, as appropriate to their social and legislative framework, including the adoption of national legislation, regulations or other suitable measures. For this purpose, governments should seek, when necessary, the cooperation of WHO, UNICEF and other agencies of the United Nations system. National policies and measures, including laws and regulations, which are adopted to give effect to the principles and aim of this Code should be publicly stated, and should apply on the same basis to all those involved in the manufacture and marketing of products within the scope of this Code.

11.2 Monitoring the application of this Code lies with governments acting individually, and collectively through the World Health Organization as provided in paragraphs 6 and 7 of this Article. The manufacturers and distributors of products within the scope of this Code, and appropriate nongovernmental organizations, professional groups, and consumer organizations should collaborate with governments to this end.

11.3 Independently of any other measures taken for implementation of this Code, manufacturers and distributors of products within the scope of this Code should regard themselves as responsible for monitoring their marketing practices according to the principles and aim of this Code, and for taking steps to ensure that their conduct at every level conforms to them.

11.4 Nongovernmental organizations, professional groups, institutions and individuals concerned should have the responsibility of drawing the attention of manufacturers or distributors to activities which are incompatible with the principles and aim of this Code, so that appropriate action can be taken. The appropriate governmental authority should also be informed.

11.5 Manufacturers and primary distributors of products within the scope of this Code should apprise each member of their marketing personnel of the Code and of their responsibilities under it.

11.6 In accordance with Article 62 of the Constitution of the World Health Organization, Member States shall communicate annually to the Director-General information on action taken to give effect to the principles and aim of this Code.

11.7 The Director-General shall report in even years to the World Health Assembly on the status of implementation of the Code; and shall, on request, provide technical support to Member States preparing national legislation or regulations, or taking other appropriate measures in implementation and furtherance of the principles and aim of this Code.

*Annex 1*

# Resolutions of the Executive Board at its Sixty-seventh Session and of the Thirty-fourth World Health Assembly on the International Code of Marketing of Breast-milk Substitutes

## Resolution EB67.R12
## Draft International Code of Marketing of Breast-milk Substitutes

The Executive Board,

Having considered the report by the Director-General on the Draft International Code of Marketing of Breast-milk Substitutes;

1. ENDORSES in its entirety the Draft International Code prepared by the Director-General;

2. FORWARDS the Draft International Code to the Thirty-fourth World Health Assembly;

3. RECOMMENDS to the Thirty-fourth World Health Assembly the adoption of the following resolution:

*28 January 1981*

[The text recommended by the Executive Board was adopted by the Thirty-fourth World Health Assembly, on 21 May 1981, as resolution WHA34.22, reproduced overleaf.]

**Resolution WHA34.22**
**International Code of Marketing of Breast-milk Substitutes**

The Thirty-fourth World Health Assembly,

Recognizing the importance of sound infant and young child nutrition for the future health and development of the child and adult;

Recalling that breast-feeding is the only natural method of infant feeding and that it must be actively protected and promoted in all countries;

Convinced that governments of Member States have important responsibilities and a prime role to play in the protection and promotion of breast-feeding as a means of improving infant and young child health;

Aware of the direct and indirect effects of marketing practices for breast-milk substitutes on infant feeding practices;

Convinced that the protection and promotion of infant feeding, including the regulation of the marketing of breast-milk substitutes, affect infant and young child health directly and profoundly, and are a problem of direct concern to WHO;

Having considered the draft International Code of Marketing of Breast-milk Substitutes prepared by the Director-general and forwarded to it by the Executive Board;

Expressing its gratitude to the Director-General and to the Executive Director of the United Nations Children's Fund for the steps they have taken in ensuring close consultation with Member States and with all other parties concerned in the process of preparing the draft International Code;

Having considered the recommendation made thereon by the Executive Board at its sixty-seventh session;

Confirming resolution WHA33.32, including the endorsement in their entirety of the statement and recommendations made by the joint WHO/UNICEF Meeting on Infant and Young Child Feeding held from 9 to 12 October 1979;

Stressing that the adoption of and adherence to the International Code of Marketing of Breast-milk Substitutes is a minimum requirement and only one of several important actions required in order to protect health practices of infant and young child feeding;

1. ADOPTS, in the sense of Article 23 of the Constitution, the International Code of Marketing of Breast-milk Substitutes annexed to the present resolution;

2. URGES all Member States:

(1) to give full and unanimous support to the implementation of the recommendations made by the joint WHO/UNICEF Meeting on Infant and Young Child Feeding and of the provisions of the International Code in its entirety as an expression of the collective will of the membership of the World Health Organization;

(2) to translate the International Code into national legislation, regulations or other suitable measures;

(3) to involve all concerned social and economic sectors and all other concerned parties in the implementation of the International Code and in the observance of the provisions thereof:

(4) to monitor the compliance with the Code;

3. DECIDES that the follow-up to and review of the implementation of this resolution shall be undertaken by regional committees, the Executive Board and the Health Assembly in the spirit of resolution WHA33.17.

4. REQUESTS the FAO/WHO Codex Alimentarius Commission to give full consideration, within the framework of its operational mandate, to action it might take to improve the quality standards of infant foods, and to support and promote the implementation of the International Code;

5. REQUESTS the Director-General:

(1) to give all possible support to Member States, as and when requested, for the implementation of the International Code, and in particular in the preparation of national legislation and other measures related thereto in accordance with operative subparagraph 6(6) of resolution WHA33.32;

(2) to use his good offices for the continued cooperation with all parties concerned in the implementation and monitoring of the International Code at country, regional and global levels;

(3) to report to the Thirty-sixth World health Assembly on the status of compliance with and implementation of the Code at country, regional and global levels;

(4) based on the conclusions of the status report, to make proposals, if necessary, for revision of the text of the Code and for the measures needed for its effective application.

*21 May 1981*

*Annex 2*

# Resolution of the Thirty-third World Health Assembly on Infant and Young Child Feeding

**Resolution WHA 33.32 Infant and young child feeding**

The Thirty-third World Health Assembly,

Recalling resolutions WHA27.43 and WHA31.47 which in particular reaffirmed that breast-feeding is ideal for the harmonious physical and psychosocial development of the child, that urgent action is called for by governments and the Director-General in order to intensity activities for the promotion of breast-feeding and development of actions related to the preparation and use of weaning foods based on local products, and that there is an urgent need for countries to review sales promotion activities on baby foods and to introduce appropriate remedial measures, including advertisement codes and legislation, as well as to take appropriate supportive social measures for mothers working away from their homes during the lactation period;

Recalling further resolutions WHA31.55 and WHA32.42 which emphasized maternal and child health as an essential component of primary health care, vital to the attainment of health for all by the year 2000;

Recognizing that there is a close interrelationship between infant and young child feeding and social and economic development, and that urgent action by governments is required to promote the health and nutrition of infants, young children and mothers, *inter alia* through education, training and information in this field;

Noting that a joint WHO/UNICEF Meeting on Infant and Young Child Feeding was held from 9 to 12 October 1979, and was attended by representatives of governments, the United Nations system and technical agencies, nongovernmental organizations active in the area, the infant-food industry and other scientists working in this field;

1. ENDORSES in their entirety the statement and recommendations made by the joint WHO/UNICEF meeting, namely on the encouragement and support of breast-feeding; the promotion and support of appropriate weaning practices; the strengthening of education, training and information; the promotion of the health and social status of women in relation to infant and young child feeding; and the appropriate marketing and distribution of breast-milk substitutes. This statement and these recommendations also make clear the responsibility in this field incumbent on the health services, health personnel, national authorities, women's and other nongovernmental organizations, the United Nations agencies and the infant-food industry, and stress the importance for countries to have a coherent food and nutrition policy and the need for pregnant and lactacting women to be adequately nourished; the joint Meeting also recommended that "There should be an international code of marketing of infant formula and other products used as breast-milk substitutes. This should be supported by both exporting and importing countries and observed by all

manufacturers. WHO and UNICEF are requested to organize the process for its preparation, with the involvement of all concerned parties, in order to reach a conclusion as soon as possible";

2. RECOGNIZES the important work already carried out by the World Health Organization and UNICEF with a view to implementing these recommendations and the preparatory work done on the formulation of a draft international code of marketing of breast-milk substitutes;

3. URGES countries which have not already done so to review and implement resolutions WHA27.43 and WHA32.42;

4. URGES women's organizations to organize extensive information dissemination campaigns in support of breast-feeding and healthy habits;

5. REQUESTS the Director-General ;

(1) to cooperate with Member States on request in supervising or arranging for the supervision of the quality of infant foods during their production in the country concerned, as well as during their importation and marketing;

(2) to promote and support the exchange of information on laws, regulations, and other measures concerning marketing of breast-milk substitutes;

6. FURTHER REQUESTS the Director-General to intensity his activities for promoting the application of the recommendations of the joint WHO/UNICEF Meeting and, in particular:

(1) to continue efforts to promote breast-feeding as well as sound supplementary feeding and weaning practices as a prerequisite to healthy child growth and development;

(2) to intensify coordination with other international and bilateral agencies for the mobilization of the necessary resources for the promotion and support of activities related to the preparation of weaning foods based on local products in countries in need of such support and to collate and disseminate information on methods of supplementary feeding and weaning practices successfully used in different cultural settings;

(3) to intensify activities in the field of health education, training and information on infant and young child feeding, in particular through the preparation of training and other manuals for primary health care workers in different regions and countries;

(4) to prepare an international code on marketing of breast-milk substitutes in close consultation with Member States and with all other parties concerned including such scientific and other experts whose collaboration may be deemed appropriate, bearing in mind that:

(a) the marketing of breast-milk substitutes and weaning foods must be viewed within the framework of the problems of infant and young child feeding as a whole;

(b) the aim of the code should be to contribute to the provision of safe and adequate nutrition of infants and young children, and in particular to promote breast-feeding and ensure, on the basis of adequate information, the proper use of breast-milk substitutes, if necessary;

(c) the code should be based on existing knowledge of infant nutrition;

(d) the code should be governed *inter alia* by the following principles:

(i) the production, storage and distribution, as well as advertising, of infant feeding products should be subject to national legislation or regulations, or other measures as appropriate to the country concerned;

(ii) relevant information on infant feeding should be provided by the health care system of the country in which the product is consumed;

(iii) products should meet international standards of quality and presentation, in particular those developed by the Codex Alimentarius Commission, and their labels should clearly inform the public of the superiority of breast-feeding;

(5) to submit the code to the Executive Board for consideration at its sixty-seventh session and for forwarding with its recommendations to the Thirty-fourth World Health Assembly, together with proposals regarding its promotion and implementation, either as a regulation in the sense of Articles 21 and 22 of the Constitution of the World Health Organization or as a recommendation in the sense of Article 23, outlining the legal and other implications of each choice;

(6) to review the existing legislation in different countries for enabling and supporting breast-feeding, especially by working mothers, and to strengthen the Organization's capacity to cooperate on the request of Member States in developing such legislation;

(7) to submit to the Thirty-fourth World Health Assembly, in 1981, and thereafter in even years, a report on the steps taken by WHO to promote breast-feeding and to improve infant and young child feeding, together with an evaluation of the effect of all measures taken by WHO and its Member States.

*23 May 1980*

*Annex 3*

## Excerpts from the Introductory Statement by the Representative of the Executive Board to the Thirty-fourth World Health Assembly on the Subject of the Draft International Code of Marketing of Breast-milk Substitutes[1]

The topic "infant and young child feeding" was extensively reviewed and discussed in May 1980 at the Thirty-third World Health Assembly, and it has also been extensively discussed this morning. Delegates will recall last year's Health Assembly's resolution WHA33.32 to this effect, which was adopted unanimously and which among other things requested the Director-General "to prepare an international code of marketing of breast-milk substitutes in close consultation with Member States and with other parties concerned". The need for such a code and the principles on which it should be developed were thus unanimously agreed upon at last year's Health Assembly.[2] It should therefore not be necessary in our deliberations today to repeat this review and these discussions.

There are two issues before the Committee today: firstly, the content of the code; and secondly, the question of whether the code should be adopted as a regulation in the sense of Articles 21 and 22 of the WHO Constitution or as a recommendation in the sense of Article 23.

The proposal now before the Committee in document A34/8 is the fourth distinct draft of the code; it is the result of a long process of consultations carried out with Member States and other parties concerned, in close cooperation with UNICEF. Few, if any, issues before the Executive Board and the Health Assembly have been the object of such extensive consultations as has the draft code.

. . . . . .

During the Executive Board's discussion on this item at its sixty-seventh session, in January 1981, many members addressed themselves to the aim and the principles of the code and stressed that, as presently drafted, it constituted the minimum acceptable requirements concerning the marketing of breast-milk substitutes. Since even at this late date, as reflect in recent newspaper articles, some uncertainty persists with respect to the content of the code, particularly its scope, I believe it would be useful to make some remarks on this point. I hasten to remind delegates, however, that the scope of the code was not the source of difficulty during the Board's discussion.

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[1] This statement by Dr Torbjørn Mork (Director-General of Health Services, Norway), representative of the Executive Board, was delivered before Committee A on 20 May 1981. The summary records of the discussion of this topic at the thirteenth, fourteenth and fifteenth meetings of Committee A are contained in document WHA34/1981/REC/3.

[2] See document WHA33/1980/REC/1, Annex 6; document WHA33/1980/REC/2, page 327; and document WHA33/1980/REC/3, pages 67-95 and 200-204.

The scope of the draft code is defined in Article 2. During the first four to six months of life, breast milk alone is usually adequate to sustain the normal infant's nutritional requirements. Breast milk may be replaced (substituted for) during this period by bona fide breast-milk substitutes, including infant formula. Any other food, such as cow's milk, fruit juices, cereals, vegetables, or any other fluid, solid or semi-solid food intended for infants and given after this initial period, can no longer be considered as a replacement for breast milk (or as its *bona fide* substitute). Such foods only complement breast milk or breast-milk substitutes, and are thus referred to in the draft code as complementary foods. They are also commonly called weaning foods or breast-milk supplements.

Products other than *bona fide* breast-milk substitutes, including infant formula, are covered by the code only when they are "marketed or otherwise represented to be suitable . . . . for use as a partial or total replacement of breastmilk". Thus the code's references to products used as partial or total replacements for breast milk are not intended to apply to complementary foods unless these foods are actually marketed — as breast-milk substitutes, including infant formula, are marketed — as being suitable for the partial or total replacement of breast milk. So long as the manufacturers and distributors of the products do not promote them as being suitable for use as partial or total replacements for breast milk, the code's provisions concerning limitations on advertising and other promotional activities do not apply to these products.

The Executive Board examined the draft code very carefully.[3] Several Board members indicated that they considered introducing amendments in order to strengthen it and to make it still more precise. The Board considered, however, that the adoption of the code by the Thirty-fourth World Health Assembly was a matter of great urgency in view of the serious situation prevailing, particularly in developing countries, and that amendments introduced at the present stage might lead to a postponement of the adoption of the code. The Board therefore unanimously recommended to this Thirty-fourth World Health Assembly the adoption of the code as presently drafted, realizing that it might be desirable or even necessary to revise the code at an early date in the light of the experience obtained in the implementation of its various provisions. This is reflected in operative paragraph 5(4) of the recommended resolution contained in resolution EB67.R12.

The second mina questions before the Executive Board was whether it should recommend the adoption of the code as a recommendation or as a regulation. Some Board members expressed a clear preference for its adoption as a regulation in the sense of Articles 21 and 22 of the WHO Constitution. It became clear, however, that, although there had not been a single dissenting voice in the Board with regard either to the need for an international code or to its scope or content, opinion was divided on the question of a recommendation versus a regulation.

[3] The summary record of the Board's discussions is contained in document EB67/1981/REC/2, pages 306-322.

It was stressed that any decision concerning the form the code should take should be based on an appreciation of which alternative had the better chance of fulfilling the purpose of the code — that is, to contribute to improved infant and child nutrition and health. The Board agreed that the moral force of a unanimous recommendation could be such that it would be more persuasive than a regulation that had gained less then unanimous support from Member States. It was considered, however, that the implementation of the code should be closely monitored according to the existing WHO constitutional procedures; that future Assemblies should assess the situation in the light of reports from Member States; and that the Assembly should take any measures it judged necessary for its effective application

After carefully weighing the different points raised during its discussion, the Board unanimously adopted resolution EB67.R12, which contains the draft resolution recommended for adoption by the World Health Assembly. In this connexion I wish to draw the Committee's particular attention to the responsibilities outlined in the draft resolution: those of Member States, the regional committees, the Director-General, the Executive Board, and the Health Assembly itself for appropriate follow-up action once the code has been adopted.

In carrying out their responsibilities, Member States should make full use of their Organization — at global, regional and country levels — by requesting its technical support in the preparation of national legislation, regulations or other appropriate measures, and in the monitoring of the application of the code.

. . . . . .

I think that I can best reflect the sentiments of the Board by closing my introduction with a please for consensus on the resolution as it was unanimously recommended to the World Health Assembly by the Board. We are not today dealing with an economic issue of particular importance only to one or a few Member States. We are dealing with a health issue of essential importance to all Member States, and particularly to developing countries, and of importance to the children of the world and thus to all future generations.

**Olle Hansson and 'Inside Ciba Geigy'** 1989

Olle Hanson Day May 23 Olle Hansson was an icon of the activist medical profession and wrote a classic in medical investigative exposure. The book was called 'INSIDE CIBA GEIGY' and published in Penang, Malaysia in 1989. It is an amazing piece and we like to share the foreword written by Anwar Fazal, former President of International Organisation of Consumers Union (IOCU), co-founder of Health Action International (HAI) and the instigator for the idea of a People Health Assembly. 'Olle was a very special inspiration to us. His courage, his competence, his commitment were rare in a profession that is more often too comfortable or too implicated to speak out against a powerful industry.' His passing on 23 May 1985 was mourned not by words but by a series of actions that will continue to inspire those working to see a more responsible pharmaceutical industry worldwide. 23 May has been designated as Olle Hansson Day and is celebrated as a day of action in India and several other countries. An Ole Hansson Award is made each year to a Third World person whose action for rational drug policies demonstrate the fine qualities of Olle, whose words, 'Now is the time for Action' will be a rallying call for all times. What this book is about is stated below by the four editors This book is in three parts. The first part is the story of a drug, clioquinol, which ruined many more lives than thalidomide did, but this disaster is much less widely known and its lessons have not yet been learned. The story spans over 20 years, from the early 1960s until now, and is told by Dr. Olle Hansson who became deeply involved in it early on and did more than anyone else to bring it towards a conclusion. The main actors are the patients who were injured, the doctors who prescribed the drug, Ciba-Geigy the Swiss multinational pharmaceutical company which introduced ENTERO- VIOFORM, and the lawyers and Hansson who helped the patients obtain compensation.

It is not only a thrilling story but also raises the question as to whether anything like it could happen again. How exceptional was it? In the second part of the book Dr. Hansson looks at other more recent examples of drug marketing by Ciba-Geigy and other companies to try to answer this question. What is unique here is the wealth of information on the discussion and decision process within Ciba-Geigy. The picture is very less disturbing, but although Hansson himself had much less inside knowledge of other companies, it seems likely that Ciba-Geigy's behaviour was no worse than that of most of its competitors.

Are pharmaceutical companies behaving more responsibly now than in the recent past? How can we tell? Hansson died before he could finish this book, but the last month of his life saw a dramatic development in his long struggle with Ciba-Geigy. The company decided that the top management should meet him personally for discussions and perhaps negotiations.

In the last part of the book Milton Silverman, who interviewed all the chief participants, describes these meetings and the events that followed. 'The fight to get rid of clioquinol increased public awareness of underlying problems in many countries, and in the developing world this encouraged consumers to campaign for more rational use of drugs. Olle Hansson acted as a catalyst and adviser for this movement. For example, as Dr. Mira Shiva of the Voluntary Health Association of India notes: 'The relevance of this fight for right to information, the right to socially just and rational drug use have increasingly made sense to us and many others. If today the drugs issue is increasingly being recognised as a health issue, a consumer issue, it is because we are ourselves convinced about it being so, and can therefore convince others. Olle Hansson facilitated this process. An important characteristic was that he never ignored (my) requests for expert comment, and responded very promptly - even when he was in hospital'. 'Olle Hansson's realationships with the media were another important element in his work. 'He had a way of combining scientific with hard fact and a campaigning zeal that is every reporter's dream. His nose for a story made it easy for him to pick up his way through unnecessary detail and hit where it hurts'. (Joan Shenton, TV journalist, London).

Oliver Gillie, then medical correspondent of the London Sunday Times adds: 'As a journalist I have met many people obsessed by a cause. Such obsession is essential if an individual is going to make battle with governments or large international corporations. Olle Hansson had a righteous cause, and the stamina to see the battle through'.

Barbro Joberger, of Dagens Nyheter, Stockholm, was struck by Hansson's respect for journalists' professional skill: 'Unlike many doctors he had no contempt for journalists. He knew that journalists had

their own code of honour. He understood that it was in his own interest to learn as much as possible about the way the media works, so that he could achieve the best results'. What is important now is that all of us should learn the lessons - doctors and other health professionals, administrators of health services, politicians and the public.

The World Health Organisation now has a major programme to encourage the rational use of drugs in all countries, especially the poorest ones. This essential work needs the wholehearted cooperation of the pharmaceutical industry, which has many important contributions to make. If this book helps to improve the ways in which we use medicines. Olle Hansson's hope will have to be realised.

Dag Nilsson, Kongsvinger, Norway; Andrew Herxheimer, London; England Eva Lachkovics, Penang, Malaysia; Mats Nilsson, Malmo, Sweden. 1989

**ANNEXE 4. Olle Hansson Award Winners**

The Award recognises the work of an individual from a developing country who best demonstrates the qualities of Olle Hansson in promoting the rational use of drugs.

The Award is named in honour of Dr Olle Hansson, a Swedish paediatric neurologist internationally known for his advocacy for SMON (Subacute myelo-optic neuropathy) victims who were paralysed or blinded after using clioquinol, an antidiarrhoeal drug. Olle Hansson was a powerful campaigner against unethical promotion and marketing of drugs. In many ways, he represented the conscience of the medical profession.

His influence was felt not only in Sweden and Japan, which have thousands of SMON victims, but also in Europe and developing countries. Olle Hansson will be remembered by all who campaign for the rational use of drugs.

Although he died of cancer on May 23, 1985, at the age of 49, he remains a continuing source of inspiration for public interest workers everywhere. May 23 is commemorated each year as 'Olle Hansson Day'.

The Award was first given in 1987. Recipients: Dr Mira Shiva of India, Dr Alfredo Bengzon of the Philippines, and Prof Dzulkifli Abdul Razak of USM, Malaysia, Dr Syed Rizwanuddin Ahmad of Pakistan, Dr Oscar Lanza of Bolivia, Dr K Balasubramaniam of Sri Lanka, and Dr Eva Ombaka of Tanzania and most recently Professor A.F. Biola Mabadeje of Nigeria.

### *1987: Dr Mira Shiva, India and Dr Alfredo Bengzon, Philippines*

***Dr Mira Shiva i***s a founder member and former Chair of Health Action International (Asia Pacific). She obtained her Post -Graduate Degree in Medicine at Christian Medical College Ludhiana, Punjab in 1978, the year of the Alma Ata Declaration on Primary Health Care (PHC), then completed a Community Health and Development Residency. For over four decades she has been engaged with Comprehensive PHC, issues of gender justice, social and health equity. She has been involved with issues of Rational Drug Policy and Rational use of Drugs, Women and Child health, Food and Nutrition security, Food Safety and Biosafety, Environment and Health, Using Law for Public Health. She was involved in relief work and health impact studies after the Bhopal Gas Tragedy.

Dr Mira is a Founder Member of Peoples Health Movement - a Steering Committee Member for two terms and currently an Advisory Committee member. Dr Mira Shiva is Coordinator of the Initiative for Health and Equity in Society and Founder Coordinator and Co-Convenor of All India Drug Action Network and was a member of the Health Committee of National Human Rights Commission.

Dr Mira is recipient of the first Dr Olle Hansson award for showing Moral Courage and for contributions Nationally and Globally for Rational Use of Medicines. She was also recipient of the Women Scientists Award in 2006 by Science and Society, Dept of Science and Technology for 'prevention of misuse of Medicines and Medical Technologies.

### *1987 Dr Alfredo Bengzon*

As the first Secretary of Health under the restored democracy, Dr Bengzon had the difficult task of reorganizing the Department of Health, restoring its soul and spirit and delivering it through a tense transition. His previous training in Business Management gave him the proper tools to execute the crucial role dealt by destiny. In his 5 years of administration, he carried out the transition successfully and carried the DOH to new heights of energy and achievement. With handpicked managers doing meticulous and systematic target-setting, planning, information processing and resource management, the discipline and order resulted in more effective delivery of services.

During his term, "disease detectives" of the Field Epidemiology Training Program (FETP), that also had a sentinel surveillance system, started to investigate and sort out epidemics and diseases. Full infant immunization coverage soared from a low of 21% to more than 80% in 3 years. Secretary Bengzon also championed the National Drug Policy Program (PNDP). The many programs and projects initiated during Secretary Bengzon's term included the following, among others: Control Of Acute Respiratory Infections, Control of Hepatitis B, Polio Eradication, National AIDS Prevention and Control Program, Non-Communicable Disease Programs (like the Cardiovascular and Cancer Control Programs), and the Philippine Health Development Project (PHDP).

Secretary Bengzon was also designated as the Peace Commissioner tasked with the formulation of the government's comprehensive peace strategy. He also served as a member of the Philippine-negotiating panel on the American bases.

During the second half of his term, he pushed the Generic Law amidst opposition from the medical practitioners and drug manufacturers. Paradoxically, Secretary Bengzon received international recognition for his work in PNDP.

### *1991 Dr Syed Rizwanuddin Ahmad*

As a young medical graduate from Pakistan, already active in the area of access to and use of essential medicines, Rizwan received the Award in 1991. He further trained in pharmacovigilance (PV), pharmacoepidemiology (PE), drug regulatory science and clinical pharmacology and now has more than 30 years' experience in civil society organizations/non-profit groups, and the public sector.

He consults in regulatory system strengthening; PV; PE; benefit-risk assessment; risk management; vaccine safety; risk communication; access to medicines; generic drugs; poison & drug information centre; medication errors; medicines policy; essential medicines; rational use of medicines; antimicrobial resistance; ethical issues in the conduct of trials; and global health. Areas of interest include active PV and TB/HIV/AIDS/malaria drugs; causality assessment; signal detection/management; training, capacity building in PV & strengthening of FDA-like agencies in resource-limited countries. He has taught at Georgetown University.

He was a reviewer at the FDA and active in education and training of FDA scientists; organised seminars; courses; and was instrumental in the launch of the first Epi for Non-Epi course. He is a recipient of a number of FDA Awards and Commissioner's Special Citation. He is active in the International Society for Pharmacoepidemiology (ISPE) and serves in the Education; and Global Development Committees. He was Chair and Vice Chair of the Government and Regulatory Council; edited ISPE's newsletter; served on the faculty of intro to pharmacoepidemiology course and has given intro PV lectures. In 2006, in recognition of his scientific contributions and service to the society, he was inducted as a Fellow in ISPE. In 2009, he was conferred Fellowship of the American College of Clinical Pharmacology. He has many publications to his credit including many book chapters on pharmacovigilance; and one on the evolution of the FDA drug approval process. In 2014, he conceived the idea for the first Vaccine Safety course which was offered at ICPE Boston 2015 and again in ICPE Dublin 2016.

### *1992 Professor Tariq Bhutta*

Prof Bhutta joined HAI in 1990. With many years of experience in paediatrics and public health, he was instrumental in instigating the withdrawal of the drug Imodium (loperamide) for diarrhoea treatment in children. A large number of children had developed paralytic ileus soon after they were given treatment at home with this drug. Prof Dr Tariq Iqbal Bhutta graduated from King Edward Medical College (KEMC) in 1962 and holds an FCPS in Paediatrics (1968); DCH (London, 1970); FRCP (Edinburgh, 1994); and FRCP (Glasgow, 1996). He has served as President of the Pakistan Medical and Dental Council (PMDC), Registrar Nishtar Hospital Multan, Senior Registrar Jinnah Postgraduate Medical Centre (JPMC), Asst Prof KEMC and Prof of Paediatrics at Nishtar Medical College (NMC) and KEMC. He retired as Principal of NMC in 2000. He has been involved with various associations, including the International Paediatric Association (IPA), where he was part of the Committee on Rational Drug Use (1996-1998); the Asia Pacific Paediatric Association (APPA), where he served on the Advisory Board (1994-2000), and the Pakistan Paediatric Association (PPA), where he held the post of Secretary (1976-1978) and President (1988-1990 and 1994-1996). Furthermore, he has served the College of Physicians and Surgeons Pakistan (CPSP) as Councillor and Vice President. He has also been affiliated with the World Health Organization (WHO), serving as an advisor in the field of immunisation and drug classification. For his outstanding work in the field of child health, he was awarded the Presidential Gold Medal in 1996.

### *1999 Professor Dzulkifli Abdul Razak*

Professor Tan Sri Dzulkifli Abdul Razak (Dzul)'s first degree was Bachelor of Pharmacy from Universiti Sains Malaysia (USM) and then he obtained Master of Science in Pharmacology from the University of Strathclyde.

Professor Dzulkifli was the Director of the National Poison Centre, Universiti Sains Malaysia (USM), when he was the first Malaysian to receive the Olle Hansson award in 1999.

He was the Vice Chancellor of the Science University of Malaysia (USM) in Penang from 2000-2011. He was responsible for enriching the very close relationship between HAIAP and the Poison Centre at that University's Medical Faculty which was one of our very first network partners. The centre was also a WHO Collaborating Centre. He left USM to become the Vice Chancellor of Albukhary International University in Kedah, Malaysia where he developed the concept of 'the humaniversity', before moving to become a Distinguished Fellow at the Malaysian Islamic University of Science (USIM)'s Faculty of Leadership and Management and Chair of Islamic Leadership in 2014.

Prior to joining USIM, he served as a member of the World Health Organization (WHO) Expert Advisory Panel on Drug Policy and Management from 1995 to 2010 and the WHO Scientific Committee of Tobacco Product Regulation from 2004 to 2006. He was also President of the International Association of Universities from 2012 to 2016.

He was made an Honorary Doctor of Science by the Universities of Portsmouth and Nottingham and Mykolas Romeris University and an Honorary Doctor of Educational Science by Istanbul Commerce University. He remains active in educating the public about their rights in the medical world in this country.

### *Dr Oscar Lanza, 2000*

Dr Oscar Lanza van den Berg was the recipient of the Olle Hansson Award for 2000. Dr. Oscar Lanza was Professor of Public Health, School of Medicine, University Mayor of San Andres, La Paz, Bolivia. He was also the founder coordinator of Health Action International Latin America (HAI/AIS). Based on his research at community and country levels, he has brought to public attention and scrutiny, unethical drug promotion and the harm caused by irrational and hazardous use of drugs, both in Bolivia and Latin America. He is pioneering work led to the enactment of the Bolivian National Legislation on ethical drug promotion, clear rules for drug prescription and use of essential drugs in their generic names.

Apart from health research and campaigns, Dr. Lanza has for over 18 years lead community health education programs, through daily radio broadcasts, broadcast in four local and native languages, reaching even the most remote areas of Bolivia.

Dr. Lanza, is also nationally and internationally well recognised as a leader in consumer protection, and a tireless activist of patient's rights, child nutrition, environmental protection and human rights. He has authored and co-authored several books and publications on various aspects of pharmaceuticals. The monthly AIS Bolivia bulletin on rational use of drugs and Primary Health care had a circulation of 10.000 copies.

He was a founder and coordinator of the Bolivian Consumers' movement (CODEDCO), the coordinator of IBFAN Bolivia and a pioneer of the Bolivian Foundation for Nature and Life protection in Bolivia (FUNAVI).

### *2006 Dr Kumariah Balasubramaniam*

Dr Kumariah Balasubramaniam (Bala), a teacher, author, strategist, guide and mentor and above all a health activist, from Jaffna, Sri Lanka graduated in medicine from the University of Sri Lanka and worked in the public sector for a few years. In the early 1960s he joined the University of Peradeniya, Department of Pharmacology to work under the late Prof Senaka Bibile who introduced the well known Pharmaceutical reforms for Sri Lanka in 1972.

Bala was appointed Associate Professor, Department of Pharmacology, University of Sri Lanka in 1975. In 1978 he left Sri Lanka to join the United Nations Conference on Trade and Development (UNCTAD) Geneva as the Senior Pharmaceutical Advisor and worked till 1986. During his career in UNCTAD, he visited several developing countries in Asia, Africa and Latin America to advise Ministries of Health in developing countries to rationalize their pharmaceutical supply system and have rational national drug policies.

In 1987 he joined Consumers International Regional Office for Asia and Pacific (CIROAP) as the Co-ordinator for Action for Rational Drugs in Asia (ARDA) which was relocated to Colombo, Sri Lanka in 2002 and renamed Health Action International Asia Pacific (HAIAP).

During his 30 year stint in the field of pharmaceuticals and health Dr Bala has received many honours and awards including the Commonwealth Vice - Chancellors' Fellowship Award 1994/95, Australia. He has published innumerable papers on a variety of topics ranging from rational use of drugs to drug prices, availability and access to medicines, intellectual property rights and access to medicines, poverty and health etc.

His knowledge, expertise, exposure, representation at local and international conferences, networking skills have influenced global pharmaceutical thinking extensively. He was founder of HAI and one of the initiators of global Peoples Health Movement (PHM). He was Coordinator of Health Action International Asia-Pacific from 2001.

### *Dr Eva Ombaka 2007*

Born in Moshi, Tanzania, Dr Eva Ombaka trained as a pharmacist in England where she also obtained her PhD (pharmacy) and her Masters in Public Health. In England she had a chance to experience the profession from hospital practice, academia, and manufacturing. For seventeen years she was involved in issues of pharmaceutical policy development and capacity building for better pharmacy practice. Her main areas of interest are in access to and the promotion of rational use of medicines (RUM). She has been involved in several RUM and drugs and therapeutic committee (DTC) courses and was the winner of Olle Hansson award for 2007 for her work in RUM. She has participated in committees addressing different aspects of access and use of medicines in organizations such as WHO, MSH, React and HAI.

She was responsible for essential medicines in the Christian Medical Commission of the World Council of Churches in Geneva before becoming coordinator of Ecumenical Pharmaceutical Network based in Kenya. As founder and board member of Sustainable Health Care Foundation, Dr Ombaka actively supported use of available local resources, including personnel, as an effective way of learning, sharing best practices and addressing issues with understanding of local context.

### *Professor AFB Mabadeje 2008*

Professor A.F. Biola Mabadeje is a Clinical Pharmacologist and was Head of Department of Pharmacology at the College of Medicine of the University of Lagos. He is also a Consultant Physician and head of the Dialysis Centre at the Lagos University Teaching Hospital He was the Chairman of the Nigerian National Formulary and Essential Drugs Review Committee from 1985 until 1994. He was a foundation member and also the Coordinator of the INRUD Nigeria Core Group. He participated in various field studies undertaken by International Network for Rational Use of Drugs (INRUD) leading to several publications: *How to investigate drug use in health facilities*; *Field tests for rational drug Use in 12 developing countries*; *Impact of a short course of pharmacotherapy for undergraduate medical students; An international multi-centre study.*

Active in drawing attention to adverse drug reactions, Dr Mabadeje has many publications in local and international journals on concepts of essential drugs and their rational use.

Annexe 5

## ‘Books on Pills’

E-DRUG celebrated its 20th birthday in February 2015. E-DRUG was launched in Boston in February 1995, by a group of volunteer moderators as the English language electronic discussion group on essential drugs and the first message was posted on February 3. Messages have been archived since June 1995 http://lists.healthnet.org/archive/html/e-drug/ and by the end of 1995 communications from Netherlands, Italy, Australia, Madagascar, Spain, Denmark, South Africa, USA, Philippines, Pakistan, Brazil, Canada had already been recorded.

Around the world, E-DRUG is used by health care professionals, researchers and policy makers to obtain and discuss current information on essential drugs, policy, program activities, education and training. Members also use E-DRUG to announce and learn of upcoming conferences or courses in their field.

Discussions focus on topics such as rational use of drugs, drug policy, economics and financing, supply and marketing, legislation and regulation, quality assurance and safety, and training. E-DRUG is especially targeted to health workers in developing countries, and is based on simple off-line e-mail technology.

If you are not a member already and would like to join - go to

e-drug-join@healthnet.org

**Books on Pills**

Over the years E-drug subscribers discussed the idea of having a list of ‘books on pills’. So many important essential drug-related ‘activist’ books have been written and it was considered very important that we remember these books and the contributions they have made to the movement for access to essential medicines.

As E-DRUG’s 20th birthday and the 30th anniversary of the Nairobi 1985 Conference on Rational Use of Drugs approach, and with the 40th anniversary of the birth of the essential medicines concept not far off, it was considered timely to revisit these books.

E-drug Moderator Douglas Ball collated the titles contributed by members and shared the results at the end of 2013. What started out described as the ‘List of books on pills’, and was initially intended as a list of 'activist' books about Big Pharma, grew to cover a wider range of books related to essential medicines such as rational use of medicines and essential medicines policies and issues. We all know the importance of Charles Medawar, Virginia Beardshaw, Ellen tHoen, Mike Muller, Diana Melrose and so many more. The list is much longer than envisaged and now the intention is that it will become a resource not just of 'activist' style literature related to Big Pharma, but also of key texts touching on the 'essential drugs movement' from its early roots to the present day.

Some additional features are included in the database: keywords and classifications are given to aid in searching the list, ISBNs, some French and Spanish titles are represented, some related films, and a list of useful links including electronic source where available.

Due to the scope of the list, it is made available as an Excel file with multiple worksheets (as well as Open Document spread-sheet format and a Word file with just the list) and can be downloaded from the E-Drug website: http://www.essentialdrugs.org/documents.php

An Excel file version sorted by date of publication can be downloaded here:
https://www.haiasiapacific.org/resources/list-of-books-on-pills/

If you are looking for that book to read or searching for references for your thesis on the activities of the pharmaceutical industry that have had an impact on the use of essential medicines, this resource could be what you have been waiting for.

### Disclaimers

1. This list is not exhaustive and is meant for information purposes only.
2. Listing a book should not be taken as an endorsement or recommendation by E-Drug or HAIAP or any other party.
3. Comments or reviews are the opinions of those who wrote them and not necessarily those of E-Drug or HAIAP members.
4. Some books are available from more than one publisher. Generally, only one has been shown (and only

one ISBN that may or may not correspond to the publisher shown) but this is should not be taken as a recommendation of this publisher or edition over other editions that might be available. Some books are available from well-known global entrepreneurs even though they are 'out of print'.

5. In some cases, new or updated editions may be available for the book that is listed.
7. While every effort has been made to be accurate, errors may be present in the titles, authors or other details.
8. This list has been compiled based on the principles and outlooks of E-Drug members and therefore many books will reflect their world view.
9. Categories, descriptions, keywords are provided to assist in browsing the list. However, these may be inaccurate or incomplete and there is overlap between categories.

### Publications not included in the List

Textbooks
Public health/consumer organisation reports (with some exceptions)
Other international NGO reports and publications
Academic/scientific/biomedical journal articles (with a few exceptions)
WHO reports and publications (the reader is directed to the WHO documentation portal – see Useful links)
Press statements and the like.

(Missing titles can be added – send suggestions to Haiasiapacific@gmail.com)

Annexe 6

# HAIAP Position Paper RATIONAL DRUG USE 2013

## 01. What is rational drug use?

**Patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community.** This means that doctors prescribe the right drug, correct dose at affordable price with clear information and instruction about the drug to the patient or guardian.

## 02. What is irrational use?

Irrational or non-rational use is the use of medicines in a way that is not compliant with rational use. Worldwide more than 50% of all medicines are prescribed, dispensed or sold inappropriately, while 50% of patients fail to take them correctly. Moreover, about 1/3 of the world' population lacks access to essential medicines and this may go up to 50% in the near future.

Common types of irrational uses are:

- Poly pharmacy (the use of too many medicines per patient)
- In appropriate use of antimicrobials, often in inadequate dosage, for non-bacterial infections.
- Over use of injections when oral formulations would be more appropriate
- Failure to prescribe in accordance with accepted clinical guidelines
- In appropriate self medication, often of prescription only medicines
- Failures to adhere the treatment, often take less than prescribed.

## 03. What are the causes?

- Irrational prescribing practices of doctors.
- Irrational dispensing by Pharmacists and Drug Sellers
- Drug pricing policies and promotional activities of the pharmaceutical industry
- Lack of information, education and communication on rational drug use to providers and consumers.
- Lack of effective control and regulatory mechanisms on drug use
- Lack of political will and leadership to promote rational use.

## 04. What are the consequences?

- Deprives patients the full benefit of available drugs leading to poor patient outcome
- Ineffective treatment and sometimes, harmful effects / adverse reactions.
- Additional burden on the Household and government drug / health expenditures.
- Increased Morbidity and Mortality
- Increased antimicrobial resistance, leads to expensive newer generation antimicrobial treatment
- Non - sterile injection use may transmit blood borne infections like Hepatitis B & HIV/AIDS.

## 05. Drug Promotion & RDU

Drug promotion creates demand for medicines in many ways. Firstly, it defines illness conditions that need treatment. It also promotes the idea that medicines are the best remedy as oppose to non-drug alternatives. Lastly, it tends to emphasis a medicine's efficacy while minimizing possible health risks.

## 06. What is Essential Drug Concept?

Essential drugs are those that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in appropriate dosage forms (WHO). Rational drug selection, good procurement practices, reliable quality assurance and efficient distribution systems comprise the central elements of the essential drug concept.

## 07. What are the layers of influence?

- Individual / Family level
- Community level
- Health care facilities / institutional level
- National level
- Regional / international level

### 08. Who are the stakeholders?

- Consumers
- Providers (Prescribers and Dispensers)
- Pharmaceutical Industry
- Local consumer groups and civil society organizations
- Regulatory Authorities / National Governments
- International Non Governmental and Multi lateral Organizations, including UN Agencies and WTO.

### 09. How to promote rational drug use at national level?

- A mandated multi-disciplinary national body to coordinate medicine use policies

- Develop and implement a comprehensive *National Drug Policy (NDP),* based on the Essential Medicines Concept, as a part of the national health policy.

- Establish transparent procedures for developing, disseminating, utilizing and revising national *Standard Treatment Guidelines (STGs)* with updated drug price information.

- Establish procedures for developing and revising an *Essential Drug List (or hospital formulary)* based on STGs and use in practice, training and supply.

- Require hospitals to establish representative *Drugs and Therapeutics Committees (DTC)* with defined responsibilities for monitoring and promoting quality use of medicines (Refer Box 1)

**Box 1: Responsibilities of a drugs and therapeutics committee**

- Developing, adapting or adopting clinical guide lines for the health institution or district
- Selecting cost-effective safe medicines (hospital / district drug formulary)
- Implementing and evaluating strategies to improve medicine use (including drug use evaluation, and liaison with antibiotic and infection control committees)
- Providing on-going staff education (training and printed materials)
- Controlling access to staff by the pharmaceutical industry with its promotional activities
- Monitoring and taking action to prevent adverse drug reactions and medication errors
- Providing advice about other drug management issues, such as quality and expenditure.

**-** Implement problem-based training in pharmacotherapy in undergraduate medical and paramedical education based on national STGs

- Encourage targeted, problem-based in-service educational programmes by professional societies, universities and the Ministry of Health, and require regular continuing education for licensure of health professionals.

- Establish a national / regional drug information centers to disseminate independent medicine information and to track after complaints on adverse effects or problem drugs.

- Encourage active involvement by consumer organizations in public education about drugs, and devote government resources to support these efforts

- Stimulate an interactive group process among health providers or consumers to review and apply information about appropriate use of medicines

- Train pharmacists and drug sellers to be active members of the health care team and to offer useful advice to consumers about health and drugs

- Appropriate and enforced regulation by a sufficiently funded Drug Regulatory Authority backed up by the judiciary. (Refer Box 2)

**Box 2: Regulatory measures to support rational use**

- Registration of medicines to ensure that only safe efficacious medicines of good quality are available in the market and that unsafe non-efficacious medicines are banned
- Limiting prescription of medicines by level of prescriber; this includes limiting certain medicines to being only available with a prescription and not available over the counter
- Setting educational standards for health professionals and developing and enforcing codes of conduct; this requires the cooperation of the professional societies and universities
- Licensing of health professionals – doctors, nurses, paramedics – to ensure that all practioners have the necessary competence with regards to diagnosis, prescribing and dispensing
- Licensing of medicine outlets – retail shops, wholesalers- to ensure that all supply outlets maintain the necessary stocking and dispensing standards
- Monitoring and regulating medicine promotion to ensure that it is ethical and unbiased. All promotional claims should be reliable, accurate, truthful, informative, balanced, up-to-date, capable of substantiation and in good taste

- Develop a strategic approach to improve prescribing in the private sector through appropriate regulation and long-term collaborations with professional associations (Refer Box 3)

**Box 3: Where to start in countries with strong private sector?**

*A. Regulation*:
- Market approval
- Re-licensing
- Re-evaluation per therapeutic category
- Regulation of promotion

*B. Training*:
- Basic training
- National clinical guidelines
- Continuing medical education by universities and professional bodies
- Re-licensing of professionals on basis of education points
- District drug and therapeutic committees
- Medical audit
- Patient information leaflets
- Public education

*C. Financial incentives*:
- Separate prescribing from dispensing
- Dispensing fee (flat or tiered)
- Price controls on generic/brand drugs
- Contracting out

*D. Insurance*:
- Reimbursement limited to essential medicines
- Reference pricing

- Establish systems to monitor key pharmaceutical indicators routinely in order to track the impact of health sector reform and regulatory changes

**-** Sufficient government expenditure to ensure availability of medicines and staff at any time

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# Annexe [7]

# Ensuring Rational Use of Medicines

Beverley Snell

## Managerial and structural strategies

### *National Medicines Policy*

A regulatory framework and a National Medicines Policy that expresses a strong commitment to the rational use of medicines, will strengthen all initiatives to promote the rational use of medicines.

### *Tools for procurement, selection and use*

- Treatment Guidelines
- Essential Medicines Lists
- National Formulary

If only essential medicines are available and they are used according to the Standard Treatment Guidelines, medicines use will be appropriate so it is important to have these tools in place.

When treatment guidelines are being prepared, it is extremely important to consult with and involve potential users (doctors, specialists, nurses, health workers). Their active participation is needed in the preparation of these guidelines to encourage ownership and interest in their use. If all the collaborators' names are included in the front of the book it helps them to feel ownership and they are likely to use and promote the guidelines.

## More strategies to assist Rational Use of Medicines

### *Distribution and supply*

If a reliable supply of essential medicines is always available, prescribers will be less likely to prescribe other second choice medicines. It is important for all prescribers to have their own copy of the Standard Treatment Guidelines to assist them.

The usual treatment schedule in Treatment Guidelines contains five items of information:

1. The name of the health problem
2. The generic name and dosage form and strength of each medicine to be used for treatment
3. The usual dose
4. The number of doses per day
5. The usual duration (number of days) of treatment

A reliable supply of essential medicines depends on a good record keeping system as well as a good ordering system. Patient records must be kept accurately.

### *Structured Order Forms for medicines*

Printed order forms including the medicines and supplies normally found at a particular level of the health service can assist greatly in making ordering easy and efficient and in helping to maintain a reliable supply.

### *Course-of-Therapy Packaging*

Sometimes medicines are supplied in packs for a course of therapy according to the Standard Treatment Guidelines, that would encourage prescribing of the correct quantity for the correct duration of treatment. The practicalities of preparing course of therapy packs will need consideration at the central level. The

recommended course of treatment with cotrimoxazole tablets is 5 days – one dose twice daily – 10 tablets. So pre-packed courses of 10 tablets could be helpful

## *Dispensers have a significant role in the Rational Use of Medicines*

### Who are Dispensers?

- Pharmacists, pharmacy technicians
- Pharmacy assistants
- Nurses, Nursing Officers
- Doctors
- Medicine sellers
- Shop keepers
- Family members?

In our world Prescribers and Dispensers are often the same person. A prescriber is anyone with a recommendation for treatment. A dispenser is anyone that gives out the treatment. Standards for prescribing and dispensing are controlled by legislation.

### Dispensers' skills and knowledge

The categories of health professionals mentioned above - Pharmacists, Pharmacy Technicians, Pharmacy Assistants, Nurses, Nursing Officers, Doctors – all have training and expertise that can qualify them to dispense medicines. They should be familiar with the Standard Treatment Guidelines and the Essential Medicines List and will have sufficient knowledge to be aware of whether a prescription they are asked to dispense is rational – if they are not the prescriber as well. They will have some knowledge of a patient's problems (or diagnosis) and would know what would be effective and safe treatments (medicines and non-medicines); dosage and duration; how to give patients adequate information and be able to evaluate treatment responses. They should be able to detect

(a) inappropriate dosage

(b) medicine-medicine interaction

(c) medicine-food interaction

(d) unintended dosage errors

(e) medication duplication

(f) inappropriate medicine therapy

(g) contraindicated medication

(h) unusual usage, eg use of medicine not in accordance with the treatment guidelines

(i) possible misuse or abuse of a medicine of dependence or

(j) any other matter which may adversely affect the patient including current nonprescription medicines being taken.

### Labeling

Patients need to understand what their medications are and how to take them. The label on the container provided by the dispenser needs to include the following information:

(a) the name and strength of the medication

(b) the route of administration

(c) the name of the patient

(d) the date of dispensing or supply and where applicable an identifying code

(e) the name and location of the health facility at which the prescription was dispensed

(f) directions for the correct use of the medicine as prescribed by the prescriber

(g) the words 'KEEP OUT OF REACH OF CHILDREN'

(h) directions for storage (where appropriate) and expiry date (where applicable) of the medicine

If the prescriber does not provide specific directions for any medicine, eg by indicating no directions, or 'take as directed', the dispenser must be satisfied that the patient knows how the prescriber expects the medicines to be taken or used.

If a patient cannot read, it is still important to label the medicines completely and accurately as above. In addition, the patient might like to have diagrammatic instructions but mostly, people who cannot read are used to remembering oral messages well. It is important to take time to make sure the patient understands all the instructions.

## *Other Skills and resources*

Other skills and resources that support the rational use of medicines are

- medicine information, access to good references
- product information
- consultation and communication skills
- promotional/marketing techniques

## *Why should we develop patient resources?*

- Patients have a right to quality health care. Provision of information helps fulfil the right to quality health care
- To enhance patient empowerment
- To help patients move through the most appropriate pathways of their health care
- To ensure patients are fully informed of options for treatment and of the risks and benefits involved
- To reduce inequalities in access to health care.

### Types of resources

There are many types of resources including brochures, flyers, fact sheets, videos, DVDs, radio programs, online and computer information. The best resources are developed in collaboration with the people who would like to have them.

Selection or development of the most appropriate resources depends on the budget, time and other resources available, on the needs of the organization and on the particular characteristics of the community you are talking to.

Resources need to be field tested and evaluated before they are accepted as 'right'. Things change too – so it important to keep evaluating resources and to modify them as needed.

## *Principles, culture and values*

**Rights:** patients have the right to information about their condition and a right to good health and high quality health care. This right means the appropriate way of doing things; it means helping people through the most appropriate pathway of care for their condition

**Accuracy:** Health information should be honest, accurate and thorough

**Family orientation:** Family includes everyone who surrounds an individual in daily life: relatives, friends, colleagues, care-workers, other community members. Patient information should avoid an individual approach. It should have a more community focussed approach and in that way it is more likely to play a part in the well-being of the patient. It is important to respect an individual's right to confidentiality and privacy.

**Confidentiality:** Care is needed not to identify a particular person with a particular health problem. Community focussed information avoids the possibly of 'pointing at' one person.

**Respect:** Patients' rights and entitlements in the health system must be respected of course. In addition, the tone of information must not be patronising or paternalistic. Patients are partners in their care and they bring special qualities to the management of their conditions. They are automatically experts in their own condition. Information and resources should empower patients to make informed decisions, and to seek support and reciprocity from the rest of the health care team.

**Responsibility:** Governments have a responsibility to provide adequate health care for their citizens. At the same time, people have a responsibility for their own health. The provision of information and resources will help empower people to take responsibility for their own health and well-being.

Self-treatment of common ailments is becoming more popular as a growing range of safe, effective medicines becomes available, without the need for a doctor's prescription. At the same time, in the absence of strong regulation patients are also exposed to a wide range of unsafe products that are freely available. Implementation of a strong comprehensive national medicine policy will control access to unsafe medicines and their use.

Although patients are exposed to a wide range of information from package inserts, promotional materials, advertising in the media and through the Internet, this information is not always accurate or complete. Pharmacists and pharmacy workers can help patients become more accurately informed by offering unbiased relevant explanations and by pointing to reliable sources.

They can discuss disease prevention and lifestyle modification together, and can also discuss how to take medicines to get the best treatment results and avoid or reduce medicine-related adverse events.

### *Improved adherence to long term treatments*

The benefits of improved long term treatment - when it is needed - include better health outcomes and improved quality of life and improved safety for the patient, as well as cost savings for everyone. Well trained health professionals provide services involving treatment with medicines and should make every effort to assist patients who wish to do so to improve adherence to their treatments.

### *Medicines safety*

Medicines safety is an important issue. Use of standard treatment guidelines is a very important part of ensuring safety of medicine but there can still be unusual reactions to medicines. Medicines can be taken in the wrong dose or at the wrong time, or sometimes patients can get access to medicines outside the treatment guidelines.

When patients return for any reason it is a good idea to ask if there is anything they don't understand or have concerns about.

### *Adverse medicines reactions*

When there is any suspicion that a patient might have an adverse reaction to a medicine it is important to get all the details, to consult the doctor and to send the information to the appropriate department. It is

**What to report**
**You do not need to be certain, just suspicious!**
Any information related to the reporter and patient identifiers is kept strictly confidential.
Adverse medicine reaction reports should be submitted for prescription medicines, vaccines, over-the-counter medicines (medicines purchased without a prescription), and complementary medicines (herbal medicines, naturopathic and/or homoeopathic medicines, and nutritional supplements such as vitamins and minerals).
Please include timing of reactions relative to medicine administration where relevant.
The regulatory authority should request reports of:

- All suspected reactions to new medicines and vaccines
- All suspected reactions to Medicines of Current Interest listed in the Australian Adverse Medicine Reactions Bulletin
- All suspected medicine interactions

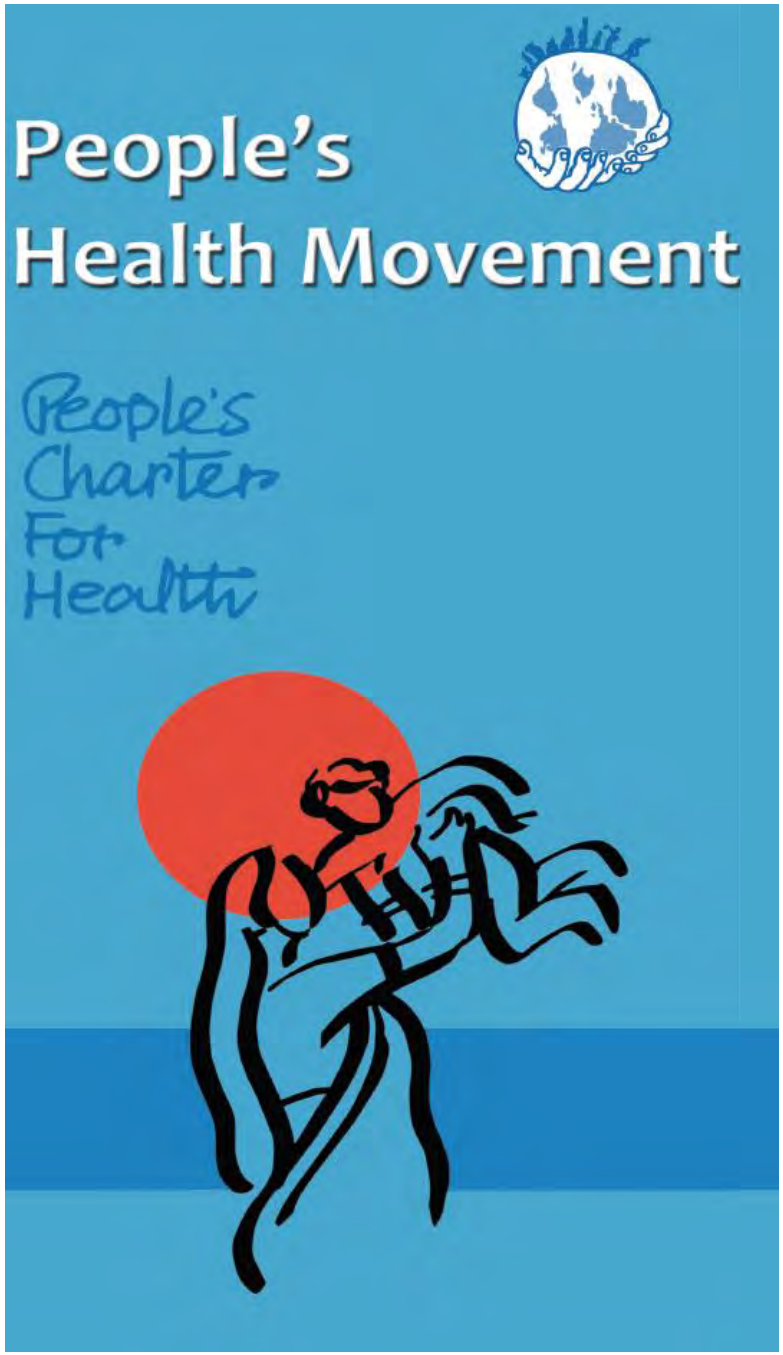
- Unexpected reactions, ie not consistent with product information or labelling

Serious reactions which are suspected of significantly affecting a patient's management, including reactions suspected of causing death, danger to life, admission to hospital, prolongation of hospital is at ion, absence from productive activity, increased investigational or treatment costs, and birth defects  All reports are assessed by a health professional and entered into the Australian Adverse Medicine Reactions System (ADRS).

## *Pharmacovigilance and recall*

In some cases, medicines may need to be recalled and withdrawn from a market or from health facilities and other places, often because there is a problem with a particular batch. This process involves action by everyone at any point in the medicines supply chain. Pharmacists have an important contribution to make to post-marketing surveillance and pharmacovigilance.

Annexe 8




1



## INTRODUCTION

In 1978, at the Alma-Ata Conference, ministers from 134 member countries in association with WHO and UNICEF declared "Health for All by the Year 2000" selecting Primary Health Care as the best tool to achieve it.

Unfortunately, that dream never came true. The health status of third world populations has not improved. In many cases it has deteriorated further. Currently we are facing a global health crisis, characterized by growing inequalities within and between countries .New threats to health are continually emerging . This is compounded by negative forces of globalization which prevent the equitable distribution of resources with regard to the health of people and especially that of the poor.

Within the health sector, failure to implement the principles of primary health care, as originally conceived in Alma-Ata has significantly aggravated the global health crisis.

Governments and the international bodies are fully responsible for this failure.

It has now become essential to build up a concerted international effort to put the goals of health for all to its rightful place on the development agenda. Genuine, people-centered initiatives must therefore be strengthened in order to increase pressure on decision- makers, governments and the private sector to ensure that the vision of Alma- Ata becomes a reality.

Several international organizations and civil society movements, NGOs and women's groups deciples to work together towards this objective. This group together with others committed to the principles of primary health care and people's perspectives organized the "People's Health Assembly" which took place form 4-8 December 2000 in Bangladesh, at Savar, on the campus of the Gonoshasthasthaya Kendra or GK (peoples Health Centre).

1453 participants form 92 countries came to the Assembly which was the culmination of eighteen months of preparatory action around the globe. The preparatory process elicited unprecedented enthusiasm and participation of a broad cross section of people who have been involved in thousands of village meetings, district level workshops and national gatherings.

The plenary sessions at the Assembly covered five main themes: Health, Life and Well-Being; Inequality, Poverty and Health; Health Care and Health Services; Environment and Survival; and The Ways Forward. People from all over the world presented testimonies of deprivation and service failure as well as those of successful people's initiatives and organization. Over a hundred concurrent sessions made it possible for participants to share and discuss in greater detail different aspects of the major themes and give voice to their specific experiences and concerns. The five days event gave participants the space to express themselves in their own idiom. They put forward the failures of their respective governments and international organizations and decided to fight together so that health and equitable development become top priorities in the policy makers agendas at the local, national and international levels.

Having reviewed their problems and difficulties and shared their experiences, they have formulated and finally endorsed the People's Charter for Health. The charter from now on will be the common tool of a worldwide citizens' movement committed to make the Alma- Ata dream reality.

We encourage and invite everyone who shares our concerns and aims to join us by endorsing the charter.

## PREAMBLE

Health is a social, economic and political issue and above all a fundamental human right. Inequality, poverty, exploitation, violence and injustice are at the root of ill-health and the deaths of poor and marginalised people. Health for all means that powerful interests have to be challenged, that globalisation has to be opposed, and that political and economic priorities have to be drastically changed. This Charter builds on perspectives of people whose voices have rarely been heard before, if at all. It encourages people to develop their own solutions and to hold accountable local authorities, national governments, international organisations and corporations.

## VISION

Equity, ecologically-sustainable development and peace are at the heart of our vision of a better world - a world in which a healthy life for all is a reality; a world that respects, appreciates and celebrates all life and diversity; a world that enables the





flowering of people's talents and abilities to enrich each other; a world in which people's voices guide the decisions that shape our lives. There are more than enough resources to achieve this vision.

## THE HEALTH CRISIS

*"Illness and death every day anger us. Not because there are people who get sick or because there are people who die. We are angry because many illnesses and deaths have their roots in the economic and social policies that are imposed on us"*

*(A voice from Central America)*

In recent decades, economic changes world-wide have profoundly affected people's health and their access to health care and other social services.

Despite unprecedented levels of wealth in the world, poverty and hunger are increasing. The gap between rich and poor nations has widened, as have inequalities within countries, between social classes, between men and women and between young and old.

A large proportion of the world's population still lacks access to food, education, safe drinking water, sanitation, shelter, land and its resources, employment and health care services. Discrimination continues to prevail. It affects both the occurrence of disease and access to health care.

The planet's natural resources are being depleted at an alarming rate. The resulting degradation of the environment threatens everyone's health, especially the health of the poor. There has been an upsurge of new conflicts while weapons of mass destruction still pose a grave threat.

The world's resources are increasingly concentrated in the hands of a few who strive to maximise their private profit. Neoliberal political and economic policies are made by a small group of powerful governments, and by international institutions such as the World Bank, the International Monetary Fund and the World Trade Organisation. These policies, together with the unregulated activities of transnational corporations, have had severe effects on the lives and livelihoods, health and well-being of people in both North and South.

Public services are not fulfilling people's needs, not least because they have deteriorated as a result of cuts in governments' social budgets. Health services have become less accessible, more unevenly distributed and more inappropriate.

Privatisation threatens to undermine access to health care still further and to compromise the essential principle of equity. The persistence of preventable ill health, the resurgence of diseases such as tuberculosis and malaria, and the emergence and spread of new diseases such as HIV/AIDS are a stark reminder of our world's lack of commitment to principles of equity and justice.

## PRINCIPLES OF THE PEOPLE'S CHARTER FOR HEALTH

- The attainment of the highest possible level of health and well-being is a fundamental human right, regardless of a person's colour, ethnic background, religion, gender, age, abilities, sexual orientation or class.
- The principles of universal, comprehensive Primary Health Care (PHC), envisioned in the 1978 Alma Ata Declaration, should be the basis for formulating policies related to health. Now more than ever an equitable, participatory and intersectoral approach to health and health care is needed.
- Governments have a fundamental responsibility to ensure universal access to quality health care, education and other social services according to people's needs, not according to their ability to pay.
- The participation of people and people's organisations is essential to the formulation, implementation and evaluation of all health and social policies and programmes.
- Health is primarily determined by the political, economic, social and physical environment and should, along with equity and sustainable development, be a top priority in local, national and international policy-making.





## A CALL FOR ACTION

To combat the global health crisis, we need to take action at all levels - individual, community, national, regional and global - and in all sectors. The demands presented below provide a basis for action.

## HEALTH AS A HUMAN RIGHT

Health is a reflection of a society's commitment to equity and justice. Health and human rights should prevail over economic and political concerns.

*This Charter calls on people of the world to:*

- Support all attempts to implement the right to health.
- Demand that governments and international organisations reformulate, implement and enforce policies and practices which respect the right to health.
- Build broad-based popular movements to pressure governments to incorporate health and human rights into national constitutions and legislation.
- Fight the exploitation of people's health needs for purposes of profit.

## TACKLING THE BROADER DETERMINANTS OF HEALTH

**Economic challenges**

The economy has a profound influence on people's health. Economic policies that prioritise equity, health and social well-being can improve the health of the people as well as the economy.

Political, financial, agricultural and industrial policies which respond primarily to capitalist needs, imposed by national governments and international organisations, alienate people from their lives and livelihoods. The processes of economic globalisation and liberalisation have increased inequalities between and within nations. Many countries of the world and especially the most powerful ones are using their resources, including economic sanctions and military interventions, to consolidate and expand their positions, with devastating effects on people's lives.

*This Charter calls on people of the world to:*

- Demand transformation of the World Trade Organisation and the global trading system so that it ceases to violate social, environmental, economic and health rights of people and begins to discriminate positively in favour of countries of the South. In order to protect public health, such transformation must include intellectual property regimes such as patents and the Trade Related aspects of Intellectual Property Rights (TRIPS) agreement.
- Demand the cancellation of Third World debt.
- Demand radical transformation of the World Bank and International Monetary Fund so that these institutions reflect and actively promote the rights and interests of developing countries.
- Demand effective regulation to ensure that TNCs do not have negative effects on people's health, exploit their workforce, degrade the environment or impinge on national sovereignty.
- Ensure that governments implement agricultural policies attuned to people's needs and not to the demands of the market, thereby guaranteeing food security and equitable access to food.
- Demand that national governments act to protect public health rights in intellectual property laws.
- Demand the control and taxation of speculative international capital flows.
- Insist that all economic policies be subject to health, equity, gender and environmental impact assessments and include enforceable regulatory measures to ensure compliance.
- Challenge growth-centred economic theories and replace them with alternatives that create humane and sustainable societies. Economic theories should recognise environmental constraints, the fundamental importance of equity and health, and the contribution of unpaid labour, especially the unrecognised work of women.

**Social and political challenges**

Comprehensive social policies have positive effects on people's lives and livelihoods. Economic globalisation and privatisation have profoundly disrupted communities, families and cultures.





Women are essential to sustaining the social fabric of societies everywhere, yet their basic needs are often ignored or denied, and their rights and persons violated.

Public institutions have been undermined and weakened. Many of their responsibilities have been transferred to the private sector, particularly corporations, or to other national and international institutions, which are rarely accountable to the people. Furthermore, the power of political parties and trade unions has been severely curtailed, while conservative and fundamentalist forces are on the rise. Participatory democracy in political organisations and civic structures should thrive. There is an urgent need to foster and ensure transparency and accountability.

*This Charter calls on people of the world to:*

- Demand and support the development and implementation of comprehensive social policies with full participation of people.
- Ensure that all women and all men have equal rights to work, livelihoods, to freedom of expression, to political participation, to exercise religious choice, to education and to freedom from violence.
- Pressure governments to introduce and enforce legislation to protect and promote the physical, mental and spiritual health and human rights of marginalised groups.
- Demand that education and health are placed at the top of the political agenda. This calls for free and compulsory quality education for all children and adults, particularly girl children and women, and for quality early childhood education and care.
- Demand that the activities of public institutions, such as child care services, food distribution systems, and housing provisions, benefit the health of individuals and communities.
- Condemn and seek the reversal of any policies, which result in the forced displacement of people from their lands, homes or jobs.
- Oppose fundamentalist forces that threaten the rights and liberties of individuals, particularly the lives of women, children and minorities.
- Oppose sex tourism and the global traffic of women and children.

**Environmental challenges**

Water and air pollution, rapid climate change, ozone layer depletion, nuclear energy and waste, toxic chemicals and pesticides, loss of biodiversity, deforestation and soil erosion have far-reaching effects on people's health. The root causes of this destruction include the unsustainable exploitation of natural resources, the absence of a long-term holistic vision, the spread of individualistic and profit-maximising behaviours, and over-consumption by the rich. This destruction must be confronted and reversed immediately and effectively.

*This Charter calls on people of the world to:*

- Hold transnational and national corporations, public institutions and the military accountable for their destructive and hazardous activities that impact on the environment and people's health.
- Demand that all development projects be evaluated against health and environmental criteria and that caution and restraint be applied whenever technologies or policies pose potential threats to health and the environment (the precautionary principle).
- Demand that governments rapidly commit themselves to reductions of greenhouse gases from their own territories far stricter than those set out in the international climate change agreement, without resorting to hazardous or inappropriate technologies and practices.
- Oppose the shifting of hazardous industries and toxic and radioactive waste to poorer countries and marginalised communities and encourage solutions that minimise waste production.
- Reduce over-consumption and non-sustainable lifestyles - both in the North and the South. Pressure wealthy industrialised countries to reduce their consumption and pollution by 90 per cent.
- Demand measures to ensure occupational health and safety, including worker-centred monitoring of working conditions.
- Demand measures to prevent accidents and injuries in the workplace, the community and in homes.
- Reject patents on life and oppose bio-piracy of traditional and indigenous knowledge and resources.





- Develop people-centred, community-based indicators of environmental and social progress, and to press for the development and adoption of regular audits that measure environmental degradation and the health status of the population.

**War, violence, conflict and natural disasters**

War, violence, conflict and natural disasters devastate communities and destroy human dignity. They have a severe impact on the physical and mental health of their members, especially women and children. Increased arms procurement and an aggressive and corrupt international arms trade undermine social, political and economic stability and the allocation of resources to the social sector.

*This Charter calls on people of the world to:*

- Support campaigns and movements for peace and disarmament.
- Support campaigns against aggression, and the research, production, testing and use of weapons of mass destruction and other arms, including all types of landmines.
- Support people's initiatives to achieve a just and lasting peace, especially in countries with experiences of civil war and genocide.
- Condemn the use of child soldiers, and the abuse and rape, torture and killing of women and children.
- Demand the end of occupation as one of the most destructive tools to human dignity.
- Oppose the militarisation of humanitarian relief interventions.
- Demand the radical transformation of the UN Security Council so that it functions democratically.
- Demand that the United Nations and individual states end all kinds of sanctions used as an instrument of aggression which can damage the health of civilian populations.
- Encourage independent, people-based initiatives to declare neighbourhoods, communities and cities areas of peace and zones free of weapons.

- Support actions and campaigns for the prevention and reduction of aggressive and violent behaviour, especially in men, and the fostering of peaceful coexistence.
- Support actions and campaigns for the prevention of natural disasters and the reduction of subsequent human suffering.

## A PEOPLE-CENTERED HEALTH SECTOR

This Charter calls for the provision of universal and comprehensive primary health care, irrespective of people's ability to pay. Health services must be democratic and accountable with sufficient resources to achieve this.

*This Charter calls on people of the world to:*

- Oppose international and national policies that privatise health care and turn it into a commodity.
- Demand that governments promote, finance and provide comprehensive Primary Health Care as the most effective way of addressing health problems and organising public health services so as to ensure free and universal access.
- Pressure governments to adopt, implement and enforce national health and drugs policies.
- Demand that governments oppose the privatisation of public health services and ensure effective regulation of the private medical sector, including charitable and NGO medical services.
- Demand a radical transformation of the World Health Organization (WHO) so that it responds to health challenges in a manner which benefits the poor, avoids vertical approaches, ensures intersectoral work, involves people's organisations in the World Health Assembly, and ensures independence from corporate interests.
- Promote, support and engage in actions that encourage people's power and control in decision-making in health at all levels, including patient and consumer rights.
- Support, recognise and promote traditional and holistic healing systems and practitioners and their integration into Primary Health Care.
- Demand changes in the training of health personnel so that they become more problem-oriented and practice-based, understand better the impact of global issues in





their communities, and are encouraged to work with and respect the community and its diversities.

- Demystify medical and health technologies (including medicines) and demand that they be subordinated to the health needs of the people.
- Demand that research in health, including genetic research and the development of medicines and reproductive technologies, is carried out in a participatory, needs-based manner by accountable institutions. It should be people- and public health-oriented, respecting universal ethical principles.
- Support people's rights to reproductive and sexual self-determination and oppose all coercive measures in population and family planning policies. This support includes the right to the full range of safe and effective methods of fertility regulation.

## PEOPLE'S PARTICIPATION FOR A HEALTHY WORLD

Strong people's organisations and movements are fundamental to more democratic, transparent and accountable decision-making processes. It is essential that people's civil, political, economic, social and cultural rights are ensured. While governments have the primary responsibility for promoting a more equitable approach to health and human rights, a wide range of civil society groups and movements, and the media have an important role to play in ensuring people's power and control in policy development and in the monitoring of its implementation.

*This Charter calls on people of the world to:*

- Build and strengthen people's organisations to create a basis for analysis and action.
- Promote, support and engage in actions that encourage people's involvement in decision-making in public services at all levels.
- Demand that people's organisations be represented in local, national and international fora that are relevant to health.
- Support local initiatives towards participatory democracy through the establishment of people-centred solidarity networks across the world.

## AMENDMENT

After the endorsement of the PCH on December 8, 2000, it was called to the attention of the drafting group that action points number 1 and 2 under Economic Challenges could be interpreted as supporting the social clause proposed by the WTO, which actually serves to strengthen the WTO and its neoliberal agenda. Given that this countervails the PHA demands for change of the WTO and the global trading system, the two paragraphs were merged and amended.

The section of War, Violence and Conflict has been amended to include natural disasters. A new action point, number 5 in this version, was added to demand the end of occupation. Furthermore, action point number 7, now number 8, was amended to read to end all kinds of sanctions. An additional action point number 11 was added concerning natural disasters.

**The People's Health Assembly and the Charter**

The idea of a People's Health Assembly (PHA) has been discussed for more than a decade. In 1998 a number of organisations launched the PHA process and started to plan a large international Assembly meeting, held in Bangladesh at the end of 2000. A range of pre- and post-Assembly activities were initiated including regional workshops, the collection of people's health-related stories and the drafting of a People's Charter for Health. The present Charter builds upon the views of citizens and people's organisations from around the world, and was first approved and opened for endorsement at the Assembly meeting in Savar, Bangladesh, in December 2000. The Charter is an expression of our common concerns, our vision of a better and healthier world, and of our calls for radical action. It is a tool for advocacy and a rallying point around which a global health moment can gather and other networks and coalitions can be formed.

**Join Us - Endorse the Charter**

We call upon all individuals and organisations to join this global movement and invite you to endorse and help implement the People's Charter for Health.

**PHM Global Secretariat**
**Email:** secretariat@phmovement.org
**Web:** www.phmovement.org

**WORLD TRADE ORGANIZATION**

**WT/MIN(01)/DEC/W/2**
14 November 2001

(01-5770)

**MINISTERIAL CONFERENCE**
**Fourth Session**
**Doha, 9 - 14 November 2001**

# DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.

3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

(a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

(b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

(c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

(d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

7. We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

1988

# Criteria for Medicinal Drug Promotion

## Introduction

1. Following the WHO Conference of Experts on the Rational Use of Drugs held in Nairobi in November 1985, WHO prepared a revised drug strategy which was endorsed by the Thirty-third World Health Assembly in May 1986 in resolution WHA39.27. This strategy includes, among other components, the establishment of ethical criteria for drug promotion based on the updating and extension of the ethical and scientific criteria established in 1968 by the Twenty-first World Health Assembly in resolution WHA21.41. The criteria that follow have been prepared in compliance with the above on the basis of a draft elaborated by an international group of experts.

## Objective

2. The main objective of ethical criteria for medicinal drug promotion is to support and encourage the improvement of health care through the rational use of medicinal drugs.

## Ethical criteria

3. The interpretation of what is ethical varies in different parts of the world and in different societies. The issue in all societies is what is proper behaviour. Ethical criteria for drug promotion should lay the foundation for proper behaviour concerning the promotion of medicinal drugs, consistent with the search for truthfulness and righteousness. The criteria should thus assist in judging if promotional practices related to medicinal drugs are in keeping with acceptable ethical standards.

## Applicability and implementation of criteria

4. These criteria constitute general principles for ethical standards which could be adapted by governments to national circumstances as appropriate to their political, economic, cultural, social, educational, scientific and technical situation, laws and regulations, disease profile, therapeutic traditions and the level of development of their health system. They apply to prescription and non-prescription medicinal drugs ("over-the-counter drugs"). They also apply generally to traditional medicines as appropriate,

and to any other product promoted as a medicine. The criteria could be used by people in all walks of life; by governments; the pharmaceutical industry (manufacturers and distributors); the promotion industry (advertising agencies, market research organizations and the like); health personnel involved in the prescription, dispensing, supply and distribution of drugs; universities and other teaching institutions; professional associations; patients' and consumer groups; and the professional and general media (including publishers and editors of medical journals and related publications). All these are encouraged to use the criteria as appropriate to their spheres of competence, activity and responsibility. They are also encouraged to take the criteria into account in developing their own sets of ethical standards in their own field relating to medicinal drug promotion.

5. The criteria do not constitute legal obligations; governments may adopt legislation or other measures based on them as they deem fit. Similarly, other groups may adopt self-regulatory measures based on them. All these bodies should monitor and enforce their standards.

**Promotion**

6. In this context, "promotion" refers to all informational and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal drugs.

7. Active promotion within a country should take place only with respect to drugs legally available in the country. Promotion should be in keeping with national health policies and in compliance with national regulations, as well as with voluntary standards where they exist. All promotion-making claims concerning medicinal drugs should be reliable, accurate, truthful, informative, balanced, up-to-date, capable of substantiation and in good taste. They should not contain misleading or unverifiable statements or omissions likely to induce medically unjustifiable drug use or to give rise to undue risks. The word "safe" should only be used if properly qualified. Comparison of products should be factual, fair and capable of substantiation. Promotional material should not be designed so as to disguise its real nature.

8. Scientific data in the public domain should be made available to prescribers and any other person entitled to receive it, on request, as appropriate to their requirements. Promotion in the form of financial or material benefits should not be offered to or sought by health care practitioners to influence them in the prescription of drugs.

9. Scientific and educational activities should not be deliberately used for promotional purposes.

## Advertising

### (a) Advertisements in all forms to physicians and health-related professionals

10. The wording and illustrations in advertisements to physicians and related health professionals should be fully consistent with the approved scientific data sheet for the drug concerned or other source of information with similar content. The text should be fully legible.

11. Some countries require that advertisements should contain full product information, as defined by the approved scientific data sheet or similar document, for a given period from the date of first promotion or for the full product life. Advertisements that make a promotional claim should at least contain summary scientific information.

12. The following list, based on the sample drug information sheet contained in the second report of the WHO Expert Committee on the Use of Essential Drugs[1] and appended for ease of reference, can serve as an illustration of the type of information that such advertisements should usually contain, among others:

- the name(s) of the active ingredient(s) using either international nonproprietary names (INN) or the approved generic name of the drug;
- the brand name;
- content of active ingredient(s) per dosage form or regimen;
- name of other ingredients known to cause problems;
- approved therapeutic uses;
- dosage form or regimen;
- side-effects and major adverse drug reactions;
- precautions, contra-indications and warnings;
- major interactions;
- name and address of manufacturer or distributor;
- reference to scientific literature as appropriate.

[1] WHO Technical Report Series, No. 722, 1985, p. 43.

13. Where advertisements are permitted without claims (reminder advertisements), they ought to include at least the brand name, the international nonproprietary name or approved generic name, the name of each active ingredient, and the name and address of the manufacturer or distributor for the purpose of receiving further information.

**(b) Advertisements in all forms to the general public**

14. Advertisements to the general public should help people to make rational decisions on the use of drugs determined to be legally available without a prescription. While they should take account of people's legitimate desire for information regarding their health, they should not take undue advantage of people's concern for their health. They should not generally be permitted for prescription drugs or to promote drugs for certain serious conditions that can be treated only by qualified health practitioners, for which certain countries have established lists. To fight drug addiction and dependency, scheduled narcotic and psychotropic drugs should not be advertised to the general public. While health education aimed at children is highly desirable, drug advertisements should not be directed at children. Advertisements may claim that a drug can cure, prevent, or relieve an ailment only if this can be substantiated. They should also indicate, where applicable, appropriate limitations to the use of the drug.

15. When lay language is used, the information should be consistent with the approved scientific data sheet or other legally determined scientific basis for approval. Language which brings about fear or distress should not be used.

16. The following list serves as an illustration of the type of information advertisements to the general public should contain, taking into account the media employed:

- the name(s) of the active ingredients(s) using either international nonproprietary names (INN) or the approved generic name of the drug;
- the brand name;
- major indication(s) for use;
- major precautions, contra-indications and warnings;
- name and address of manufacturer or distributor.

Information on price to the consumer should be accurately and honestly portrayed.

**Medical Representatives**

17. Medical representatives should have an appropriate educational background. They should be adequately trained. They should possess sufficient medical and technical knowledge and integrity to present information on products and carry out other promotional activities in an accurate and responsible manner. Employers are responsible for the basic and continuing training of their representatives. Such training should include instruction regarding appropriate ethical conduct taking into consideration the WHO criteria. In this context, exposure of medical representatives and trainees to feed-back from the medical and allied professions and from independent members of the public, particularly regarding risks, can be salutary.

18. Medical representatives should make available to prescribers and dispensers complete and unbiased information for each product discussed, such as an approved scientific data sheet or other source of information with similar content.

19. Employers should be responsible for the statements and activities of their medical representatives. Medical representatives should not offer inducements to prescribers and dispensers. Prescribers and dispensers should not solicit such inducements. In order to avoid over-promotion, the main part of the remuneration of medical representatives should not be directly related to the volume of sales they generate.

**Free samples of prescription drugs for promotional purposes**

20. Free samples of legally available prescription drugs may be provided in modest quantities to prescribers, generally on request.

**Free samples of non-prescription drugs to the general public for promotional purposes**

21. Countries vary in their practices regarding the provision of free samples of non-prescription drugs to the general public, some countries permitting it, some not. Also, a distinction has to be made between provision of free drugs by health agencies for the care of certain groups and the provision of free samples to the general public for promotional purposes. The provision of free samples of non-prescription drugs to the general public for promotional purposes is difficult to justify from a health perspective. If this practice is legally permitted in any country, it should be handled with great restraint.

**Symposia and other scientific meetings**

22. Symposia are useful for disseminating information. The objective scientific content of such meetings should be paramount, and presentations by independent scientists and health professionals are helpful to this end. Their educational value may be enhanced if they are organized by scientific or professional bodies.

23. The fact of sponsorship by a pharmaceutical manufacturer or distributor should clearly be stated in advance, at the meeting and in any proceedings. The latter should accurately reflect the presentations and discussions. Entertainment or other hospitality, and any gifts offered to members of the medical and allied professions, should be secondary to the main purpose of the meeting and should be kept to a modest level.

24. Any support to individual health practitioners to participate in any domestic or international symposia should not be conditional upon any obligation to promote any medicinal product.

**Post-marketing scientific studies, surveillance and dissemination of information**

25. Post-marketing clinical trials for approved medicinal drugs are important to ensure their rational use. It is recommended that appropriate national health authorities be made aware of any such studies and that relevant scientific and ethical committees confirm the validity of the research. Intercountry and regional cooperation in such studies may be useful. Substantiated information on such studies should be reported to the appropriate national health authorities and disseminated as soon as possible.

26. Post-marketing scientific studies and surveillance should not be misused as a disguised form of promotion.

27. Substantiated information on hazards associated with medicinal drugs should be reported to the appropriate national health authority as a priority, and should be disseminated internationally as soon as possible.

**Packaging and labelling**

28. Appropriate information being important to ensure the rational use of drugs, all packaging and labelling material should provide information consistent with that approved by the country's drug regulatory authority. Where one does not exist or is rudimentary, such material should provide information consistent with that approved by the drug regulatory authority of the country from which the drug is imported or other reliable sources of information with similar content. Any wording and illustration on the

package and label should conform to the principles of ethical criteria enunciated in this document.

**Information for patients: package inserts, leaflets and booklets**

29. Adequate information on the use of medicinal drugs should be made available to patients. Such information should be provided by physicians or pharmacists whenever possible. When package inserts or leaflets are required by governments, manufacturers or distributors should ensure that they reflect only the information that has been approved by the country's drug regulatory authority. If package inserts or leaflets are used for promotional purposes, they should comply with the ethical criteria enunciated in this document. The wording of the package inserts or leaflets, if prepared specifically for patients, should be in lay language on condition that the medical and scientific content is properly reflected.

30. In addition to approved package inserts and leaflets wherever available, the preparation and distribution of booklets and other informational material for patients and consumers should be encouraged as appropriate. Such material should also comply with the ethical criteria enunciated in this document.

**Promotion of exported drugs**

31. Ethical criteria for the promotion of exported drugs should be identical with those relating to drugs for domestic use. It is desirable that exporting and importing countries that have not already done so should use the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.

**Appendix**

Sample Drug Information Sheet[2]

Drug information sheets

Various types of information are needed by prescribers and consumers to ensure the safe and effective use of drugs. The following list is a sample that should be adjusted to meet the needs and abilities of the prescriber.

(1) International Nonproprietary Name (INN) of each active substance.

(2) Pharmacological data: a brief description of pharmacological effects and mechanism of action.

(3) Clinical Information:

- (a) Indications: whenever appropriate, simple diagnostic criteria should be provided.
- (b) Dosage regimen and relevant pharmacokinetic data:
  - ! average and range for adults and children;
  - ! dosing interval;
  - ! average duration of treatment;
  - ! special situations, e.g., renal, hepatic, cardiac, or nutritional insufficiencies that require either increased or reduced dosage.
- (c) Contra-indications.
- (d) Precautions and warnings (reference to pregnancy, lactation, etc.).
- (e) Adverse effects (quantify by category, if possible).
- (f) Drug interactions (include only if clinically relevant; drugs used for self-medication should be included).
- (g) Overdosage:
  - ! brief clinical description of symptoms;
  - ! non-drug treatment and supportive therapy;
  - ! specific antidotes.

(4) Pharmaceutical information:

- (a) Dosage forms.
- (b) Strength of dosage form.
- (c) Excipients.
- (d) Storage conditions and shelf-life (expiry date).
- (e) Pack sizes.
- (f) Description of the product and package.
- (g) Legal category (narcotic or other controlled drug, prescription or non-prescription.
- (h) Name and address of manufacturer(s) and importer(s).

*Copies of the WHO Criteria for Medicinal Drug Promotion are available in English, French, Spanish, Russian, Chinese and Arabic from: World Health Organization, Distribution and Sales, 1211 Geneva 27, Switzerland. Price: Sw.fr.8.-/US$7.20 and in developing countries Sw.fr.5.60.*

[2]Reproduced from *The use of essential drugs: second report of the WHO Expert Committee on the Use of Essential Drugs* (WHO Technical Report Series, No. 722, 1985, p. 43).

Annexe 11

F. No. 5/3/2009-PI-I/PI-II (Vol.III)
Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals
*****

Shastri Bhawan, New Delhi-110 001
Dated, the 12th December, 2014

To

IPA/OPPI/IDMA/CIPI/FOPE/SPIC

**Subject:** Uniform Code of Pharmaceuticals Marketing Practices (UCPMP) – reg.

.....

Sir,

I am directed to refer to this Department's letter of even number dated 19.03.2012 on the subject mentioned above and to enclose a copy of the Uniform Code of Pharmaceuticals Marketing Practices (UCPMP) prepared by the Department of Pharmaceuticals based on the comments/inputs received from various stakeholders on the draft UCPMP.

The UCPMP is to be voluntarily adopted and complied with by the Pharma Industry for a period of six months w.e.f 01.01.2015. It would be reviewed thereafter on the basis of the inputs received.

Yours faithfully,

***Encl: as above***

(Raj Kumar)
Under Secretary to Govt. of India
Tele: 23071162
Telefax: 23385765

# Uniform Code for Pharmaceuticals Marketing Practices (UCPMP)

**This is a voluntary code of Marketing Practices for Indian Pharmaceutical Industry for the present and its implementation will be reviewed after a period of six months from the date of its issue. If it is found that it has not been implemented effectively by the Pharma Associations/Companies, the Government may consider making it a statutory code.**

## 1. General Points

1.1 A drug must not be promoted prior to receipt of the marketing approval by the competent authority, authorizing its sale or supply.

1.2 The promotion of a drug must be consistent with the terms of the marketing approval.

1.3 Information about drugs must be up-to-date, verifiable and accurately reflect current knowledge or responsible opinion.

1.4 Information about drugs must be accurate, balanced, fair, objective, and must not mislead either directly or by implication.

1.5 Information must be capable of substantiation.

1.6 Substantiation that is requested pursuant to para 1.5 above must be provided without delay at the request of members of the medical and pharmacy professions including the members of those professions employed in the pharmaceutical industry.

## 2. Claims & Comparisons

2.1 Claims for the usefulness of a drug must be based on an up-to-date evaluation of all the evidence.

2.2 The word "safe" must not be used without qualification and it must not be stated categorically that a medicine has no side effects, toxic hazards or risk of addiction.

2.3 The word "new" must not be used to describe any drug which has been generally available, or therapeutic indication which has been generally promoted, in India for more than 12 months.

2.4 Comparisons of drugs must be factual, fair and capable of substantiation. In presenting a comparison, care must be taken to ensure that it does not mislead by distortion, by undue emphasis, omission or in any other way.

2.5 Brand names of products of other companies must not be used in comparison unless the prior consent of the companies concerned has been obtained.

2.6 Other companies, their products, services or promotions must not be disparaged either directly or by implication.

2.7 The clinical and/or scientific opinions of members of healthcare professionals must not be disparaged either directly or by implication.

## 3. Textual and Audio-Visual Promotional Material

3.1 All promotional material issued by an authorized holder or with his authority, must be consistent with the requirements of this Code.

3.2 Where the purpose of promotional material is to provide persons qualified to prescribe or supply with sufficient information upon which to reach a decision for prescribing or for use, then the following minimum information, must be given clearly and legibly and must be an integral part of the promotional material:

(i) The relevant drug, the name and address of the holder of the authorization of the drug or the business name and address of the part of the business responsible for placing the drug on the market;

(ii) The name of the drug and a list of the active ingredients using the generic name, placed immediately adjacent to the most prominent display of the name of the drug;

(iii) Recommended dosage, method of use and where not obvious, method of administration;

(iv) Adverse reactions, warnings and precautions for use and relevant contraindications of the product;

(v) A statement that additional information is available on request;

(vi) The date on which the above particulars were generated or last updated.

3.3 Promotional material such as mailings and journal advertisements must not be designed to disguise their real nature. Where a pharmaceutical company pays for or otherwise secures or arranges the publication of promotional material in journals, such promotional material must not resemble editorial matter.

3.4 All promotional materials appearing in journals, the publication of which is paid for or secured or arranged by a company and referring by brand name to any product of that company, must comply with Clause3.3 of this Code as appropriate, irrespective of the editorial control of the material published.

3.5 Promotional material must conform, both in text and illustration, to canons of good taste and must be expressed so as to recognize the professional standing of the recipients and not be likely to cause offence.

3.6 The names or photographs of healthcare professionals must not be used in promotional material.

3.7 Promotional material must not imitate the devices, copy slogans or general layout adopted by other companies in a way that is likely to mislead or confuse.

3.8 Where appropriate (for example, in technical and other informative material), the date of printing or of the last review of promotional material must be stated.

3.9 Postcards, other exposed mailings, envelopes or wrappers must not carry matter which might be regarded as advertising to the lay public or which could be considered unsuitable for public view.

3.10 Audio-visual material must be supported by all relevant printed material so that all relevant requirements of the Code are complied with.

**4. Medical Representatives**

4.1 The term "medical representative" means sales representatives, including personnel retained by way of contract with third parties and any other company representatives who call on healthcare professionals, pharmacies, hospitals or other healthcare facilities in connection with the promotion of drugs.

4.2 Medical representatives must at all times maintain a high standard of ethical conduct in the discharge of their duties. They must comply with all relevant requirements of the Code.

4.3 Medical representatives must not employ any inducement or subterfuge to gain an interview. They must not pay, under any guise, for access to a healthcare professional.

4.4 Companies are responsible for the activities of all their employees including Medical Representatives for ensuring compliance of the Code. This would be additionally ensured by the companies through appropriate clause in the contract

of the employment between the companies and its employees/Medical Representatives.

4.5 Other third parties working for or on behalf of pharmaceutical companies, and those that do not act on behalf of companies (such as joint ventures and licensees) commissioned to engage in activities covered by the Code should also have a good working knowledge of the Code.

**5. Samples**

5.1 Free samples of drugs shall not be supplied to any person who is not qualified to prescribe such product.

5.2 Where samples of products are distributed by a medical representative, the sample must be handed directly to a person qualified to prescribe such product or to a person authorized to receive the sample on their behalf.

5.3 The following conditions shall be observed in the provision of samples to a person qualified to prescribe such product:

(i) Such samples are provided on an exceptional basis only (see (ii) to (vii) below) and for the purpose of acquiring experience in dealing with such a product;

(ii) Such sample packs shall be limited to prescribed dosages for three patients for required course of treatment;

(iii) Any supply of such samples must be in response to a signed and dated request from the recipient;

(iv) An adequate system of control and accountability must be maintained in respect of the supply of such samples;

(v) Each sample pack shall not be larger than the smallest pack present in the market;

(vi) Each sample shall be marked "free medical sample – not for sale" or bear another legend of analogous meaning;

(vii) Each sample shall be accompanied by a copy of the most up-to-date version of the Product Information (As required in Drug and Cosmetic Act,1940) relating to that product.

5.4 A pharmaceutical company shall not supply a sample of a drug which is an anti-depressant, hypnotic, sedative or tranquillizer.

5.5 The companies will maintain details, such as product name, doctor name, Quantity of samples given, Date of supply of free samples distributed to Healthcare practitioners etc.

**6. Gifts**

6.1 No gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to persons qualified to prescribe or supply drugs, by a pharmaceutical company or any of its agents i.e. distributors, wholesalers, retailers etc.

6.2 Gifts for the personal benefit of healthcare professionals and family members(both immediate and extended) (such as tickets to entertainment events) also are not be offered or provided.

**7. Relationship with Healthcare Professionals**

7.1 **Travel facilities**: Companies or their associations/representatives or any person acting on their behalf shall not extend any travel facility inside the country or outside, including rail, air, ship, cruise tickets, paid vacations, etc., to HealthCare Professionals and their family members for vacation or for attending conference, seminars, workshops, CME programme etc. as a delegate. It is hereby clarified that in any seminar, conference or meeting organized by a pharmaceutical company for promoting a drug or disseminating information, if a medical practitioner participates as a delegate , it will be on his/her own cost.

7.2 **Hospitality**: Companies or their associations/representatives shall not extend any hospitality like hotel accommodation to Healthcare Practitioners and their family members under any pretext.

7.3 **Cash or monetary grants:** Companies or their associations/representatives shall not pay any cash or monetary grants to any healthcare professional for individual purpose in individual capacity under any pretext. Funding for medical research, study etc., can only be extended through approved institutions by modalities laid down by law/rules/guidelines adopted by such approved institutions, in a transparent manner. It shall always be fully disclosed.

**Where there is any item missing, the code of MCI as per "Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulation, 2002 as amended from time to time, will prevail.**

**8. Mode of Operation**

8.1 All the Indian Pharmaceutical Manufacturer associations will have UCMP uploaded on their website.

8.2 All the associations will upload the detail procedure (as stated in Para 10) of lodging complaints.

8.3 All the associations will also have a provision on their website for uploading the details of complaints received i.e. the nature of complaint, the company against whom the complaint has been made, the action taken by the committees under the association including the present status in the complaint and such details of a complaint should remain uploaded for three years. The details of proceedings in a complaint and decisions thereafter will be sent by the concerned Association on Quarterly basis, to National Pharmaceutical Pricing Authority, on following address:

**Member Secretary, NPPA,**
**3rd Floor,**
**YMCA Cultural Centre Building,**
**1, Jai Singh Road,**
**New Delhi- 110001.**

8.4 If a complaint received in a particular association is not concerned with its members, the receiving association will input the details of the complaint but in the column of action taken, it will mention that the complaint has been transferred to such and such association as the respondent company is member of the other association.

8.5 In case of companies, who are not a member of any Association or member of more than one Association, the complaint will be handled by the Pharma Industry Association to whom the complainant has addressed the complain. The Association will then, take up the complaint for the required course of action as stipulated in UCPMP.

**9. Committee for Complaint Handling:**

9.1 There will be a committee for handling the complaints named as "**Ethics Committee for Pharma Marketing Practices (ECPMP)**" in each of the associations.

9.2 The committee will have 3 members, represented by the Executive Head of the companies or a nominee from the Executive Head, but not below the rank of Director in the Board of Company.

9.3 In case of conflict of interest, the Head of the association will decide 3 members, who will handle the complaint.

9.4 There will be a review committee for handling the review of the decisions of ECPMP, if any of the parties (complainant or respondent) desire so. This committee will be named as "**Apex Ethics Committee for Pharmaceuticals Marketing Practices (AECPMP)**" and will consist of 5 members, represented by the Executive Head of the companies or a nominee from the Executive Head, but

not below the rank of Director in the Board of Company. The members of the committee will be nominated by the Head of the Association.

**10. Procedure of Lodging a Complaint:**

10.1 All complaints, related to the breach of the code should be addressed to the "Ethics Committee for Pharma Marketing Practices (ECPMP)", Secretary General/Chairman/President, "Name of Association".

10.2 All complaints about any one activity of breach of code should to the extent practicable be made at one time. The complaint must be made within three month of breach of code.

10.3 Complaints must be in writing and for each case **THE COMPLAINANT** should:

i) identify himself (whether a company or an individual) with a full mailing address (fax number, if possible, mobile telephone nos.). When the complaint is from a pharmaceutical company, the complaint must be signed or authorized in writing by the company's managing director or chief executive or equivalent and must state those clauses of the Code which are alleged to have been breached.

ii) identify the company which is alleged to be in breach of the Code, and the name of any company personnel, product or products which are specifically involved.

iii) give the details of the activity which is alleged to be in breach of the Code.

iv) give the date of the alleged breach of the Code.

v) provide supporting evidence of the alleged breach(es).

10.4 A non-refundable amount of Rs.1,000/- is to be deposited by the complainant along with the complaint. **The associations will elaborate how this payment is to be made within a month of issue of the code and upload the same on their website.**

10.5 When it appears from media reports (other than letters to the editor of a publication) that a company may have breached the Code, the matter will be treated as a complaint and the committee may request the concerned publication for further information.

10.6 A published letter, from which it appears that a company may have breached the Code, will be dealt with as a complaint with the author being treated as the complainant.

10.7 Any complaint received by the Department of Pharmaceuticals will also be forwarded to the concerned Association for necessary action. In such cases, the concerned association will further take up the matter with the complainant directly.

**11. Procedure of Handling of Complaints**

11.1 Once a complaint is lodged, the process of enquiry shall be completed by the committee even if it is withdrawn.

11.2 The Head of the association will personally take note of the complaint.

11.3 The Head of the association will refer the complaint to the senior most (by designation) member (Chairman) of ECPMP and also indicate the names of other two members of the committee in case of conflict of interest.

11.4 The decision will be made by majority.

11.5 When the committee(ECPMP) receives information from which it appears that a company may have contravened the Code, the managing director or chief executive or equivalent of the company concerned will be requested to provide a complete response to the matters of complaint.

11.6 To assist companies in ensuring that a complete response is submitted the committee may suggest to the respondent company about the relevant supporting material to be supplied. It is the responsibility of the respondent company to ensure that a full response is submitted.

11.7 The company against which the complaint is made should provide supporting evidence even if it thinks that the Code has not been breached.

11.8 The respondent company shall submit its comments and supporting documents to the committee within 10 working days after receipt of information from the committee.

11.9 The Committee shall render a decision within 30 days of receipt of the complaint with supporting documentation and shall promptly notify the parties of its decision, and the reasons therefore, in writing and by registered mail.

11.10 Where the committee decides no breach of the Code because it considers the matter of complaint is not within the scope of the Code, the complainant will be so advised in writing.

11.11 Where the committee, after enquiry decides that there is breach of the Code, the complainant and the respondent company are so advised in writing and are given the reasons for the decision.

11.12 If there is no request of review within the stipulated period (clause13.4), the decision of ECPMP shall be final and binding, and adherence to the decision shall be a condition of continued membership of the Association. The decisions shall be uploaded on the website of the Association.

## 12. PENALTY PROVISIONS

Once it is established that a breach of code has been made by a company, the committee can propose one of the following decisions against the alleged company to the Head of the Association for action:

(i) To suspend or expel the company from the Association.

(ii) To reprimand the company and publish details of that reprimand.

(iii) To require the company to issue a corrective statement in the media (covering all media) which was used to issue promotional material textual & audio visual; details of the proposed content and mode and timing of

dissemination of the corrective statement must be provided by the company to the committee for approval.

(iv) To ask the company to recover items from the concerned persons, given in violation of the code as stipulated in clauses 6 and 7; details of the action taken must be provided by the company in writing to the Committee.

**13. Review of Decisions of the Complaints:**

13.1 If a party to the complaint is dissatisfied with the decision of ECPMP, it may request for review of the decision from AECPMP. Any party requesting a review of a decision of ECPMP shall notify the same to the Head of the Association.

13.2 The complainant or the respondent company may file a review application for review against a ruling of ECPMP and the ruling of the review committee (AECPMP) shall be final.

13.3 A review by the complainant must be notified within five working days of the notification of the ruling of ECPMP and the review should be lodged within ten working days of notification of the ruling of ECPMP.

13.4 Where the respondent company appeals for review, it must give notice of appeal within five working days of notification of the ruling of ECPMP and must lodge the review within ten working days of notification of the ruling of ECPMP.

13.5 Where review is asked by the complainant, the respondent company shall give comments on the reasons given by the complainant for the review within ten working days and these comments will be circulated to the members of the review committee(AECPMP) and the complainant.

13.6 Where review is asked by the respondent company, the complainant shall give comment on the reasons given by the respondent company for the review within ten working days and these comments will be circulated to the respondent company and to the members of the review committee (AECPMP).

13.7 If AECPMP decides that there is a breach of code, the respondent company will provide a written undertaking within five working days that the promotional activity or use of the material in question and any similar material (if not already discontinued or no longer in use) will cease forthwith and that all possible steps will be taken to avoid a similar breach of the Code in the future. If the decision of the committee is about the recovery of items given in violation of the code, the company will inform the action taken in this regard within fifteen (15) working days. This undertaking must be signed by the managing director or chief executive or equivalent of the company or with his authority and must be accompanied by details of the actions taken by the company to implement the undertaking, including the date on which the promotional material was finally used or appeared and/ or the last date on which the promotional activity took place.

13.8 The final decision of AECPMP and the corrective statements/ actions taken by the concerned company shall be uploaded on the website of the Association.

**14. Finally, the Managing Director/CEO of the company is ultimately responsible for ensuring the adherence to the code and a self declaration, in the format given in annexure shall be submitted by the executive head of the company within two months of date of issue of UCPMP and thereafter within two months of end of every financial year to the Association for uploading the same on the website of the Association. The same must be uploaded on the website of the company also.**

**Annexure**

**A. Self-Declaration By Executive Head Of The Company Regarding Compliance To The Uniform Code For Pharmaceuticals Marketing Practices, to be made within two months of issue of the code**

"This is to declare that .....(name of the company), Headquarters at ....., will comply with the provisions laid down in the Uniform Code for Pharmaceuticals Marketing Practices."

Name and Designation
Seal of the company

**B. Self-Declaration By Executive Head Of The Company Regarding Compliance To The Uniform Code For Pharmaceuticals Marketing Practices, to be made within two months of end of every financial year:**

"This is to declare that .....(name of the company) , Headquarters at ....., has complied with the provisions laid down in the Uniform Code for Pharmaceuticals Marketing Practices . This declaration is for the financial year....."

Name and Designation
Seal of the company

Hai news

Health for all now

Hai news reports on the developments in the international campaign for more rational and fairer health and drug policies worldwide. The communication tool of Health Action International, an informal network of non-governmental organisations and individuals committed to striving for 'health for all now', this newsletter also carries material supportive of the participants' work.

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Double Issue

# People's Health Assembly

## By K. Bala

In 1978, the world community adopted the Alma Ata Declaration - "Health for All by the year 2000" [HFA]. The key to HFA was primary health care [PHC], and community participation in all health related plans, policies and activities was identified as a critical input to the success of HFA.

As early as 1983 the then Director General of the World Health Organization [WHO], Dr Halfdan Mahler, the architect of the Alma Ata Declaration, complained that governments have neglected to give PHC its due place in national health policy and excluded communities and people in any policy planning and implementation.

The abandoning of the Alma Ata Declaration by developing countries led to a paradoxical situation. The world entered the 21st century with very bright hopes. Remarkable gains in health, rapid economic growth and unprecedented scientific advance could lead us to a new era of human progress. But over a billion people entered the 21st century without having benefited from the health revolution; their lifes remain short and scarred by disease. In some countries particularly in sub-saharan Africa there have been increases in infant mortality and decrease in life expectancy.

The Alma Ata Declaration identified active participation by people in health policy planning and implementation. This was completely ignored by governments in developing countries. The People's Health Assembly [PHA] was planned to provide a forum to hear the people's voice and to hear the unheard. The PHA was an international multisectoral initiative aimed at bringing together individual groups, organizations, networks and movements working at community levels and long involved in the struggle for health. All those involved in the PHA believe that health is a fundamental human right that cannot be fulfilled without commitment to equity and social justice. Through the active and collective participation of well-informed and concerned people, the fight for a healthier, more just and sustainable world is certainly possible.

**Editors' note:**

Starting 2001, HAI News will be produced on a quarterly basis.

**HAI News** reports on the developments in national and international campaigns for access to essential drugs, rational drug use and formulation and implementation of national health and drug policies. HAI news is published by Action for Rational Drugs in Asia (ARDA), Consumers International Regional Office for Asia and the Pacific.

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Health Action International (HAI) is an informal network of individuals and NGOs working towards ensuring the availability of and rational use of medicines. Website: http://www.haiweb.org

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The prime objective of the PHA was to give a "voice to the people and make their voices heard" in decisions affecting their health and well-being. It is through collective action that people can change the unjust, unfair and unsustainable top-down process of globalisation and its negative impact on peoples' health and well-being. The PHA process had three phases: pre assembly activities; a major international Assembly and post-assembly activities.

This paper describes the international Assembly held in Gonoshasthaya Kendra, Savar, Bangladesh, December 4-8, 2000.

It was symbolic that the PHA was held in Gonoshasthaya Kendra [GK], an internationally renowned peoples' health complex. GK, a Bangladesh NGO, has constructed a hospital, a generic drugs factory and a medical school. GK put into practice primary health care by training thousands of health workers, mostly women, to raise the health standards in the villages in Bangladesh.

The 1,500 participants from 93 countries saw for themselves that Health for All can be realised with the active participation and empowerment of the people.

The Auditorium to accommodate 1,500 people was a part of the four storey building put up by the people of Bangladesh in about six months.

The second symbolic significance was the time selected for the Assembly - the last month of the year 2000 set by the WHO and UNICEF in Alma Ata, Kazakhstan in 1978 to make healthcare available to everyone.

The architect of the Alma-Ata Declaration, Dr Halfdan Mahler, a former Director-General of the WHO, told the delegates on the opening day that the whole UN system had forgotten the struggle of humanity against inequity and injustice which, among others, include lack of access to basic healthcare services.

The 1,500 participants included health workers, academics, ecologists and grass roots activists. There were more community health activists working at grass-root levels than professional policy advocates. Delegates from developing countries far out-numbered those from industrialised countries. Participants included Palestinian medical workers arriving straight from strife-torn Gaza, Ukraine ecologists from Chernobyl and Maori healthcare providers from New Zealand.

Participants were told that in 1978, the UN system, supporting the Alma Ata Declaration, seriously talked of a New International Economic Order [NIEO] to remedy the growing wealth and technology gap between the developed and developing countries.

The PHA then went on to critically examine the failure of the Alma Ata Declaration. Governments had failed to invest sufficient resources and empower communities and peoples' organizations to ensure the components of primary health care including adequate nutrition, clean water, environmental sanitation, education, maternity and child health, basic healthcare services and provision of essential drugs.

While internal problems in several developing countries contributed to this failure, the more important reason was the policy and budgetary constraints imposed upon these countries by the World Bank [WB], International Monetary Fund [IMF] and the multilateral trade agreements by the World Trade Organization [WTO]. In addition to these, the other perverse influence was the privatization of healthcare in several developing countries. Healthcare in the market removes access to healthcare for the poor.

In spite of this depressing and bleak scenario, several delegates related their own successes to illustrate what could be achieved with determination and organization in spite of difficulties. What these success stories and those achieved by the host GK conveyed to the PHA in song, dance and theatre revealed was that it was not for lack of knowledge or resources that primary health care failed but due to lack of political will from the village to international levels.

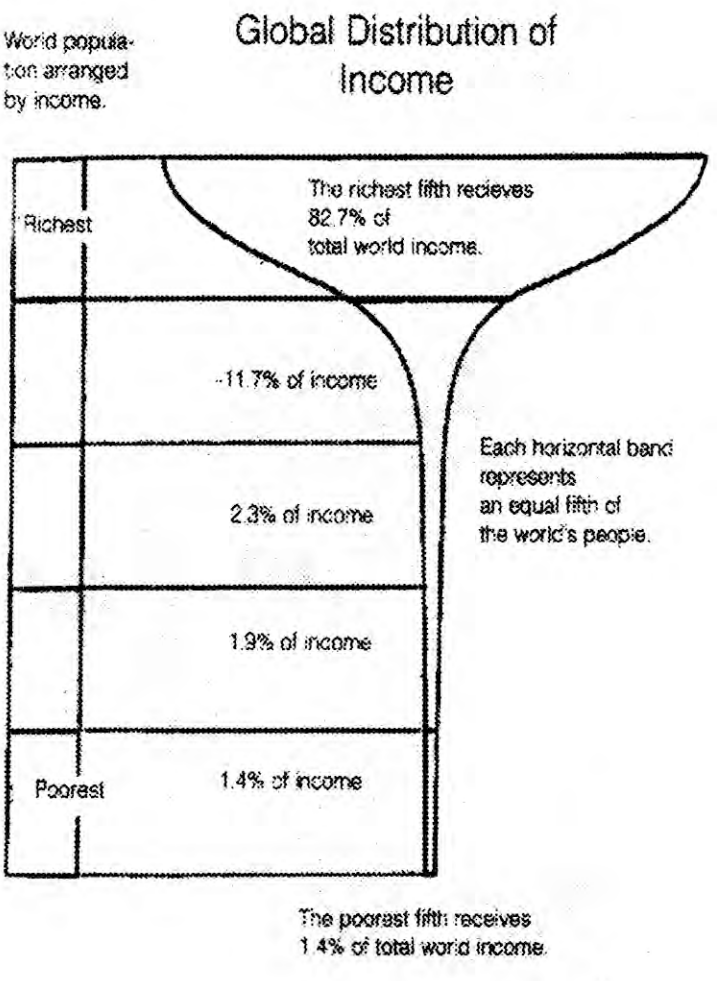
Political will can be mobilised through concerted action of the peoples of the world. The tool to mobilise support would be the Peoples' Charter for Health [PCH] which was unanimously adopted and can be viewed online.
[see http://www.pha2000.org/pch8Dec.html].

The Charter was the result of a bottom up approach that spanned a period of about 18 months. Ideas, suggestions and recommendations were collected at the community level and passed to an analytical group which compiled them and shared several drafts and revisions with health workers, professionals and academics around the globe. The final amendments to the draft were made during the Assembly in GK and presented to the Plenary on 8th December.

The Charter has identified actions for positive changes at local community, national and international levels.

At the international level, the Charter calls for the cancellation of the Third World debt, major changes at the World Bank, IMF and WTO, effective regulations to control the activities of multinational corporations and controls on speculative international capital flows. It also includes provisions on safeguarding the environment and abolition of war and violence.

The Charter calls for a far-reaching coalition of a wide range of diverse sectors and movements including health activists from all nations, NGOs, labour unions, women's and human rights groups, watchdog groups, environmentalists, health promoters, community health workers, progressive political parties, social activists in diverse fields, eco-economists, peace/antiwar and antinuclear groups and groups working for universal health coverage. This wide coalition of like-minded people will use the Peoples' Charter for Health as a lobbying and advocacy tool to assert that health is a fundamental human right and that health and human rights should prevail over economic and commercial concerns and ensure the provision of universal and comprehensive primary health care for all irrespective of peoples' ability to pay.




*Source: Health Wrights, March 2001*

HAI News · No 135 Oct-Dec 2005

# NETWORK NEWS

**ASIA AND THE PACIFIC**

**India**

## India Uses Flexibilities in Changing its Patents Act

The Indian Patents Act,1970 (IPA), one of the most praised Acts for developing indigenous industry in the Third World countries was axed when India gave up opposition to the inclusion of patent in the GATT system in 1993. The US Omnibus Trade and Competitiveness Act adopted Super and Special 301 section in its act to crowbar the market of the Third World countries threatening to impose trade sanction on any foreign country for violation of US domestic Act. The specter of trade sanction by USA haunted the then Prime Minister of India to send his Trade Minister to sign GATT (WTO) Agreement at Marrakech in 1994. This was a great surrender of India along with nearly 150 other nations of the world who well aware of the danger of such agreements signed it to save from imminent onslaught of the US and the EU.

A decade later the ills of TRIPS started erupting with all its ugly manifestations. Nation after nation in the Third World remain vulnerable to the rapid infestation of HIV/AIDS, Malaria, TB and many tropical diseases since the prices of patent covered essential medicines which would have prevented many deaths remained out of reach of the people who needed them the most. Under such a compelling situation, several countries had raised voice and expressed that apart from many deadly diseases TRIPS has become another killer preventing access to medicines among the poor. The Doha meeting amidst anger and dissatisfaction from many nations came out with a declaration even disobeying the sacrosanct rigidity of the TRIPS articles. Finally, the Doha declaration admitted that the amendments to the Agreement would be required.

Under the above circumstances, the Indian government was supposed to change its Patents Act. The first change was made in 1998 to include the applicability of Exclusive Marketing Right (EMR) as required in the TRIPS Agreement for the interim period until product patent was enforced. But in face of strong opposition this change could not come through a Parliamentary process. The change was to be brought as an ordinance (decree) of the President of the country. The same National Democratic Alliance (NDA) government brought an amendment bill for massive change in the IPA in 2003 attempting brick by brick changes in the IPA for a very strong patent regime. The NDA government was changed subsequently and the bill was shelved for some time. The new Congress (I) government came to power with support of the Left Parties from outside. Expressing its helplessness to the obligations of TRIPS Agreement, the govt. rushed to reintroduce the same bill prepared by the NDA Government. in 2003. The Left Parties placed the following to the Commerce Minister to consider while bringing any amendment.

a. To use the spirit of Doha Declaration particularly on Compulsory Licensing and Parallel Imports.

b. To use maximum flexibilities available in the TRIPS Agreement.

c. To take advantage of undefined areas of the TRIPS Agreement.

d. To protect the interest of the largest indigenous pharma ceutical industry in the Third World for supplying essential medicines at a cheaper price.

Left parties prepared necessary clause by clause amendments and pursued with the government but they did not agree for any change under flimsy pretext.

International communi ties also expressed concern of the fact that drastic changes in the IPA may create a situation that Indian medicines now supplied at cheaper prices in many countries would be stopped. The WHO wrote to the Health Minister on 16 December 2004 expressing concern and requested that no unnecessary changes should be made while amending the Act. Similar concern was also expressed by the UNDP. Despite this, the government went ahead

and imposed an ordinance in December 2004 bringing changes of almost all good clauses of IPA. According to the Indian Constitution, such an amendment needs to be passed in the form of an Act in the Parliament or else the amendment remains active only up to six months.

Consequences of the amendment imposed would have been disastrous since it was prepared under the design of the developed countries. It was found that nearly 7000 applications have piled up in the 'Mail Box' following the EMR system and most of them were pharmaceuticals. The amend ment allowed granting of patents with retrospective effect. This would force Indian companies to give up production and sales of many patented products which they had been manufacturing because no product patents were allowed in the existing act. It was estimated that production of 38 medicines so far produced by the Indian companies amounting to sales worth Rs. 40 billion would have to be stopped from March 2005 if the amendment is passed in to an Act. The amendment also made Compulsory Licensing almost ineffective; so were the Parallel Imports. It made opposition of patents impossible but kept the option for secondary patents. Nothing was considered on using the flexibilities available.

Against such attempt of the government, campaigns and protests were raised throughout the country. People's Health Movement (PHM)-India (Jan Swasthya Abhiyan or JSA) prepared a critique of the amendment and circulated it among various groups. JSA also met the Members of the Parliament several times and suggested appropriate amendments to the team of MPs who were negotiating with the Commerce Minister. Conventions were held in almost all large cities which were usually attended by 300 to 500 people from many civic society organizations. Federation of Medical and Sales Representatives' Associations of India (FMRAI), a constituent of JSA declared a protest day when its branches in each town and city staged rallies, street corner meetings and groups meetings. Two big rallies by various groups were staged at Mumbai and at Delhi. Civic society groups in their respective countries staged demonstrations before the Indian Embassies in many places from Paris to South Korea. It is on the wake of such protest and open declaration of the Left parties that they would oppose the bill in the Parliament in the event it endangers the stability of the Congress (I) government, the ministry gave up and finally accepted 13 out of 15 amendments proposed by the Left Parties. The other two amendments were sent to a Parliamentary Committee for consideration.

The amendment was then passed in the Parliament unopposed which is now known as the Indian Patents Amend ment 2005 Act. Following important features of the Act can be mentioned.

1. India was the last developing country to change its Patents Act.
2. India used maximum flexibilities allowed by the TRIPS and Doha Declaration.
3. No other country has dared to maintain so many safeguards for their domestic industry.
4. The changed Act retained many advantages of the former Indian Patents Act, 1970

Narration of some clauses may be necessary to understand the bold stand ultimately the government of India had taken.

Despite dictation by the TRIPS Act, the Indian Act now refuses to give any patent to computer software. It also denied grant of patent to the mailbox applications retrospectively (not from the date of application). Thus the Indian companies who had been producing and selling patented medicines would not be charged for patent infringement. The Act also provides that even after the patent is granted to these medicines, Indian companies would be able to continue production on payment of reasonable royalty to the patent holders.

One most significant feature of the Act is that it protects from secondary patenting of the same pharmaceutical molecule. It forbids patenting of -'salts, esters, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substances...unless they differ significantly in properties with regard to efficacy.'

The Act also provides enough scope for pre and post grant objection of the patents. It describes 11 areas where one can raise objection on granting of patent. This includes objection to patent on already existing knowledge in the public domain (prior art). This holds good for domestic invention and for the materials which are existing through import. "That the invention so far has claimed in any claim of the complete specification was publicly known or publicly used in India before the priority date of the claim"[sec.25(d)] is not patentable.

The Act now has made a provision under Sec. 107A(b) providing for import of patented commodity from anywhere in the world where it is cheaper even though it is patented in India which is known as parallel import. For the purpose it will also not be required to obtain authorization by the patentee. The Act simply says that '(the exporter) who is duly authorized under law to produce and sell or distribute the product' will become the source for Indian importers.

One of the most important areas of the Act is its provisions for Compulsory Licensing. The act clearly directs that 'Compulsory License is granted with a predominant purpose of supply in the Indian market and that the licensee may also export the patented product'. The license shall also be granted to remedy a practice determined after a judicial or administrative process to be anti-competitive. This particular clause may be carefully used to control exorbitantly high prices of patented products.

The issue of Compulsory License had been most important for the availability of medicines in the developing countries. This empowers for the interest of a country to allow a domestic company to produce a particular medicine if the patent holder company do not produce or supply the medicine. Doha Declaration directed the TRIPS Council to review the provisions of Compulsory Licensing and Parallel Imports. This direction was successfully subverted in the decisions of the General Council in their August, 2003 Decision. New guidelines have made Compulsory Licensing more difficult.

In all the above procedure the TRIPS Council shall be required to be consulted. Even after overcoming all the restrictions if Compulsory Licensing can be available for a certain quantity of import and for each import the same procedure would be required to follow whatever little quantity of import may be.

In contrast to this, the Indian Act dared to design its provisions of Compulsory Licensing in a more suitable way for the Indian industry. The Section 92A(1) of the Act says-"Compulsory License will be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public heath problems, provided Compulsory Licensing has been granted by such country or such has, by notification or otherwise, allow importation of the patented pharmaceutical products from India."

In other words, a country may simply by notification announce the need of importing any patented medicine from India which may then be given to any Indian company for manufacturing and export under Compulsory Licensing. The other important section of the Act is that a Compulsory License may be requested on the ground that the establishment or development of commercial activities in India is prejudiced. For the purpose the applicant has to make efforts to obtain a license from the patent holder on reasonable terms and conditions and when such efforts have not been successful within six months, he will be granted a Compulsory License.

It may be noted that such wide allowance for obtaining Compulsory Licesing is not available in the patent laws of any other country. It has therefore caused a lot of dissatisfaction of the developed countries. The US Trade Representative has already expressed that the Indian Patents Act, after amendment is not fully TRIPS compliant and the USA may file complaint to the TRIPS Council against India. The multinational medicine companies have declared that they would not introduce any new medicines or invest in production activity in India unless the Act is substantially changed to suit their purpose.

Even now there are certain areas where the Indian Act would require being more specific for example, data exclusivity which is required for production of

generic medicines. Whenever the patent period of a medicine expires, the test data will always be required for production of generic by any other company. In absence of the test or trial data, production or application for manufacturing license may not be possible for generic manufacturers.

It is now apprehended that sufficient pressure would be poured on the Indian government to change the Act further. A strong international opinion needs to be built up against such pressure whenever such incidents occur.

*Source: Reported by HAIAP member Amitava Guha. He is the Joint General Secretary of the Federation of Medical and Sales Representatives Associations of India and Joint Convener of Jan Swasthya Aviyan (PHM-India).*

# Background document on The Indian Patent Act and TRIPS

Dr. Amit Sengupta, of the National Campaign Committee for Drug Policy
2005 - The Indian Patent Act and TRIPS.

## History of Negotiations

In 1986 a new round of negotiations was initiated under GATT (General Agreement on Tariffs and Trade). Popularly known as the Uruguay Round of negotiations, this new round was used by the developed countries to orient world trade to suit their interests. It was used to introduce a number of issues on the agenda, which were hitherto not considered as trade issues and hence not covered by GATT. Prominent among these were issues related to Patents, Investment, Environment and Labour standards. The ploy was clear - to use the threat of trade embargoes to force developing countries to follow the dictates of developed countries on a whole range of economic and industrial policies on one hand, and on the other to use these new issues to create barriers against developing countries wishing to access the domestic markets of developed countries.

The basis for negotiations was the infamous Dunkel Draft (named after Arthur Dunkel - the key author of the negotiating text). The most contentious portion of the Dunkel Draft was that which related to Patents - termed as Trade Related Intellectual Property Rights (TRIPS) in the Dunkel Draft. Patent is a form of monopoly that is granted to an inventor for a limited period (20 years according to the final agreement), during which the inventor has the sole right to use the invention and benefit from its applications. Patents are granted as an incentive for innovation. At the same time Patent laws all over the world have safeguards to prevent the abuse of the monopoly granted to the Patent holder.

India, since 1970, had a Patent law that was seen by many as a model for other developing countries. The Indian Law stressed on the obligations of the Patent holder and had strong provisions that prevented the abuse of the Patent holder' s monopoly rights. Of particular importance was the fact that the Indian Patent law did not provide for monopoly rights in the area of drugs and agro-chemicals. The results were clear - the Indian drug industry developed to become the strongest and most self-reliant industry in the developing world. Today the campaign on access to drugs draws strength from Indian companies like Cipla who are offering anti-AIDS drugs at one tenth to one fortieth of the prices being charged by large pharmaceutical companies. This became possible because of India s liberal Patent law of 1970.

It was, hence, natural that India (along with Brazil, Argentine, Thailand, etc.) opposed the inclusion of TRIPS in the negotiating agenda. They argued that the issue of Patents was a non-trade issue and that the history of Patent laws across the globe shows that all countries have evolved their domestic laws in consonance with the stage of economic development and development of scientific and technological capabilities. Laws that provide strong Patent protection limit the ability of developing countries to enhance their S&T capabilities and retard dissemination of knowledge. But in the negotiations giant pharmaceutical MNCs railroaded all opposition and forced the signing of the TRIPS accord. The draft which formed the basis of the accord was prepared by industry representatives from the US, Europe and Japan. Curiously, in 1988-89 India made a complete volte-face and agreed to the inclusion of TRIPS in the GATT negotiations. The capitulation by India punctured the opposition of other developing countries, and TRIPS entered the negotiations on world trade. The TRIPS agreement was signed in 1995 (as part of the WTO agreement) and countries like India were provided a transition period of ten years till 2005, to enact laws that were compliant with the provisions of TRIPS.

## Global Opposition to TRIPS

Since 1995, however, public opinion against TRIPS has hardened across the globe. In large measure this is because of the outcry regarding the HIV-AIDS epidemic. Since the nineties almost the whole continent of Africa has come under the grip of this epidemic and in some countries an estimated third of the adult population is infected by HIV. The tragedy was compounded when drugs to contain HIV started being developed. These drugs allowed HIV positive patients the opportunity to live normal lives even if they were infected. But there was a catch. Because of Patent protection these drugs were priced beyond the reach of

patients in developing countries. The ridiculous effect of Patent protection was evident when one found that the cost of treating HIV patients in some African countries was many times their total GNP! Even more ridiculous, and tragic, when we know that these drugs can be produced at one fortieth of prices being charged by MNCs.

HIV infection has become a rallying point for activists from all parts of the world and developing country governments alike. The coalition that was built around the HIV and AIDS issue. Clarifications from the WTO supported the testimony that the TRIPS accord did not prevent country governments from legislating in favour of protection of public health. In this assertion they were supported by almost the entire community of developing nations. The global pharmaceutical MNCs fought to the last to prevent this interpretation. But the momentum of the global movement was able to force the adoption of a declaration at the WTO Ministerial Conference in Doha in November 2001 that clarified that countries could legislate to curb the monopoly powers provided by patent protection to pharmaceutical MNCs, in order to safeguard public health.

## Amendments in the Indian Law

In order to comply with the TRIPS Agreement the Indian Patent Act has been amended twice - in 1999 and 2002. A third Amendment would be moved before January 2005 – the TRIPS deadline. Unfortunately, the previous amendment and the Third Amendment failed even to use the flexibilities available in the TRIPS agreement. As we have seen earlier, the TRIPS agreement was bad for developing countries. The Indian Government made it worse by not even using the possibilities available in the agreement and the clarification issued in the Doha Declaration of 2001. Two significant areas where the Indian Law seeks to go beyond what the TRIPS agreement requires it to, relate to the areas of compulsory licensing and pre-grant opposition.

The former (compulsory licensing) is an instrument that the TRIPS allows by which Governments can allow domestic manufacturers to manufacture patented products within 3 years of their introduction. In the Indian law this provision is still weak and cumbersome. Pre-grant opposition is an instrument by which Patent applications can be challenged and a strong provision would help in limiting the numbers of Patents granted. The new amendment seeks to drastically dilute this provision. What is disturbing is that these provisions in the Indian law are unnecessary for us to comply with the obligations laid down by the TRIPS agreement. In other words, when asked to bend the Government is willing to kneel!

## Implications of a New Law

What are the implications of the new Act? Over a period of time Indian companies will lose the opportunity to develop processes for patent protected drugs in the country. India will become dependent on MNCs for technology to produce new drugs. Votaries of the new Patents Act argue that old drugs will not be affected by this Act. While this is true, it must be understood that the rate of obsolescence of old drugs is extremely fast today. Further, technological dependence on MNCs is the proverbial thin edge which will be used by the MNCs to establish their dominance over the Indian drug market once again (a position they had lost after the mid seventies). They will then again start charging exorbitant prices for drugs in the Indian market. Since the early eighties, the categories of drugs which show the maximum rise in sales are categories which include overwhelming majority of drugs still under Product Patent or whose Product patents have expired recently. In other words - if we had a product patent regime today, the drugs showing fastest growth would have been priced way beyond the capacity of the average consumer. Today Indian companies have been the largest suppliers of low cost drugs to developing countries. For example, an estimated 60% of drugs to treat HIV-AIDS have come from India. The new law will make this impossible, thereby threatening the lives of hundreds of thousands not only in India, but across the globe.

# Text of the Convention

## Contents

# Convention on International Trade in Endangered Species of Wild Fauna and Flora

**Signed at Washington, D.C., on 3 March 1973**
**Amended at Bonn, on 22 June 1979**
**Amended at Gaborone, on 30 April 1983**

The Contracting States,

*Recognizing* that wild fauna and flora in their many beautiful and varied forms are an irreplaceable part of the natural systems of the earth which must be protected for this and the generations to come;

*Conscious* of the ever-growing value of wild fauna and flora from aesthetic, scientific, cultural, recreational and economic points of view;

*Recognizing* that peoples and States are and should be the best protectors of their own wild fauna and flora;

*Recognizing*, in addition, that international co-operation is essential for the protection of certain species of wild fauna and flora against over-exploitation through international trade;

*Convinced* of the urgency of taking appropriate measures to this end;

*Have agreed* as follows:

## Article I Definitions

For the purpose of the present Convention, unless the context otherwise requires:

(a) "Species" means any species, subspecies, or geographically separate population thereof;

(b) "Specimen" means:

(i) any animal or plant, whether alive or dead;

(ii) in the case of an animal: for species included in Appendices I and II, any readily recognizable part or derivative thereof; and for species included in Appendix III, any readily recognizable part or derivative thereof specified in Appendix III in relation to the species; and

(iii) in the case of a plant: for species included in Appendix I, any readily recognizable part or derivative thereof; and for species included in Appendices II and III, any readily recognizable part or derivative thereof specified in Appendices II and III in relation to the species;

(c) "Trade" means export, re-export, import and introduction from the sea;

(d) "Re-export" means export of any specimen that has previously been imported;

(e) "Introduction from the sea" means transportation into a State of specimens of any species which were taken in the marine environment not under the jurisdiction of any State;

(f) "Scientific Authority" means a national scientific authority designated in accordance with Article IX;

(g) "Management Authority" means a national management authority designated in accordance with Article IX;

(h) "Party" means a State for which the present Convention has entered into force.

## Article II Fundamental principles

1. Appendix I shall include all species threatened with extinction which are or may be affected by trade. Trade in specimens of these species must be subject to particularly strict regulation in order not to endanger further their survival and must only be authorized in exceptional circumstances.

2. Appendix II shall include:

   (a) all species which although not necessarily now threatened with extinction may become so unless trade in specimens of such species is subject to strict regulation in order to avoid utilization incompatible with their survival; and

   (b) other species which must be subject to regulation in order that trade in specimens of certain species referred to in sub-paragraph (a) of this paragraph may be brought under effective control.

3. Appendix III shall include all species which any Party identifies as being subject to regulation within its jurisdiction for the purpose of preventing or restricting exploitation, and as needing the co-operation of other Parties in the control of trade.

4. The Parties shall not allow trade in specimens of species included in Appendices I, II and III except in accordance with the provisions of the present Convention.

## Article III Regulation of trade in specimens of species included in Appendix I

1. All trade in specimens of species included in Appendix I shall be in accordance with the provisions of this Article.

2. The export of any specimen of a species included in Appendix I shall require the prior grant and presentation of an export permit. An export permit shall only be granted when the following conditions have been met:

   (a) a Scientific Authority of the State of export has advised that such export will not be detrimental to the survival of that species;

   (b) a Management Authority of the State of export is satisfied that the specimen was not obtained in contravention of the laws of that State for the protection of fauna and flora;

   (c) a Management Authority of the State of export is satisfied that any living specimen will be so prepared and shipped as to minimize the risk of injury, damage to health or cruel treatment; and

   (d) a Management Authority of the State of export is satisfied that an import permit has been granted for the specimen.

3. The import of any specimen of a species included in Appendix I shall require the prior grant and presentation of an import permit and either an export permit or a re-export certificate. An import permit shall only be granted when the following conditions have been met:

   (a) a Scientific Authority of the State of import has advised that the import will be for purposes which are not detrimental to the survival of the species involved;

   (b) a Scientific Authority of the State of import is satisfied that the proposed recipient of a living specimen is suitably equipped to house and care for it; and

   (c) a Management Authority of the State of import is satisfied that the specimen is not to be used for primarily commercial purposes.

4. The re-export of any specimen of a species included in Appendix I shall require the prior grant and presentation of a re-export certificate. A re-export certificate shall only be granted when the following conditions have been met:

   (a) a Management Authority of the State of re-export is satisfied that the specimen was imported into that State in accordance with the provisions of the present Convention;

   (b) a Management Authority of the State of re-export is satisfied that any living specimen will be so prepared and shipped as to minimize the risk of injury, damage to health or cruel treatment; and

   (c) a Management Authority of the State of re-export is satisfied that an import permit has been granted for any living specimen.

5. The introduction from the sea of any specimen of a species included in Appendix I shall require the prior grant of a certificate from a Management Authority of the State of introduction. A certificate shall only be granted when the following conditions have been met:

   (a) a Scientific Authority of the State of introduction advises that the introduction will not be detrimental to the survival of the species involved;

   (b) a Management Authority of the State of introduction is satisfied that the proposed recipient of a living specimen is suitably equipped to house and care for it; and

   (c) a Management Authority of the State of introduction is satisfied that the specimen is not to be used for primarily commercial purposes.

## Article IV — Regulation of trade in specimens of species included in Appendix II

1. All trade in specimens of species included in Appendix II shall be in accordance with the provisions of this Article.

2. The export of any specimen of a species included in Appendix II shall require the prior grant and presentation of an export permit. An export permit shall only be granted when the following conditions have been met:

   (a) a Scientific Authority of the State of export has advised that such export will not be detrimental to the survival of that species;

   (b) a Management Authority of the State of export is satisfied that the specimen was not obtained in contravention of the laws of that State for the protection of fauna and flora; and

   (c) a Management Authority of the State of export is satisfied that any living specimen will be so prepared and shipped as to minimize the risk of injury, damage to health or cruel treatment.

3. A Scientific Authority in each Party shall monitor both the export permits granted by that State for specimens of species included in Appendix II and the actual exports of such specimens. Whenever a Scientific Authority determines that the export of specimens of any such species should be limited in order to maintain that species throughout its range at a level consistent with its role in the ecosystems in which it occurs and well above the level at which that species might become eligible for inclusion in Appendix I, the Scientific Authority shall advise the appropriate Management Authority of suitable measures to be taken to limit the grant of export permits for specimens of that species.

4. The import of any specimen of a species included in Appendix II shall require the prior presentation of either an export permit or a re-export certificate.

5. The re-export of any specimen of a species included in Appendix II shall require the prior grant and presentation of a re-export certificate. A re-export certificate shall only be granted when the following conditions have been met:

   (a) a Management Authority of the State of re-export is satisfied that the specimen was imported into that State in accordance with the provisions of the present Convention; and

   (b) a Management Authority of the State of re-export is satisfied that any living specimen will be so prepared and shipped as to minimize the risk of injury, damage to health or cruel treatment.

6. The introduction from the sea of any specimen of a species included in Appendix II shall require the prior grant of a certificate from a Management Authority of the State of introduction. A certificate shall only be granted when the following conditions have been met:

   (a) a Scientific Authority of the State of introduction advises that the introduction will not be detrimental to the survival of the species involved; and

   (b) a Management Authority of the State of introduction is satisfied that any living specimen will be so handled as to minimize the risk of injury, damage to health or cruel treatment.

7. Certificates referred to in paragraph 6 of this Article may be granted on the advice of a Scientific Authority, in consultation with other national scientific authorities or, when appropriate, international scientific authorities, in respect of periods not exceeding one year for total numbers of specimens to be introduced in such periods.

## Article V — Regulation of trade in specimens of species included in Appendix III

1. All trade in specimens of species included in Appendix III shall be in accordance with the provisions of this Article.

2. The export of any specimen of a species included in Appendix III from any State which has included that species in Appendix III shall require the prior grant and presentation of an export permit. An export permit shall only be granted when the following conditions have been met:

   (a) a Management Authority of the State of export is satisfied that the specimen was not obtained in contravention of the laws of that State for the protection of fauna and flora; and

   (b) a Management Authority of the State of export is satisfied that any living specimen will be so prepared and shipped as to minimize the risk of injury, damage to health or cruel treatment.

3. The import of any specimen of a species included in Appendix III shall require, except in circumstances to which paragraph 4 of this Article applies, the prior presentation of a certificate of origin and, where the import is from a State which has included that species in Appendix III, an export permit.

4. In the case of re-export, a certificate granted by the Management Authority of the State of re-export that the specimen was processed in that State or is being re-exported shall be accepted by the State of import as evidence that the provisions of the present Convention have been complied with in respect of the specimen concerned.

## Article VI — Permits and certificates

1. Permits and certificates granted under the provisions of Articles III, IV, and V shall be in accordance with the provisions of this Article.

2. An export permit shall contain the information specified in the model set forth in Appendix IV, and may only be used for export within a period of six months from the date on which it was granted.

3. Each permit or certificate shall contain the title of the present Convention, the name and any identifying stamp of the Management Authority granting it and a control number assigned by the Management Authority.

4. Any copies of a permit or certificate issued by a Management Authority shall be clearly marked as copies only and no such copy may be used in place of the original, except to the extent endorsed thereon.

5. A separate permit or certificate shall be required for each consignment of specimens.

6. A Management Authority of the State of import of any specimen shall cancel and retain the export permit or re-export certificate and any corresponding import permit presented in respect of the import of that specimen.

7. Where appropriate and feasible a Management Authority may affix a mark upon any specimen to assist in identifying the specimen. For these purposes "mark" means any indelible imprint, lead seal or other suitable means of identifying a specimen, designed in such a way as to render its imitation by unauthorized persons as difficult as possible.

## Article VII — Exemptions and other special provisions relating to trade

1. The provisions of Articles III, IV and V shall not apply to the transit or transhipment of specimens through or in the territory of a Party while the specimens remain in Customs control.

2. Where a Management Authority of the State of export or re-export is satisfied that a specimen was acquired before the provisions of the present Convention applied to that specimen, the provisions of Articles III, IV and V shall not apply to that specimen where the Management Authority issues a certificate to that effect.

3. The provisions of Articles III, IV and V shall not apply to specimens that are personal or household effects. This exemption shall not apply where:

   (a) in the case of specimens of a species included in Appendix I, they were acquired by the owner outside his State of usual residence, and are being imported into that State; or

   (b) in the case of specimens of species included in Appendix II:

      (i) they were acquired by the owner outside his State of usual residence and in a State where removal from the wild occurred;

      (ii) they are being imported into the owner's State of usual residence; and

      (iii) the State where removal from the wild occurred requires the prior grant of export permits before any export of such specimens;

   unless a Management Authority is satisfied that the specimens were acquired before the provisions of the present Convention applied to such specimens.

4. Specimens of an animal species included in Appendix I bred in captivity for commercial purposes, or of a plant species included in Appendix I artificially propagated for commercial purposes, shall be deemed to be specimens of species included in Appendix II.

5. Where a Management Authority of the State of export is satisfied that any specimen of an animal species was bred in captivity or any specimen of a plant species was artificially propagated, or is a part of such an animal or plant or was derived therefrom, a certificate by that Management Authority to that effect shall be accepted in lieu of any of the permits or certificates required under the provisions of Article III, IV or V.

6. The provisions of Articles III, IV and V shall not apply to the non-commercial loan, donation or exchange between scientists or scientific institutions registered by a Management Authority of their State, of herbarium specimens, other preserved, dried or embedded museum specimens, and live plant material which carry a label issued or approved by a Management Authority.

7. A Management Authority of any State may waive the requirements of Articles III, IV and V and allow the movement without permits or certificates of specimens which form part of a travelling zoo, circus, menagerie, plant exhibition or other travelling exhibition provided that:

   (a) the exporter or importer registers full details of such specimens with that Management Authority;

   (b) the specimens are in either of the categories specified in paragraph 2 or 5 of this Article; and

   (c) the Management Authority is satisfied that any living specimen will be so transported and cared for as to minimize the risk of injury, damage to health or cruel treatment.

## Article VIII Measures to be taken by the Parties

1. The Parties shall take appropriate measures to enforce the provisions of the present Convention and to prohibit trade in specimens in violation thereof. These shall include measures:

   (a) to penalize trade in, or possession of, such specimens, or both; and

   (b) to provide for the confiscation or return to the State of export of such specimens.

2. In addition to the measures taken under paragraph 1 of this Article, a Party may, when it deems it necessary, provide for any method of internal reimbursement for expenses incurred as a result of the confiscation of a specimen traded in violation of the measures taken in the application of the provisions of the present Convention.

3. As far as possible, the Parties shall ensure that specimens shall pass through any formalities required for trade with a minimum of delay. To facilitate such passage, a Party may designate ports of exit and ports of entry at which specimens must be presented for clearance. The Parties shall ensure further that all living specimens, during any period of transit, holding or shipment, are properly cared for so as to minimize the risk of injury, damage to health or cruel treatment.

4. Where a living specimen is confiscated as a result of measures referred to in paragraph 1 of this Article:

   (a) the specimen shall be entrusted to a Management Authority of the State of confiscation;

   (b) the Management Authority shall, after consultation with the State of export, return the specimen to that State at the expense of that State, or to a rescue centre or such other place as the Management Authority deems appropriate and consistent with the purposes of the present Convention; and

   (c) the Management Authority may obtain the advice of a Scientific Authority, or may, whenever it considers it desirable, consult the Secretariat in order to facilitate the decision under sub-paragraph (b) of this paragraph, including the choice of a rescue centre or other place.

5. A rescue centre as referred to in paragraph 4 of this Article means an institution designated by a Management Authority to look after the welfare of living specimens, particularly those that have been confiscated.

6. Each Party shall maintain records of trade in specimens of species included in Appendices I, II and III which shall cover:

   (a) the names and addresses of exporters and importers; and

   (b) the number and type of permits and certificates granted; the States with which such trade occurred; the numbers or quantities and types of specimens, names of species as included

in Appendices I, II and III and, where applicable, the size and sex of the specimens in question.

7. Each Party shall prepare periodic reports on its implementation of the present Convention and shall transmit to the Secretariat:

   (a) an annual report containing a summary of the information specified in sub-paragraph (b) of paragraph 6 of this Article; and

   (b) a biennial report on legislative, regulatory and administrative measures taken to enforce the provisions of the present Convention.

8. The information referred to in paragraph 7 of this Article shall be available to the public where this is not inconsistent with the law of the Party concerned.

## Article IX Management and Scientific Authorities

1. Each Party shall designate for the purposes of the present Convention:

   (a) one or more Management Authorities competent to grant permits or certificates on behalf of that Party; and

   (b) one or more Scientific Authorities.

2. A State depositing an instrument of ratification, acceptance, approval or accession shall at that time inform the Depositary Government of the name and address of the Management Authority authorized to communicate with other Parties and with the Secretariat.

3. Any changes in the designations or authorizations under the provisions of this Article shall be communicated by the Party concerned to the Secretariat for transmission to all other Parties.

4. Any Management Authority referred to in paragraph 2 of this Article shall, if so requested by the Secretariat or the Management Authority of another Party, communicate to it impression of stamps, seals or other devices used to authenticate permits or certificates.

## Article X Trade with States not party to the Convention

Where export or re-export is to, or import is from, a State not a Party to the present Convention, comparable documentation issued by the competent authorities in that State which substantially conforms with the requirements of the present Convention for permits and certificates may be accepted in lieu thereof by any Party.

## Article XI Conference of the Parties

1. The Secretariat shall call a meeting of the Conference of the Parties not later than two years after the entry into force of the present Convention.

2. Thereafter the Secretariat shall convene regular meetings at least once every two years, unless the Conference decides otherwise, and extraordinary meetings at any time on the written request of at least one-third of the Parties.

3. At meetings, whether regular or extraordinary, the Parties shall review the implementation of the present Convention and may:

   (a) make such provision as may be necessary to enable the Secretariat to carry out its duties, and adopt financial provisions;

   (b) consider and adopt amendments to Appendices I and II in accordance with Article XV;

   (c) review the progress made towards the restoration and conservation of the species included in Appendices I, II and III;

   (d) receive and consider any reports presented by the Secretariat or by any Party; and

   (e) where appropriate, make recommendations for improving the effectiveness of the present Convention.

4. At each regular meeting, the Parties may determine the time and venue of the next regular meeting to be held in accordance with the provisions of paragraph 2 of this Article.

5. At any meeting, the Parties may determine and adopt rules of procedure for the meeting.

6. The United Nations, its Specialized Agencies and the International Atomic Energy Agency, as well as any State not a Party to the present Convention, may be represented at meetings of the Conference by observers, who shall have the right to participate but not to vote.

7. Any body or agency technically qualified in protection, conservation or management of wild fauna and flora, in the following categories, which has informed the Secretariat of its desire to be represented at meetings of the Conference by observers, shall be admitted unless at least one-third of the Parties present object:

   (a) international agencies or bodies, either governmental or non-governmental, and national governmental agencies and bodies; and

   (b) national non-governmental agencies or bodies which have been approved for this purpose by the State in which they are located.

   Once admitted, these observers shall have the right to participate but not to vote.

## Article XII The Secretariat

1. Upon entry into force of the present Convention, a Secretariat shall be provided by the Executive Director of the United Nations Environment Programme. To the extent and in the manner he considers appropriate, he may be assisted by suitable inter-governmental or non-governmental international or national agencies and bodies technically qualified in protection, conservation and management of wild fauna and flora.

2. The functions of the Secretariat shall be:

   (a) to arrange for and service meetings of the Parties;

   (b) to perform the functions entrusted to it under the provisions of Articles XV and XVI of the present Convention;

   (c) to undertake scientific and technical studies in accordance with programmes authorized by the Conference of the Parties as will contribute to the implementation of the present Convention, including studies concerning standards for appropriate preparation and shipment of living specimens and the means of identifying specimens;

   (d) to study the reports of Parties and to request from Parties such further information with respect thereto as it deems necessary to ensure implementation of the present Convention;

(e) to invite the attention of the Parties to any matter pertaining to the aims of the present Convention;

(f) to publish periodically and distribute to the Parties current editions of Appendices I, II and III together with any information which will facilitate identification of specimens of species included in those Appendices;

(g) to prepare annual reports to the Parties on its work and on the implementation of the present Convention and such other reports as meetings of the Parties may request;

(h) to make recommendations for the implementation of the aims and provisions of the present Convention, including the exchange of information of a scientific or technical nature;

(i) to perform any other function as may be entrusted to it by the Parties.

## Article XIII International measures

1. When the Secretariat in the light of information received is satisfied that any species included in Appendix I or II is being affected adversely by trade in specimens of that species or that the provisions of the present Convention are not being effectively implemented, it shall communicate such information to the authorized Management Authority of the Party or Parties concerned.

2. When any Party receives a communication as indicated in paragraph 1 of this Article, it shall, as soon as possible, inform the Secretariat of any relevant facts insofar as its laws permit and, where appropriate, propose remedial action. Where the Party considers that an inquiry is desirable, such inquiry may be carried out by one or more persons expressly authorized by the Party.

3. The information provided by the Party or resulting from any inquiry as specified in paragraph 2 of this Article shall be reviewed by the next Conference of the Parties which may make whatever recommendations it deems appropriate.

## Article XIV Effect on domestic legislation and international conventions

1. The provisions of the present Convention shall in no way affect the right of Parties to adopt:

   (a) stricter domestic measures regarding the conditions for trade, taking, possession or transport of specimens of species included in Appendices I, II and III, or the complete prohibition thereof; or

   (b) domestic measures restricting or prohibiting trade, taking, possession or transport of species not included in Appendix I, II or III.

2. The provisions of the present Convention shall in no way affect the provisions of any domestic measures or the obligations of Parties deriving from any treaty, convention, or international agreement relating to other aspects of trade, taking, possession or transport of specimens which is in force or subsequently may enter into force for any Party including any measure pertaining to the Customs, public health, veterinary or plant quarantine fields.

3. The provisions of the present Convention shall in no way affect the provisions of, or the obligations deriving from, any treaty, convention or international agreement concluded or which may be concluded between States creating a union or regional trade agreement establishing or maintaining a common external Customs control and removing Customs control between the

parties thereto insofar as they relate to trade among the States members of that union or agreement.

4. A State party to the present Convention, which is also a party to any other treaty, convention or international agreement which is in force at the time of the coming into force of the present Convention and under the provisions of which protection is afforded to marine species included in Appendix II, shall be relieved of the obligations imposed on it under the provisions of the present Convention with respect to trade in specimens of species included in Appendix II that are taken by ships registered in that State and in accordance with the provisions of such other treaty, convention or international agreement.

5. Notwithstanding the provisions of Articles III, IV and V, any export of a specimen taken in accordance with paragraph 4 of this Article shall only require a certificate from a Management Authority of the State of introduction to the effect that the specimen was taken in accordance with the provisions of the other treaty, convention or international agreement in question.

6. Nothing in the present Convention shall prejudice the codification and development of the law of the sea by the United Nations Conference on the Law of the Sea convened pursuant to Resolution 2750 C (XXV) of the General Assembly of the United Nations nor the present or future claims and legal views of any State concerning the law of the sea and the nature and extent of coastal and flag State jurisdiction.

## Article XV Amendments to Appendices I and II

1. The following provisions shall apply in relation to amendments to Appendices I and II at meetings of the Conference of the Parties:

   (a) Any Party may propose an amendment to Appendix I or II for consideration at the next meeting. The text of the proposed amendment shall be communicated to the Secretariat at least 150 days before the meeting. The Secretariat shall consult the other Parties and interested bodies on the amendment in accordance with the provisions of sub-paragraphs (b) and (c) of paragraph 2 of this Article and shall communicate the response to all Parties not later than 30 days before the meeting.

   (b) Amendments shall be adopted by a two-thirds majority of Parties present and voting. For these purposes “Parties present and voting” means Parties present and casting an affirmative or negative vote. Parties abstaining from voting shall not be counted among the two-thirds required for adopting an amendment.

   (c) Amendments adopted at a meeting shall enter into force 90 days after that meeting for all Parties except those which make a reservation in accordance with paragraph 3 of this Article.

2. The following provisions shall apply in relation to amendments to Appendices I and II between meetings of the Conference of the Parties:

   (a) Any Party may propose an amendment to Appendix I or II for consideration between meetings by the postal procedures set forth in this paragraph.

   (b) For marine species, the Secretariat shall, upon receiving the text of the proposed amendment, immediately communicate it to the Parties. It shall also consult inter-governmental bodies having a function in relation to those species especially with a view to obtaining scientific data these bodies may be able to provide and to ensuring co-ordination with any conservation measures enforced by such bodies. The Secretariat shall communicate the views expressed and data provided by these bodies and its own findings and recommendations to the Parties as soon as possible.

   (c) For species other than marine species, the Secretariat shall, upon receiving the text of the proposed amendment, immediately communicate it to the Parties, and, as soon as possible thereafter, its own recommendations.

(d) Any Party may, within 60 days of the date on which the Secretariat communicated its recommendations to the Parties under sub-paragraph (b) or (c) of this paragraph, transmit to the Secretariat any comments on the proposed amendment together with any relevant scientific data and information.

(e) The Secretariat shall communicate the replies received together with its own recommendations to the Parties as soon as possible.

(f) If no objection to the proposed amendment is received by the Secretariat within 30 days of the date the replies and recommendations were communicated under the provisions of sub-paragraph (e) of this paragraph, the amendment shall enter into force 90 days later for all Parties except those which make a reservation in accordance with paragraph 3 of this Article.

(g) If an objection by any Party is received by the Secretariat, the proposed amendment shall be submitted to a postal vote in accordance with the provisions of sub-paragraphs (h), (i) and (j) of this paragraph.

(h) The Secretariat shall notify the Parties that notification of objection has been received.

(i) Unless the Secretariat receives the votes for, against or in abstention from at least one-half of the Parties within 60 days of the date of notification under sub-paragraph (h) of this paragraph, the proposed amendment shall be referred to the next meeting of the Conference for further consideration.

(j) Provided that votes are received from one-half of the Parties, the amendment shall be adopted by a two-thirds majority of Parties casting an affirmative or negative vote.

(k) The Secretariat shall notify all Parties of the result of the vote.

(l) If the proposed amendment is adopted it shall enter into force 90 days after the date of the notification by the Secretariat of its acceptance for all Parties except those which make a reservation in accordance with paragraph 3 of this Article.

3. During the period of 90 days provided for by sub-paragraph (c) of paragraph 1 or sub-paragraph (l) of paragraph 2 of this Article any Party may by notification in writing to the Depositary Government make a reservation with respect to the amendment.

   Until such reservation is withdrawn the Party shall be treated as a State not a Party to the present Convention with respect to trade in the species concerned.

## Article XVI Appendix III and amendments thereto

1. Any Party may at any time submit to the Secretariat a list of species which it identifies as being subject to regulation within its jurisdiction for the purpose mentioned in paragraph 3 of Article II. Appendix III shall include the names of the Parties submitting the species for inclusion therein, the scientific names of the species so submitted, and any parts or derivatives of the animals or plants concerned that are specified in relation to the species for the purposes of sub-paragraph (b) of Article I.

2. Each list submitted under the provisions of paragraph 1 of this Article shall be communicated to the Parties by the Secretariat as soon as possible after receiving it. The list shall take effect as part of Appendix III 90 days after the date of such communication. At any time after the communication of such list, any Party may by notification in writing to the Depositary Government enter a reservation with respect to any species or any parts or derivatives, and until such reservation is withdrawn, the State shall be treated as a State not a Party to the present Convention with respect to trade in the species or part or derivative concerned.

3. A Party which has submitted a species for inclusion in Appendix III may withdraw it at any time by notification to the Secretariat which shall communicate the withdrawal to all Parties. The withdrawal shall take effect 30 days after the date of such communication.

4. Any Party submitting a list under the provisions of paragraph 1 of this Article shall submit to the Secretariat a copy of all domestic laws and regulations applicable to the protection of such species, together with any interpretations which the Party may deem appropriate or the Secretariat may request. The Party shall, for as long as the species in question is included in Appendix III, submit any amendments of such laws and regulations or any interpretations as they are adopted.

## Article XVII Amendment of the Convention

1. An extraordinary meeting of the Conference of the Parties shall be convened by the Secretariat on the written request of at least one-third of the Parties to consider and adopt amendments to the present Convention. Such amendments shall be adopted by a two-thirds majority of Parties present and voting. For these purposes “Parties present and voting” means Parties present and casting an affirmative or negative vote. Parties abstaining from voting shall not be counted among the two-thirds required for adopting an amendment.

2. The text of any proposed amendment shall be communicated by the Secretariat to all Parties at least 90 days before the meeting.

3. An amendment shall enter into force for the Parties which have accepted it 60 days after two-thirds of the Parties have deposited an instrument of acceptance of the amendment with the Depositary Government. Thereafter, the amendment shall enter into force for any other Party 60 days after that Party deposits its instrument of acceptance of the amendment.

## Article XVIII Resolution of disputes

1. Any dispute which may arise between two or more Parties with respect to the interpretation or application of the provisions of the present Convention shall be subject to negotiation between the Parties involved in the dispute.

2. If the dispute can not be resolved in accordance with paragraph 1 of this Article, the Parties may, by mutual consent, submit the dispute to arbitration, in particular that of the Permanent Court of Arbitration at The Hague, and the Parties submitting the dispute shall be bound by the arbitral decision.

## Article XIX Signature

The present Convention shall be open for signature at Washington until 30th April 1973 and thereafter at Berne until 31st December 1974.

## Article XX Ratification, acceptance, approval

The present Convention shall be subject to ratification, acceptance or approval. Instruments of ratification, acceptance or approval shall be deposited with the Government of the Swiss Confederation which shall be the Depositary Government.

## Article XXI Accession

1. The present Convention shall be open indefinitely for accession. Instruments of accession shall be deposited with the Depositary Government.
2. This Convention shall be open for accession by regional economic integration organizations constituted by sovereign States which have competence in respect of the negotiation, conclusion and implementation of international agreements in matters transferred to them by their Member States and covered by this Convention.
3. In their instruments of accession, such organizations shall declare the extent of their competence with respect to the matters governed by the Convention. These organizations shall also inform the Depositary Government of any substantial modification in the extent of their competence. Notifications by regional economic integration organizations concerning their competence with respect to matters governed by this Convention and modifications thereto shall be distributed to the Parties by the Depositary Government.
4. In matters within their competence, such regional economic integration organizations shall exercise the rights and fulfil the obligations which this Convention attributes to their Member States, which are Parties to the Convention. In such cases the Member States of the organizations shall not be entitled to exercise such rights individually.
5. In the fields of their competence, regional economic integration organizations shall exercise their right to vote with a number of votes equal to the number of their Member States which are Parties to the Convention. Such organizations shall not exercise their right to vote if their Member States exercise theirs, and vice versa.
6. Any reference to “Party” in the sense used in Article I (h) of this Convention to “State”/”States” or to “State Party”/”State Parties” to the Convention shall be construed as including a reference to any regional economic integration organization having competence in respect of the negotiation, conclusion and application of international agreements in matters covered by this Convention.

## Article XXII Entry into force

1. The present Convention shall enter into force 90 days after the date of deposit of the tenth instrument of ratification, acceptance, approval or accession, with the Depositary Government.
2. For each State which ratifies, accepts or approves the present Convention or accedes thereto after the deposit of the tenth instrument of ratification, acceptance, approval or accession, the present Convention shall enter into force 90 days after the deposit by such State of its instrument of ratification, acceptance, approval or accession.

## Article XXIII Reservations

1. The provisions of the present Convention shall not be subject to general reservations. Specific reservations may be entered in accordance with the provisions of this Article and Articles XV and XVI.
2. Any State may, on depositing its instrument of ratification, acceptance, approval or accession, enter a specific reservation with regard to:
   (a) any species included in Appendix I, II or III; or
   (b) any parts or derivatives specified in relation to a species included in Appendix III.
3. Until a Party withdraws its reservation entered under the provisions of this Article, it shall be treated as a State not a Party to the present Convention with respect to trade in the particular species or parts or derivatives specified in such reservation.

## Article XXIV Denunciation

Any Party may denounce the present Convention by written notification to the Depositary Government at any time. The denunciation shall take effect twelve months after the Depositary Government has received the notification.

## Article XXV Depositary

1. The original of the present Convention, in the Chinese, English, French, Russian and Spanish languages, each version being equally authentic, shall be deposited with the Depositary Government, which shall transmit certified copies thereof to all States that have signed it or deposited instruments of accession to it.
2. The Depositary Government shall inform all signatory and acceding States and the Secretariat of signatures, deposit of instruments of ratification, acceptance, approval or accession, entry into force of the present Convention, amendments thereto, entry and withdrawal of reservations and notifications of denunciation.
3. As soon as the present Convention enters into force, a certified copy thereof shall be transmitted by the Depositary Government to the Secretariat of the United Nations for registration and publication in accordance with Article 102 of the Charter of the United Nations.

*In witness whereof* the undersigned Plenipotentiaries, being duly authorized to that effect, have signed the present Convention.

*Done* at Washington this third day of March, One Thousand Nine Hundred and Seventy-three.

**Table 1** Summary of analytic framework linking provisions, pathways, and potential impacts

| Provisions | Pathways | Potential impacts on core pharmaceutical policy objectives |
|---|---|---|
| TRIPS-Plus intellectual property protection | • Extended periods of exclusivity for patented medicines and obstacles to market entry for generic and biosimilar medicines can reduce competition and lead governments and consumers to pay monopoly prices for longer periods of time | • Access to affordable medicines may be reduced |
| Investment protection: investor-state dispute settlement mechanism; investment chapter with IP covered in definition of investment | • Disputes, or the threat of a dispute, may cause reversal of pharmaceutical policy decisions or regulatory chill—possibly resulting in extended exclusivity periods, relaxation of regulatory standards or inability to support local producers | • Access to affordable medicines may be reduced<br>• Rational use of medicines may be compromised<br>• Local production and health security may be compromised |
| Procedural requirements for national pharmaceutical pricing and reimbursement programs | • Industry objectives and values may be given priority over public health and access to medicines<br>• Pharmaceutical companies may be given additional opportunities to provide input to, or to contest, decision-making regarding pricing and/or reimbursement<br>• Flexibility regarding prioritization and timing of listing drugs for reimbursement may decrease<br>• Scarce health resources may be diverted towards implementing procedural requirements with no public benefit<br>• Pharmaceutical policy-making may come under pressure from trade partners with large pharmaceutical industries<br>• Excessive prices may not reflect clinical value of medicines | • Access to affordable medicines may be reduced<br>• Rational use of medicines may be compromised |
| Provisions with implications for regulation of pharmaceutical marketing | • Attempts to prohibit or restrict pharmaceutical promotion to health professionals (to encourage better prescribing) or consumers (to encourage better use of medicines) may be reversed or chilled<br>• Restrictions on pharmaceutical marketing may be difficult to enforce (for cross-border advertising services) | • Rational use of medicines may be compromised |
| Regulatory requirements for assessing safety, efficacy and quality | • Standards may be lowered through harmonization to the lowest common denominator, pressure from trade partners to adopt lower standards or greater involvement of the pharmaceutical industry in standard-setting<br>• Pressure to speed up regulatory approval processes may result in increase in safety risks<br>• Constraints on public information about pharmaceutical inspections may compromise safety and quality<br>• Cooperation on pharmaceutical inspection issues may improve the quality of medicines thereby improving consumer safety | • Safety, efficacy and quality of medicines may be compromised<br>• Manufacturing quality of medicines may be lowered or improved |
| Reduction/elimination of tariffs on pharmaceuticals or their ingredients | • Prices of imported pharmaceuticals may fall, in some circumstances (if additional mark-ups are not applied at other points in the supply chain)<br>• Viability of local generic pharmaceutical industry in question if there is greater competition—potentially reducing supply and compromising health security | • Access to affordable medicines may increase<br>• Local production and health security may be compromised |
| Rules applying to government procurement of pharmaceuticals | • Governments/hospitals may pay lower prices as a result of open tendering, depending on the nature of the procurement process and institutions<br>• Viability of fledgling domestic pharmaceutical industries may be reduced if government and hospital purchasing cannot preference local suppliers | • Access to affordable medicines may increase<br>• Local production and health security may be compromised |
| Rules applying to state-owned enterprises and designated monopolies | • Viability of domestic pharmaceutical industry in developing countries may be affected if state-owned pharmaceutical companies are required to operate as commercial entities and cannot be given financial support or preferential treatment, or cannot give preference to local suppliers<br>• Pressure for reform of state owned enterprises may result in greater competition and lower prices | • Local production and health security may be compromised, or improved |
| Procedural requirements for customs administration and trade facilitation | • Movement of generic pharmaceuticals across borders may be impeded, or facilitated, in cases of suspected breaches of IP laws | • Access to affordable medicines may be reduced, or improved |
| Rules applying to regulatory practices, cooperation and coherence | • Pharmaceutical industry may have additional levers to provide input to, or contest pharmaceutical policy<br>• Potential for industry representation on or input to expert advisory groups may compromise optimal pharmaceutical policy outcomes | • Access to affordable medicines may be reduced<br>• Safety, efficacy and quality of medicines may be compromised<br>• Rational use of medicines may be compromised<br>• Local production and health security may be compromised |

**Table 2** Types of TRIPS-Plus IP provisions common in recent regional trade agreements

| Type of provision | Mechanism for prolonging exclusivity |
|---|---|
| Requirement to grant patents for new uses of known products, new methods of using known products, or new processes of using known products | Enables firms to obtain additional patent protection for new forms or uses of existing products, which may reduce the use of equivalent versions after the expiry of primary patents on original molecules. |
| Patent term adjustments to compensate for delays in granting patents and/or in marketing approval processes | Extends the length of patent terms. |
| Data protection for new pharmaceutical products including biologics (an alternative pathway for maintaining monopoly control based on the clinical trial data submitted to regulators in order to gain marketing approval) | Can add to the length of exclusivity if the period of data protection extends beyond the expiration of relevant patents.<br>Can provide monopoly protection for drugs or biologics that are not protected by patents (e.g., where a drug or biologic is not eligible for a patent or where the key patent has been invalidated).<br>Provides a time-limited but absolute monopoly which cannot be challenged in court (as in the case of a patent) and may prevent or delay marketing approval of generics produced under a compulsory or government use license. |
| Additional data protection for new indications/formulations/methods of administration or for combination products containing a chemical entity that has not previously been approved | |
| New and/or longer periods of data protection or market exclusivity for biologic products;[a] | |
| Patent linkage mechanisms (linking patent status with marketing approval of generics); | Can extend periods of exclusivity if marketing approval is denied due to patents of questionable validity, patents that are not being infringed by the generic product or patents for changes that have no direct therapeutic applications. |
| Trade secrets protection | Unlike a patent, trade secret protection does not provide a time-limited monopoly, so it can potentially exclude competition indefinitely.[b] |
| TRIPS-Plus provisions for the enforcement of intellectual property rights | Strict enforcement of, and penalties for, suspected violations of intellectual property rights, including seizure of suspected counterfeit goods at the border (i.e., goods suspected of violating IP rules rather than being of deliberately inferior quality), excessive damages, provisional measures, and criminal enforcement of patent infringement. |

[a]Biologic products are a new class of medicines which are derived from living cells using biotechnological processes and that need to be delivered by injection or intravenously. These include many expensive treatments for cancer and autoimmune diseases, and account for a growing share of the global pharmaceutical market and of pharmaceutical expenditure in many countries. [21]. IMS Institute for Healthcare Informatics. The Global Use of Medicines: Outlook through 2017. IMS Health, 2013

[b]Protection of trade secrets is likely to play an increasing role in excluding competition due to the growing dominance of biologics and the emergence of personalized medicine. The manufacturing processes for developing these newer treatments are very complex, and may make it essentially impossible to create a biosimilar that is identical to the reference product. [22]. Lyman GH, Zon R, Harvey RD, Schilsky RL. Rationale, opportunities, and reality of biosimilar medications. New England Journal of Medicine 2018;378:2036–2044

**Statement of PHM opposition to RCEP at PHA4**

**A Statement of opposition to the Regional Comprehensive Economic Partnership was released at the 4th global People's Health Assembly, Savar Bangladesh, 15-19 November 2018**

We, the undersigned civil society groups and individuals, who are committed to Health For All Now and the principles set out in the Alma-Ata Declaration of 1978, condemn the secretly negotiated Regional Comprehensive Economic Partnership (RCEP) which will erode people's sovereignty and undermine health equity. We call on our governments to reject a RCEP agreement that serves *Ruthless Companies Entrenching Power* and to embrace an alternative RCEP, recognising that *Real Cooperation Empowers People.*

We reject the neoliberal free trade and investment model of RCEP because it will

- Further accelerate the race to the bottom
- deny the people our right to determine the policies that govern our lives and our health
- guarantee that commercial interests have primacy over human rights especially the right to health
- exclude peoples' participation in decisions and shield governments and corporations from accountability
- intensify climate change, the biggest threat to people and planet in the 21 century
- have a destructive impact on women's lives and livelihoods and other vulnerable groups
- worsen job insecurity and workers' rights, especially for exploited and migrant workers
- perpetuate the centuries-long genocide of indigenous peoples
- deny people's sovereignty over food, traditional medicines, and bio-diversity
- further entrench the power of pharmaceutical companies to extract super-profits for medicines and deprive millions of people from affordable treatment
- further promote the privatisation of public health services and profiteering by transnational corporations (TNCs)
- strengthen corporate lobbying and influence over health policy decisions
- embolden alcohol, tobacco, sugar, and processed food industries that are drivers of non-communicable diseases
- endanger national sovereignty by enabling foreign investors to hold our governments to ransom through investor-state dispute settlement (ISDS)
- further erode public revenue through tariff cuts and corporate tax avoidance
- transfer control over health data to untrustworthy private firms to use and abuse
- erect another barrier to a world of health for all, social justice and survival of the planet.

Recognising that *Real Cooperation Empowers People*, we demand an alternative RCEP consistent with the principles of Alma-Ata and which commits to

- the positive pursuit of internationally recognised human rights and health obligations
- universal quality public health services and a valued public health workforce
- actively empower women as the catalysts for personal and community self-determination in health and life
- achieve targets that will genuinely reverse the onset of catastrophic climate change
- guarantee access to affordable medicines through publicly provided health programmes
- food sovereignty, strong food safety standards, and health-based product labelling
- ban toxic agro-chemicals and make agricultural work safe
- impose enforceable obligations on corporations, especially foreign investors, including a strong UN Binding Instrument on Human Rights Responsibilities of TNCs
- guarantee the rights of people to control their health data
- negotiate and implement this alternative through open, participatory and accountable ways, and
- conduct participatory human rights and health impact assessments prior to, during and after agreements to ensure the alternative RCEP deliver on these goals.

**RCEP trade deal could impede post-Covid local industry recovery and ignores labour rights and environmental standards**

## 10 types of provisions in FTAs that can affect access to medicines

Prepared by Deborah Gleeson, Belinda Townsend, et al

**Ten types of provisions in trade agreements that could impact on domestic pharmaceutical policy and regulation:**

1. TRIPS-Plus intellectual property protections;
2. Investment protections, including investor-state dispute settlement;
3. Procedural requirements for pharmaceutical pricing and reimbursement programs;
4. Provisions with implications for regulation of pharmaceutical marketing;
5. Regulatory requirements for assessment of safety, efficacy, and quality;
6. Reduction/elimination of tariffs on medicines or their ingredients;
7. Rules applying to government procurement of pharmaceuticals;
8. Rules applying to state-owned enterprises and designated monopolies;
9. Procedural requirements for customs administration and trade facilitation; and
10. Rules applying to regulatory practices, cooperation and coherence.

- FTAs provide expansive rights and privileges to foreign investors, with the obligation on governments to provide protection of such rights. These provisions can mean that a government is not able to use its own regulatory power over how companies operate within their own country. FTAs can override a country's own legislation that has been put in place to safeguard access to affordable medicines though use of compulsory licence and provision of generics.
- FTAs can prevent governments from imposing conditions on the conduct of business of foreign investors, even when the conditions are imposed in the interests of protecting public health and promoting access to medicines. The host government may be prevented from requiring the domestic producer to continue to produce the essential medicine products locally.
- The broad definitions of 'investment' and the obligation to protect investors and their investments has meant that the tobacco Company Philip Morris has been able to sue both Australia and Uruguay because those countries have anti-tobacco legislation even though the legislation is in the interests of the health of the people. Investor-state dispute settlement mechanisms (ISDS) included in FTAs provide 'the teeth' to force partner countries to meet their obligations allow companies in the developer/investor country to sue a partner country for interference in the profits of the investor. That chapter can interfere with a country's right to use the TRIPS flexibilities such as the Compulsory License clause, the Parallel import clause or the Government Use clause to provide affordable essential medicines and can sue a country that attempts to use its rights to access affordable medicines when there is a clause on the Agreement that provides for the use of the Originator brand from the investor country. (Cross ref Page XXX)
- The ISDS would allow for the possibility that an investor could sue a government on the grounds that the use of compulsory licensing (or another TRIPS flexibility) is in violation of both the provisions of the investment chapter (because there could be a negative impact on the investor's profits) and the provisions of the TRIPS Agreement. [164] Such a course of action would effectively create a TRIPS-plus or WTO-plus forum in which corporations could challenge governments on the implementation of the TRIPS Agreement on the grounds of its effect on investors' rights

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**Draft resolution submitted by the President of the General Assembly**

# Political Declaration of the high-level meeting of the General Assembly on antimicrobial resistance

*The General Assembly*,

*Recalling* its resolutions 70/183 of 17 December 2015 and 70/297 of 25 July 2016, in which it decided to hold a high-level meeting on antimicrobial resistance on 21 September 2016,

*Adopts* the following Political Declaration approved by the high-level meeting of the General Assembly on antimicrobial resistance on 21 September 2016:

## Political Declaration of the high-level meeting of the General Assembly on antimicrobial resistance

We, Heads of State and Government and representatives of States and Governments, meeting at United Nations Headquarters in New York on 21 September 2016, in accordance with General Assembly resolution 70/183, in which the Assembly decided to hold a high-level meeting in 2016 on antimicrobial resistance:

1. Reaffirm that the blueprint for tackling antimicrobial resistance is the World Health Organization global action plan on antimicrobial resistance[1] and its five overarching strategic objectives developed by the World Health Organization in collaboration with, and subsequently adopted by, the Food and Agriculture Organization of the United Nations and the World Organization for Animal Health;

2. Also reaffirm that the 2030 Agenda for Sustainable Development[2] offers a framework to ensure healthy lives, and recall commitments to fight malaria, HIV/AIDS, tuberculosis, hepatitis, the Ebola virus disease and other communicable diseases and epidemics, including by addressing growing antimicrobial resistance

[1] See World Health Organization, document WHA64/2015/REC/1, annex 3.
[2] Resolution 70/1.

and neglected diseases affecting developing countries in particular, while reiterating that antimicrobial resistance challenges the sustainability and effectiveness of the public health response to these and other diseases as well as gains in health and development and the attainment of the 2030 Agenda;

3. Acknowledge that the resistance of bacterial, viral, parasitic and fungal microorganisms to antimicrobial medicines that were previously effective for treatment of infections is mainly due to: the inappropriate use of antimicrobial medicines in the public health, animal, food, agriculture and aquaculture sectors; lack of access to health services, including to diagnostics and laboratory capacity; and antimicrobial residues into soil, crops and water: within the broader context of antimicrobial resistance, resistance to antibiotics, which are not like other medicines, including medicines for the treatment of tuberculosis, is the greatest and most urgent global risk, requiring increased attention and coherence at the international, national and regional levels;

4. Also acknowledge that, due to antimicrobial resistance, many achievements of the twentieth century are being gravely challenged, in particular: the reduction in illness and death from infectious diseases achieved through social and economic development; access to health services and to quality, safe, efficacious and affordable medicines; hygiene, safe water and sanitation; disease prevention in community and health-care settings, including immunization; nutrition and healthy food; improvements in human and veterinary medicine; and the introduction of new antimicrobial and other medicines;

5. Recognize that the above achievements are now gravely challenged by antimicrobial resistance, including: the development of resilient health systems and progress towards the goal of universal health coverage; treatment options for HIV and sexually transmitted infections, tuberculosis and malaria, as well as other infections acquired in community and health-care settings; gains in infection prevention and control in community and health-care settings; advances in agriculture and animal husbandry that help to ensure that the quality of food is preserved; and prevention and treatment options for infectious diseases in veterinary medicine;

6. Also recognize that, due to antimicrobial resistance, there will be fewer options for the protection of people most vulnerable to serious life-threatening infections, especially women giving birth, newborns, patients with certain chronic diseases or those undergoing chemotherapy or surgery;

7. Note with concern that the fulfilment of the right to the enjoyment of the highest attainable standard of physical and mental health, as well as access for millions of people to health services and to quality, safe, efficacious and affordable antimicrobial medicines, food, clean water and a healthy environment, remain a distant goal, especially in developing countries;

8. Also note with concern that while the current lack of access to health services and access to antimicrobial medicines in developing countries contributes to more deaths than antimicrobial resistance, without an effective One Health approach and other multisectoral cooperation and actions, antimicrobial resistance is projected to cause millions of deaths worldwide, with massive social, economic and global public health repercussions;

9. Recognize that the keys to tackling antimicrobial resistance are: the prevention and control of infections in humans and animals, including immunization, monitoring and surveillance of antimicrobial resistance; sanitation, safe and clean water and healthy environments; investing in strong health systems capable of providing universal health coverage; promoting access to existing and new quality safe, efficacious and affordable antimicrobial medicines based, where available, on diagnostic tests; sustained research and development for new antimicrobial and alternative medicines; rapid diagnostic tests, vaccines and other important technologies, interventions and therapies; promoting affordable and accessible health care; and resolving the lack of investment in research and development, including through the provision of incentives to innovate and improve public health outcomes, particularly in the field of antibiotics;

10. Also recognize that the overarching principle for addressing antimicrobial resistance is the promotion and protection of human health within the framework of a One Health approach, emphasize that this requires coherent, comprehensive and integrated multisectoral action, as human, animal and environmental health are interconnected, and in this regard:

(a) Recognize further that effective antimicrobial medicines and their prudent use represent a global public benefit and, for addressing antimicrobial resistance, it is essential to allow people to have access to efficient and resilient health systems; as well as to quality, safe, efficacious and affordable antimicrobial medicines and other technologies, when they are needed; and healthy food and environments;

(b) Underline that basic and applied innovative research and development, including in areas such as microbiology, epidemiology, traditional and herbal medicine and social and behavioural sciences, as appropriate, are needed in order to better understand antimicrobial resistance and to support research and development on quality, safe, efficacious and affordable antimicrobial medicines, especially new antibiotics and alternative therapies, vaccines and diagnostics;

(c) Underline also that all research and development efforts should be needs-driven, evidence-based and guided by the principles of affordability, effectiveness and efficiency and equity, and should be considered as a shared responsibility: in this regard, we acknowledge the importance of delinking the cost of investment in research and development on antimicrobial resistance from the price and volume of sales so as to facilitate equitable and affordable access to new medicines, diagnostic tools, vaccines and other results to be gained through research and development, and welcome innovation and research and development models that deliver effective solutions to the challenges presented by antimicrobial resistance, including those promoting investment in research and development; all relevant stakeholders, including Governments, industry, non-governmental organizations and academics, should continue to explore ways to support innovation models that address the unique set of challenges presented by antimicrobial resistance, including the importance of the appropriate and rational use of antimicrobial medicines, while promoting access to affordable medicines;

(d) Underline further that affordability and access to existing and new antimicrobial medicines, vaccines and diagnostics should be a global priority and

should take into account the needs of all countries, in line with the World Health Organization global strategy and plan of action on public health, innovation and intellectual property,[3] and taking into consideration its internationally agreed follow-up processes;

(e) Improve surveillance and monitoring of antimicrobial resistance and the use of antimicrobials to inform policies and work with stakeholders from industry, agriculture and aquaculture, local authorities and hospitals to reduce antimicrobial residues in soil, crops and water;

(f) Enhance capacity-building, technology transfer on mutually agreed terms and technical assistance and cooperation for controlling and preventing antimicrobial resistance, as well as international cooperation and funding to support the development and implementation of national action plans, including surveillance and monitoring, the strengthening of health systems and research and regulatory capacity, without jeopardizing, in particular in the case of low- and middle-income countries, health or posing barriers for access to care;

(g) Acknowledge that increasing awareness and knowledge on antimicrobial resistance and all of its implications requires the sharing of good practices and findings, collaboration with the media and national and multisectoral actors and the provision of sufficient financing for these activities across sectors;

11. Recognize that national conditions and priorities should be taken into account at all levels, and that relevant sectors of government should be engaged in the development and implementation of multisectoral national action plans, policies, regulations and regional initiatives, taking into account the national context, legislation and jurisdictional responsibilities;

12. We therefore commit to work at national, regional and global levels to:

(a) Develop, in line with World Health Assembly resolution 68.7,[1] multisectoral national action plans, programmes and policy initiatives, in line with a One Health approach and the global action plan on antimicrobial resistance, including its five overarching strategic objectives, with a view to implementing national measures for strengthening appropriate antibiotic use in humans and animals: to support the implementation of such plans, national and international collaboration is needed to assess resource needs and to provide sustained technical and financial investment in shared research, laboratories and regulatory capacities, as well as professional education and training, with a view to safeguarding human health, animal health and welfare and the environment;

(b) Mobilize adequate, predictable and sustained funding and human and financial resources and investment through national, bilateral and multilateral channels to support the development and implementation of national action plans, research and development on existing and new antimicrobial medicines, diagnostics, vaccines and other technologies and to strengthen related infrastructure, including through engagement with multilateral development banks and traditional and voluntary innovative financing and investment mechanisms, based on priorities and local needs set by governments, and ensuring public return on investment;

[3] See World Health Organization, document WHA62/2009/REC/1, resolution 62.16.

(c) Take steps to ensure that national action plans include the development and strengthening, as appropriate, of effective surveillance, monitoring and regulatory frameworks on the preservation, use and sale of antimicrobial medicines for humans and animals that are enforced according to national contexts and consistent with international commitments;

(d) Initiate, increase and sustain awareness and knowledge-raising activities on antimicrobial resistance in order to engage and encourage behavioural change in different audiences; promote evidence-based prevention, infection control and sanitation programmes; the optimal use of antimicrobial medicines in humans and animals and appropriate prescriptions by health professionals; the active engagement of patients, consumers and the general public, as well as professionals, in human and animal health; and professional education, training and certification among health, veterinary and agricultural practitioners; and consider, as appropriate, innovative approaches to increase consumer awareness, giving attention to local conditions and needs;

(e) Support a multisectoral One Health approach to address antimicrobial resistance, including through public health-driven capacity-building activities and innovative public-private partnerships and incentives and funding initiatives, together with relevant stakeholders in civil society, industry, small- and medium-sized enterprises, research institutes and academia, to promote access to quality, safe, efficacious and affordable new medicines and vaccines, especially antibiotics, as well as alternative therapies and medicines to treatment with antimicrobials, and other combined therapies, vaccines and diagnostic tests;

13. Call upon the World Health Organization, together with the Food and Agriculture Organization of the United Nations and the World Organization for Animal Health, to finalize a global development and stewardship framework, as requested by the World Health Assembly in its resolution 68.7, to support the development, control, distribution and appropriate use of new antimicrobial medicines, diagnostic tools, vaccines and other interventions, while preserving existing antimicrobial medicines, and to promote affordable access to existing and new antimicrobial medicines and diagnostic tools, taking into account the needs of all countries and in line with the global action plan on antimicrobial resistance;

14. Call upon the World Health Organization, in collaboration with the Food and Agriculture Organization of the United Nations, the World Organization for Animal Health, regional and multilateral development banks, including the World Bank, relevant United Nations agencies and other intergovernmental organizations, as well as civil society and relevant multisectoral stakeholders, as appropriate, to support the development and implementation of national action plans and antimicrobial resistance activities at the national, regional and global levels;

15. Request the Secretary-General to establish, in consultation with the World Health Organization, the Food and Agriculture Organization of the United Nations and the World Organization for Animal Health, an ad hoc inter-agency coordination group, co-chaired by the Executive Office of the Secretary-General and the World Health Organization, drawing, where necessary, on expertise from relevant stakeholders, to provide practical guidance for approaches needed to ensure sustained effective global action to address antimicrobial resistance, and also

request the Secretary-General to submit a report for consideration by Member States by the seventy-third session of the General Assembly on the implementation of the present declaration and on further developments and recommendations emanating from the ad hoc inter-agency group, including on options to improve coordination, taking into account the global action plan on antimicrobial resistance.

**The Manhattan Principles**

As defined during the meeting titled
*Building Interdisciplinary Bridges to Health in a "Globalized World"* held in 2004

**Background**

In September 2004, WCS convened health experts from around the world to discuss the movements of diseases among human, domestic animal, and wildlife populations. Held at Rockefeller University in New York City, the symposium set priorities for an international, interdisciplinary strategy for combating threats to the health of life on Earth.

**The Manhattan Principles**

These "Manhattan Principles" urge world leaders, civil society, the global health community, and institutions of science to holistically approach the prevention of epidemic/epizootic disease and the maintenance of ecosystem integrity by:

1. Recognizing the link between human, domestic animal, and wildlife health, and the threat disease poses to people, their food supplies and economies, and the biodiversity essential to maintaining the healthy environments and functioning ecosystems we all require.

2. Recognizing that decisions regarding land and water use have real implications for health. Alterations in the resilience of ecosystems and shifts in patterns of disease emergence and spread manifest themselves when we fail to recognize this relationship.

3. Including wildlife health science as an essential component of global disease prevention, surveillance, monitoring, control, and mitigation.

4. Recognizing that human health programs can greatly contribute to conservation efforts.

5. Devising adaptive, holistic, and forward-looking approaches to the prevention, surveillance, monitoring, control, and mitigation of emerging and resurging diseases that fully account for the complex interconnections among species.

6. Seeking opportunities to fully integrate biodiversity conservation perspectives and human needs (including those related to domestic animal health) when developing solutions to infectious disease threats.

7. Reducing demand for and better regulating the international live wildlife and bushmeat trade, not only to protect wildlife populations but to lessen the risks of disease movement, cross-species transmission, and the development of novel pathogen-host relationships. The costs of this worldwide trade in terms of impacts on public health, agriculture, and conservation are enormous, and the global community must address this trade as the real threat it is to global socioeconomic security.

8. Restricting the mass culling of free-ranging wildlife species for disease control to situations where there is a multidisciplinary, international scientific consensus that a wildlife population

poses an urgent, significant threat to human health, food security, or wildlife health more broadly.

9. Increasing investment in the global human and animal health infrastructure commensurate with the serious nature of emerging and resurging disease threats to people, domestic animals and wildlife. Enhanced capacity for global human and animal health surveillance and for clear, timely information-sharing (that takes language barriers into account) can only help improve coordination of responses among governmental and nongovernmental agencies, public and animal health institutions, vaccine / pharmaceutical manufacturers, and other stakeholders.

10. Forming collaborative relationships among governments, local people, and the private and public (i.e. non-profit) sectors to meet the challenges of global health and biodiversity conservation.

11. Providing adequate resources and support for global wildlife health surveillance networks that exchange disease information with the public health and agricultural animal health communities as part of early warning systems for the emergence and resurgence of disease threats.

12. Investing in educating and raising awareness among the world's people and in influencing the policy process to increase recognition that we must better understand the relationships between health and ecosystem integrity to succeed in improving prospects for a healthier planet.

# BANGKOK DECLARATION ON ANTIMICROBIAL RESISTANCE FOOD SYSTEMS AND FARMING

FEBRUARY 2019

***Signatories***

*Alliance to Save Our Antibiotics*
*Centre for Science and Environment*
*Citizen consumer and civic Action Group*
*Consumers' Association of Penang*
*Consumer Online Foundation*
*Ecumenical Pharmaceutical Network*
*European Public Health Alliance*
*Oceana Chile*
*Patient Safety & Access Initiative of India Foundation*
*ReAct – Action on Antibiotic Resistance*
*ReAct Africa*
*ReAct Asia Pacific*
*ReAct Europe*
*ReAct Latin America*
*ReAct Strategic Policy Program*
*Sahabat Alam Malaysia (Friends of the Earth Malaysia)*
*School of Pharmaceutical Sciencea, Universiti Sains Malaysia*
*Society for International Development*
*Third World Network*
*University of Agriculture, Faisalabad, Pakistan*
*Yayasan Orang Tua Peduli (The Concerned and Caring Parents Foundation)*

**Bangkok Declaration on Antimicrobial Resistance, Food Systems and Farming**

**Introduction:**

In most countries, antibiotics are greatly overused and misused in livestock farming, overwhelmingly for growth promotion or for routine disease prevention and control. The increasing industrialization of livestock farming, poor husbandry standards with low levels of animal health and welfare, and the drive to increase productivity and lower food prices are all reasons for the global increase in farm antibiotic use. It has recently been estimated that 73% of all antibiotics are now used in livestock.

There is far greater potential for large and rapid reductions in antibiotic use in farming than in human medicine. Even in Europe, where controls on farm antibiotic use are often tighter than elsewhere, some countries use up to 100 times more antibiotics per unit of livestock than other countries, whereas the differences in human medicine are only three or four-fold. Furthermore, in many low- and middle-income countries (LMICs), farm antibiotic use is very poorly regulated.

There is now an urgent need for strong action in all parts of the world to contain the emergence and spread of antimicrobial resistance (AMR) from animal sources. Governments must take firm regulatory action to address antibiotic misuse and commit adequate resources to support a shift to more sustainable farming practices. The European Union will be banning preventative mass medication on January 28, 2022, and the WHO is calling for similar action around the world, but the US, industry groups and organizations like FAO and OIE do not support this change.

Governments must mobilize technical and financial support for National Action Plan and program implementation, monitor country progress and ensure sustained political commitment to addressing AMR. To address the One Health challenge of antimicrobial resistance, governments, funders and industry must commit to effective innovation of both new technologies, like vaccines and diagnostics, and of sustainable practices for agriculture. Civil society has a key role to play to turn the rising tide of drug-resistant infections by catalyzing change, mobilizing support and resources for implementation, and ensuring accountability of our food system.

While the AMR problem is global, the key contributing factors and preparedness to contain the AMR crisis tend to vary with the local context in different country settings. For example, aiming to reduce meat consumption may not be a useful proposition for a country with low per capita intake of meat and plans to address undernutrition and malnutrition through animal protein. Whereas industrialized country markets have registered success in curbing antimicrobial use in food production through procurement and the labeling of food, the significant role and share of the market not within the reach of the informal economy and wet markets may require different strategies. Therefore, while acknowledging that food-animal production practices in LMICs are influenced by global trends, all solutions and measures proposed must take LMIC context and concerns into account. For instance, all interventions suggested must consider the costs, both real and perceived, for farmers during the transition to production of safer food.

In December 2018, nearly 40 civil society representatives convened from around the world for a three-day conference, "Globalizing Food Campaigns: Sharing Strategies to Address Antimicrobial Resistance" in Bangkok, Thailand. These deliberations build upon the work of the Antibiotic Resistance Coalition (ARC), which brought together in 2014 a One Health alliance of civil society groups with a shared set of principles in the Antibiotic Resistance Declaration. Based on the discussions held during the Bangkok meeting, civil society groups agreed on the following Declaration to guide global action to address AMR through agriculture and food systems globally.

## I. Addressing antibiotic misuse:

*ARC declaration (2014):*

- *The preservation of effective antibiotics for human health should take priority over their use for commercial gain in food production. A disproportionately high amount of antibiotics is used in animals, particularly in the industrial production of food animals. Antibiotics should only be used for treating animals when indicated by a genuine therapeutic need and based on antibiotic therapeutic guidelines.*
- *Antibiotics considered critically important for humans must not be used for animals, except in specific circumstances in order to save life or prevent serious suffering.*
- *Regulations should be instituted and enforced to ensure antibiotics are marked with appropriate warnings and clear distinctions between human and animal use, so as to help control and monitor antibiotic consumption.*
- *Governments should initiate regulatory measures to control the environmental pollution that allows the spread of antibiotic resistant genes across soil, water and air. Environmental movements have an important role in supporting and mobilizing actions towards limiting such pollution.*

1. **Antibiotics are routinely overused and misused in livestock farming all around the world. The preservation of effective antibiotics for human health should take priority over their use for commercial gain in agriculture.**
   - 1.1. A large majority of farm antibiotic use is for growth promotion or for preventative group treatments (prophylaxis). In addition, highest-priority critically important antibiotics (HPCIAs) for human medicine (fluoroquinolones and 3rd and 4th generation cephalosporins), and the last-resort antibiotic colistin are frequently misused in animals, even when other treatments are available.
   - 1.2. In many countries, veterinarians who prescribe antibiotics are also permitted to sell the medicines to the farmers, creating an incentive to overprescribe.
   - 1.3. In some LMICs, animal feed and veterinary products containing antibiotics are not properly labelled, and farmers may be unintentionally giving antibiotics to their animals.
   - 1.4. Antibiotics remain important for the treatment of diseased animals, but should not be used to support poor animal husbandry and intensive and unhygienic conditions for raising livestock.
2. Governments must urgently take **regulatory action** to end routine farm antibiotic use.

2.1. Governments must enforce bans on use for growth promotion and for purely preventative group treatments. Metaphylactic group treatments, where all of the animals in a group are treated even though only some of them have been diagnosed as infected, should be limited to exceptional cases where there is a risk of disease spread, and alternatives are not available. Use of HPCIAs should be limited to the treatment of individual sick animals where sensitivity testing shows alternative treatments are unlikely to work. And no use of the last-resort antibiotic colistin should be permitted in livestock.

2.2. All animal feeds and veterinary products containing antibiotics should be **labelled** as such.

2.3. The 2017 **WHO guidelines** on the use of medically important antibiotics in food-producing animals call for a ban on the use of antibiotics important for human medicine for growth promotion and disease prevention. In 2018, the European Union also adopted legislation to end the overuse of antibiotics in farming by banning purely preventative mass medication of groups of animals from 2022 onwards. Such steps must be coupled with efforts to find, develop and enable the use of alternatives to antimicrobials in agriculture, particularly in resource-limited settings.

2.4. Feeds and veterinary products no longer meeting the respective countries' policies on antimicrobial use must be recalled from the market.

2.5. Governments must **restrict pharmaceutical companies' rights to market** and advertise products for use in food production, banning the promotion of antimicrobials directly to farmers and food animal producers, especially in LMICs.

2.6. **Veterinarians** permitted to prescribe antibiotics should not be permitted to profit from selling the medicines.

2.7. In some settings, efforts to **increase veterinary and implementation capacity including laboratory support** should be targeted along with enforcement of regulations.

2.8. Regulation is not sufficient in all settings due to a lack of veterinarians, testing laboratories and implementation capacity, but it can play an important role in all countries and serve as a baseline for further action.

## II. Sustainable agriculture

*ARC declaration (2014):*

- *Antibiotic use for mass disease prevention must not substitute for good animal husbandry and welfare. Farm practices such as overcrowding, unhygienic conditions, inappropriate diets, and early weaning requiring routine antibiotic administration, must be prohibited.*
- *To help secure effective antibiotics for the future, the role of veterinarians should be delineated, to guide infection prevention and discourage non-therapeutic use of antibiotics.*
- *The Codex Alimentarius, the joint WHO and FAO international food standards, should develop new sets of standards for antibiotic use in food animals which take into account not only residues in food, but also antibiotic resistance.*
- *FAO and OIE should prioritize efforts to ensure radical reductions of antibiotic use in food production and processing, and not shy away from the far-reaching implications this may have on the industrial agriculture model of food production.*

1. **Antibiotic misuse is linked to poor farming systems,** and the link between intensive farming and high antibiotic use needs to be emphasized.
   1.1. The stress associated with intensive, indoor, large-scale production can lead to an increased risk of livestock contracting and transmitting disease. High pathogenic loads and rapid transmission of disease can lead to routine reliance on antibiotic group treatments.
   1.2. Husbandry practices aimed solely at increasing productivity can harm animal health and welfare and result in higher levels of antibiotic use. For example, very early weaning of piglets can result in frequent diarrhoea and high levels of antibiotic treatment or treatment with zinc oxide, which also selects for resistance to medically important antibiotics.
   1.3. Highly productive breeds may have poor disease resistance and require higher levels of antibiotic use. Very fast-growing broilers are more prone to disease than slower-growing breeds and generally require more antibiotic treatments. Highly productive sows can be unable to provide sufficient milk to their high number of piglets. Dairy cows have been selected for very high levels of milk production, resulting in more mastitis and feet problems requiring antibiotic treatment.

2. **A transition to more sustainable farming systems is required.**
   2.1. Antibiotic use for mass prophylaxis (disease prevention) must not substitute for good animal husbandry and welfare. In some intensive farming systems, significant cuts in antibiotic use can be achieved without significantly altering husbandry, through reliance on alternatives like coccidiostats. However, much larger and more sustainable reductions are achievable in less intensive systems with higher levels of animal health and welfare.

2.2. The farming and medication practices promoted by large corporations and integrators, that in many countries dominate production of food animals, should be specially monitored to bring about changes in how antibiotics are used.

2.3. Farming systems that are unable to achieve a sustainable reduction in antibiotic use to very low levels should be phased out. Farm practices such as overcrowding, unhygienic conditions, inappropriate diets and breeds, and early weaning requiring routine antibiotic administration must be discouraged or prohibited.

2.4. Animal husbandry practices that reduce stress, disease incidence and antibiotic use should be encouraged. This should include later weaning, less intensive husbandry, provision of straw, enriched housing, outdoor raising, slower-growing broilers and reduced stocking densities.

3. Strategies to **support the transition** to more sustainable farming methods are needed.

3.1. There is a need for **increased capacity building** to enable the transition to sustainable agriculture, particularly in LMICs. Creating a network of trained veterinarians or similar workforce can help plug the gaps in universal access to veterinary services. In low-resource settings with few veterinarians, other professionals must be trained appropriately to maintain adequate oversight. Collaborative communities connecting farm practitioners should support knowledge dialogues among those working under similar conditions and among people with different areas of expertise. A global and national facility for providing expert advice tailored to LMIC context could be set up to compensate for a lack of trained personnel.

3.2. **Global and national funding is needed to support country-level transition** of agricultural livelihoods to animal husbandry and aquaculture practices less reliant on the use of antimicrobials. With the growing intensification of food production, a financial support mechanism could help small-scale farmers make the necessary transition to achieve a more sustainable farming system, less reliant on antibiotic use. The productivity of farming systems may be lower during the transition towards a more sustainable model, so farmers need to be convinced and supported in making the transition and sustaining change. Establishing insurance schemes could address fears about productivity losses associated with the withdrawal of routine antibiotic use. Market-altering mechanisms are needed to ensure sustainable change and promote supply chains for responsibly raised livestock and fish.

4. **Antimicrobial misuse and overuse on farms lead to the spread of antimicrobial residues, resistant bacteria and other AMR determinants through the environment.** The environmental aspect of AMR needs to be considered when advocating for sustainable food production models.

4.1. **Governments** should ensure that all food-animal farms, slaughter houses, fish, meat and dairy-processing units, animal-feed manufacturing units, and veterinary-care units are registered. They should also develop guidelines for siting, biosecurity and land

application of manure as well as Standard Operating Procedures (SOPs) and standards for antibiotic residues in waste.

4.2. The government should encourage less risky waste management approaches such as in cases where sewage or manure is used as bio-fertilizers. These could include, for example, biogas generation, proper litter and manure composting before land application and preventing the use of poultry litter in aquaculture. Governments should also ensure that safe disposal practices are adopted for unused antibiotics and that programs for drug take-back across the supply chain are weaved into existing producer-responsibility programs.

4.3. A major part of antibiotic pollution could be best addressed by **eliminating antibiotic misuse** in the first place. Towards this, private players engaging in intensive food-animal production should focus on eliminating antibiotic misuse in addition to ensuring an AMR-centric approach to waste management.

4.4. **Improper waste management or antibiotic disposal** (e.g., discharge of untreated effluent from pharmaceutical manufacturing industries or disposal of unused antibiotics from farms, factories and domestic settings) can pave the way for entry of antibiotic residues in the larger external environment and contaminate the input water for aquaculture and agriculture farms. Therefore, appropriate waste management at all other sources which are manufacturing or using antibiotics should also be ensured.

4.5. **Greater disclosure** by antibiotic and feed manufacturers, retailers and food animal producers on the amount of antibiotics sold, procured, used and discharged as effluent would enable better assessment of antibiotics in the environment and of the contributions of different sectors. Standards and guidelines that help harmonize testing methods, analysis and reporting across different sectors, sub-sectors and geographies should be formulated.

4.6. Research efforts should focus on **environmental risk assessments** that can serve as a basis for evidence-based regulations and on strategies to remove antibiotic residues from environmental discharge.

## III. Procurement

*ARC Declaration (2014):*

- *Food produced without routine use of antibiotics and without antibiotic residues should be labelled through reliable, certified schemes to facilitate consumer choice. Food produced with routine use of antibiotics must be clearly labelled, until effective prohibition of such antibiotic use can be introduced.*
- *Food produced without antibiotics in animal feed, or routinely used in any other way for its production, should be a pre-requisite in all public procurement of food. Hospitals should take a leadership role in procuring food produced without routine use of antibiotics, as doing so is consistent with their core health mission.*
- *Civil society and consumer movements should target the supply chain by exposing and boycotting corporations that produce or provide food with routine use of antibiotics.*

1. **Companies and governments should establish procurement policies** that meet WHO guidelines*. Policies should be documented publicly, phased in over a reasonable time frame, and include third-party verification.
    1. *Medically important antibiotics used only for the treatment of sick animals. No use allowed for growth promotion or routine disease prevention purposes. Limited use to treat a diagnosed illness or outbreak.

2. **Procurement, particularly by the public sector,** can powerfully shape how food products are sourced and raised without the routine use of antibiotics. Consumer groups can ask those institutions in a position to procure, such as schools, hospitals, restaurants, grocery chains, the military, railways and airlines, for 1) public commitment to source food products raised without the routine use of antibiotics; 2) clear timelines for following through on this public commitment; and 3) agreement to independent, verifiable audit of compliance with such commitment. The recent improvements in antibiotic policies by big food chains in North America should be applied throughout their global markets and in LMICs. Depending on the country context, these restaurants or retail food outlets may not command as significant share of the market, and so the effective reach of these campaigns will vary in different settings.

3. Procurement and supply chain policies must include **environmentally preferable purchasing criteria** to guide manufacturers, producers, suppliers, and distributors to be accountable to responsible antimicrobial use and associated pollution. As an example within the healthcare sector, Health Care Without Harm has shown how a virtual global network of hospitals and health systems can work to achieve measurable improvements in greening the practices of these institutions through the “Global Green and Healthy Hospitals” project.

4. Consistent with the regulatory guidance established under the Codex Alimentarius Commission, standards for **antibiotic labelling to consumers** should be established for food animal products to increase consumer awareness and enable consumers to leverage their demand to shape the market. The labelling standards should contain unambiguous and strict limitations on preventative use and ban growth promotion. Preventative use should be limited to individual treatment, as allowing for therapeutic use of antibiotics in food-animals should not compensate for poor animal husbandry. Labeling should be simple, mandatory and reflect adherence to this standard. Standard labels can also enable traceability of meat products.

5. All **feed used in food animal production should also be labelled** as containing antibiotics or being free of antibiotics. All veterinary products, if containing antimicrobial agents, should be clearly labeled as “antibiotics” in the local language instead of just listing their individual ingredients. Medicated feed for therapeutic use should be labelled as such, including a clear indication of the drug withdrawal period to prevent antibiotic residues in meat. Countries

should implement strong National Regulations for quality control and appropriate use of medicated feed in animal agriculture.

## IV. Monitoring for accountability

*ARC Declaration (2014):*

- *All countries should participate in a global surveillance system that promotes and supports infrastructure and periodic survey data to assess animal antibiotic use and resistance patterns in farm animals and foods.*

1. The **critical data** to collect includes:
   - Antibiotic production, sales, price, volume exported or imported in trade and consumption by sector (human/animal), species (e.g. aquaculture, poultry), purpose (treatment, metaphylactic, prophylactic, growth promotion), class, and farming system (intensive, extensive, organic, etc.)
   - Amount and class of antibiotics used per company
   - Antibiotic resistant bacteria in animals
   - Antibiotic residues and resistant bacteria in meat
   - Antibiotic residues and resistant bacteria in waste of farms and processing units (and fate of unused antibiotic)
   - Progress vis-à-vis antibiotic reduction targets

2. **Aggressive targets for reductions** in antimicrobial use should be set. Some countries have already achieved large reductions in just a few years. Setting easy-to-achieve targets could slow down progress, so targets must be ambitious. National Action Plans (NAP) are ambitious, so expectations should be set accordingly.
3. **Rather than a "one size fits all" approach, both indicators and programs could lay out a series of stepping stones**, with expectations growing as local infrastructure and capacity do and as external technical and financial support is received. These stepping stones would take into account the country's stage of development, level of resources, and local context such as the size of the livestock industry. By offering a tiered approach, lower resourced countries might participate in the global reporting system at an earlier stage. By setting country-level targets for AMR reduction, governments working with different assets and resources might chart different pathways to the same goals. Flexibility in adapting the modalities of tackling AMR to the local context is key.
4. There is a need for governments and intergovernmental organizations to support and promote **data transparency**, which makes benchmarking, the setting of meaningful targets, and monitoring for accountability feasible. Making the data publicly available would allow for analysis, comparison, and accountability from these findings. At the country level, non-transparency sometimes results not from lack of capacity to collect such data, but from a wish to prioritize commercial confidentiality. Public health concerns should override concerns over

commercial confidentiality, and all collected data on antimicrobial use must be publicly disclosed. Providing information may be a burden on companies and governments but is critical for civil society to hold them accountable.

5. There is a need for a **harmonized system** to measure and compare antimicrobial use across different systems (hospitals, communities, plant and animal agriculture) and across countries. **Scorecards** can serve as a powerful tool for accountability, enabling civil society, professional societies, governments, intergovernmental organizations and other groups to perform cross-country and stakeholder comparisons. The use of scorecards for key procurers of food products can help motivate data transparency and also public accountability for effective stewardship of antimicrobials in the food production process. The successful model provided by the Chain Reaction Antibiotics Scorecard, which rates the top U.S. restaurant chains on their antibiotic policies and practices, could be applied to other corporations, hospitals, hotels, schools and public-sector networks. Scorecards could be expanded to include details such as amount, types and classes of antibiotics used, antibiotic used per kilogram of meat, use of Highest Priority Critically Important Antibiotics, Critically Important Antibiotics and medically important antibiotics, purpose of use (treatment, metaphylactic, prophylactic, growth promotion), and routes for use (feed, water, injectables).
6. **Trade data** on antimicrobials could help target the biggest importers and exporters of antimicrobials for food production and of food animal products for a targeted response. The trade of food animal products is concentrated into the hands of a few countries, both on the export and on the import sides. Therefore, the impact of AMR-related trade restrictions by importing countries on the adoption of more sustainable food production deserves further analysis.

## V. Linking AMR to other global priorities and movements

1. AMR ties into various **ongoing global movements**. Mainstreaming AMR into broader universal health coverage, sustainable development, food system and environment agendas is key, both to scaling and to sustaining efforts to address AMR. The impact of antibiotic use in agriculture and of intensive agricultural systems on climate change and planetary health cannot be neglected. Antibiotic discharge and residue mitigation should be considered in shaping environmental discharge regulations. The link between high meat consumption and non-communicable diseases should also be highlighted, as should the link between high meat consumption and greenhouse gas emissions.
2. Antibiotic access and resistance play important roles in achieving the **Sustainable Development Goals**. Tackling AMR is a priority that can and should be addressed in SDG2 (Zero Hunger), but also in SDG12 (Ensure sustainable consumption and production patterns), thereby considering reduction of food waste and changes in the food production model. AMR-specific indicators, both in healthcare and food-production systems, should be integrated with the Sustainable Development Goals.
3. On the consumer side, AMR should be incorporated into movements advocating for **sustainable healthy diets** by promoting “fewer but better” meat products, farming systems that ensure fair

prices for farmers and adequate labor conditions for food workers, and agricultural systems with high animal welfare standards. It is estimated that antimicrobial consumption will increase by 67% by 2030, two thirds of which is due to an increase in the number of animals raised for food production. Decreasing the demand for animal products in the appropriate country settings (mostly high- and middle-income countries) can therefore both improve diets for health reasons and decrease antimicrobial use.

4. Meeting the **food security** goals of SDG 2 does not necessarily imply increasing production of all food system models. Increasing industrial farming for animal production is not sustainable. According to the European Food Safety Authority and the European Medicines Agency, "The stress associated with intensive, indoor, large scale production may lead to an increased risk of livestock contracting disease." These European agencies say that some intensive farming systems rely on routine antimicrobial use, and therefore may be "unsustainable in the absence of antimicrobials". According to the UK Review on Antimicrobial Resistance, growth promotion and preventative treatments are "particularly prevalent in intensive agriculture, where animals are kept in confined conditions"., Instead of further intensification, more sustainable food-production practices are the solution, not the challenge, to achieving adequate food security and concurrently lowering antimicrobial use in this sector.
5. To enable civil society to do its part, intergovernmental organizations and funders should support a **Civil Society Challenge Facility for AMR**, independently administered, financed with public sector monies, and capable of enabling global, regional and local as well as cross-sectoral action to tackle antimicrobial resistance.

सत्यमेव जयते

Government of India

# Delhi Declaration on Antimicrobial Resistance

## – *an inter-ministerial consensus*

We, the ministers and policy-makers from various Ministries under the Government of India, assembled at the Inter-Ministerial Consultation on Antimicrobial Resistance, pledge to adopt a holistic and collaborative approach towards prevention and containment of antimicrobial resistance (AMR) in India, and :

**Acknowledge** that resistance of microorganisms to antimicrobials is a matter of serious concern; and is mainly due to inappropriate use in human, animal, food and agriculture sectors. Within AMR, resistance to antibiotics is the greatest and most urgent risk that requires focussed and immediate attention;

**Recognize** that emergence and spread of AMR is negating many twentieth century achievements, particularly reduction in illness and death from infectious diseases; and note with concern that without effective One Health and other multisectoral cooperation and actions, AMR is projected to cause millions of deaths worldwide (and in India) with massive social, economic and public health repercussions;

**Realize** that the overarching principle for addressing AMR is the promotion and protection of human health with a One Health approach and emphasize that this requires coherent, comprehensive and integrated multisectoral action;

**Reaffirm** that the 2030 Agenda for Sustainable Development offers a framework to ensure healthy lives, reiterating that AMR challenges the gains in health and development and attainment of the 2030 Agenda, and sustainable action against AMR shall contribute towards the achievement of 27 targets across 11 Sustainable Development Goals;

**Reaffirm** that the roadmap for containment of AMR in India is the National Action Plan on Antimicrobial Resistance with its six strategic priorities that are aligned with the Global Action Plan on AMR:

1. Improve awareness and understanding of AMR through effective communication, education and training;
2. Strengthen knowledge and evidence through surveillance of antimicrobial resistance in human, animal, food and environment sectors with focus on strengthening laboratories;
3. Reduce the incidence of infection in health care, animal health, community and environment settings through effective infection prevention and control;
4. Optimize the use of antimicrobial agents in human health, animals and food with focus on strengthening regulations, access and surveillance of antimicrobial use and antimicrobial stewardship in human/animal health and agriculture;
5. Promote investments for AMR activities, research and innovations with focus on development of new antibiotics; innovations in diagnostics, vaccines and alternatives and sustainable financing for AMR; and
6. Strengthen India's leadership on AMR with focus on international, national and state/district level collaborations.

**Reaffirm** that national and local priorities shall be the basis to develop and implement the multisectoral national and state action plans on AMR taking into account the national, state and local context;

We therefore **commit** to work towards:

- **Developing** and **implementing** national and state action plans on AMR with a multisectoral One Health approach in consonance with six overarching strategic objectives;
- **Taking** steps to ensure that national and state action plans on AMR include the development and strengthening of appropriate and effective surveillance, monitoring and regulatory frameworks on the preservation, use and sales of antimicrobial medicines for human and animals;
- **Mobilizing** adequate and sustained funding and human resources to support the development and implementation of the national and state action plans on AMR;
- **Initiating** and **sustaining** activities to raise awareness and knowledge about AMR, to engage and encourage behavioural change in different audiences; promote evidence-based prevention, infection control and sanitation programs in alignment with the *Swachh Bharat Abhiyan, Kayakalp* and *Swachh Swasth Sarvatra* initiatives of the Government of India; and
- **Addressing** AMR in a mission mode; duly involving research institutes, civil society, industry, small- & medium-sized enterprises and encouraging public-private partnerships in alignment with *Make in India;*

**Call** on all stakeholders including WHO, FAO, other UN agencies/partners, civil society and other multisectoral stakeholders to support the development and implementation of the national and state action plans on AMR;

**Recommend** the establishment of a National Authority for Containment of AMR (NACA) to provide oversight and monitoring to ensure sustained effective national action on AMR as part of India's initiatives towards managing this public health challenge.


New Delhi | 19 April 2017

Joint Declaration endorsed by the Ministries of Agriculture and Farmers Welfare, AYUSH, Chemicals and Fertilizers, Consumer Affairs Food and Public Distribution, Drinking Water and Sanitation, Environment Forest and Climate Change, Finance, Food Processing Industries, Health and Family Welfare, Human Resource Development, Information and Broadcasting, and Science and Technology, at the Inter-Ministerial Consultation on Antimicrobial Resistance.

# 1st International One Health Congress
# Summary
# 14 – 16 February 2011


**Key messages arising from the inaugural International One Health Congress:**

**The One Health approach**

- **Recognises the interdependence of, and seeks to improve human, animal and environmental health**
- **Recognises that communication, collaboration and trust between human and animal health practitioners is at the heart of the One Health concept**
- **Has a broad vision and includes other disciplines such as economics and social behavior that are essential to success**
- **Needs to promote the 'doable' such as improving surveillance and response for emerging infectious diseases whilst developing the broader approach**
- **Emphasises community participation and development of community capacity, and especially, an open transparent dialogue**
- **Requires both 'ground up 'and 'top down' action**
- **Recognises that understanding ecosystems, including molecular ecobiology, are an essential part of One Health.**
- **Recognises that One Health is a major component of food security and safety**

The summary below highlights the key activities and discussions at the meeting along with identifying some science innovations. It does no real justice to all that presented and discussed during the Congress but does provide a broad overview.

More than 650 people from over 60 countries attended the 1st International One Health Conference, held in Melbourne on 14 – 16 February 2011. Scientists, clinicians, government and community members from a range of disciplines came together to discuss the benefits of working together to promote a One Health approach to human, animal and environmental health. One Health embraces systems thinking and recognising the interdependence of people, animals and environment. The conference was hosted by the Commonwealth Scientific and Industrial Research Organisation (CSIRO) and was supported by international agencies, Australian and Canadian governments and industry.

The Organizing Committee recognized from the outset, the need to provide a forum not just for scientific presentation, but for open discussion and dialogue around the policy and political issues, as well as the science that drives the One Health agenda. The Committee was also cognizant of the need to embrace a definition of One Health that includes food security and food safety and includes the social and economic pressures that shapes human, animal and environmental health. The meeting was therefore organized under four Themes with Plenary sessions followed by breakout parallel sessions for each of these. The Themes covered, Disease Emergence; Environmental Drivers; Trade, Food Security and Food Safety and Science Policy and Political Action. The Plenary Session commenced with one or two keynote presentations by world leaders on the topic being covered, followed by Panel discussions involving 6 – 8 experts and involving all participants at the Congress. Each of the panel members spoke briefly on the topic covered by the keynote speaker and were asked to be as provocative as possible. The discussions that followed were designed to debate and discuss the keynote presentations and the Panel members comments. This was followed by 6 – 8 parallel breakout sessions involving in depth papers on the session's topic. As much as was possible, the papers were grouped under general headings but the sessions were organized in such a way, that participants could move freely around these parallel sessions to pick and choice the particular papers they wished to hear. Importantly throughout the conference at various times, sponsored sessions dealt with particular areas of science or policy providing a further framework not only to learn current science but for debate and discussion.

The conference began with dances, stories and song from the traditional peoples of the Wurundjeri. The songs and stories told of the need of harmony between the earth, animals and man for physical, mental and spiritual wellbeing.

The plenary speakers at the opening session, 'Setting the Scene', put forward the challenges that framed and informed the three days of intense discussion. It was fitting that humanitarian, scientist and Nobel Laureate, Professor Peter Doherty, opened the conference.

**Setting the Scene**

Professor Doherty's keynote speech dealt with the growing evidence of negative impact of human behavior on the health of the world and the likely risk to humankind. He called on the scientific world to push for a collaborative, principled plan to examine and provide evidence based pathways addressing causes and effects of deteriorating global ecosystems.

> *'Anthropogenic change is an unacceptable experiment. We are dumping fossil fuel into the atmosphere and do not know what the outcome will be.'*
> *Professor Peter Doherty*

This was followed by a series of presentations to set the scene for developing the later discussions at the international, national and local levels. Dr Takeshi Kasai, Director of Health Security and Emergencies at the WHO Western Pacific Regional Office provided an overview of some of the regional disease threats, and then discussed the processes which WHO have developed to ensure that *rapid reporting of outbreaks of international public health concern is achieved through the new International Health Regulations*, and the bi-regional Asia Pacific Strategy for Emerging Diseases in which a One Health approach with support from FAO and OIE forms a major component in providing a response to zoonotic disease threats. Dr Suwit Wibulpolprasert, senior adviser in disease control to the Thailand Ministry of Health, spoke of the challenges of applying a One Health approach to global health. *The four main challenges he delineated as: determining definition and scope, being clear whose wellbeing we are talking about, working together as a team and with trust, and, fourthly – how to avoid failing!* To the fourth challenge he presented five points.

1. Regular meetings – confirm we are working together and what allows us to share
2. Consensus, commitment and collective actions
3. Horizontal and vertical social trends to form strong 'social fabrics'
4. Respect seniority, culture and historical objects
5. Respect those who are weaker – children, women, elders, animals, plants.

> *'Is social equity and justice considered in One Health? If social justice is not included, we cause 'unjust'. A more sustainable world is a more just world.'*
> *Dr Suwit Wibulpolprasert*

David Butler Jones, the Chief Public Health Officer of Canada, noted in his speech, '*Breaking down barriers and creating connections'*, that the fundamental resources for health are peace, shelter, education, food, income, stable ecosystems and sustainable resources. He reiterated Professor Doherty's call for holistic science based action, pointing out the need for systems consideration and research, noting, for example that '*climate change is not a linear model – it cannot be predicted lineally'*. Dr Brian Evans, Chief Scientist for the Canadian Food Inspection Agency, put forward that *a One Health approach was a necessity and one in which politics, trade and economics could not be separated*. Dr Jim Bishop, Australian Chief Medical Officer, and Dr Bob Biddle, representing the Chief Veterinary Officer, discussed the impact of One Health on national public health and animal health issues specific for Australia, many of which are common to other countries, but which also impinge on aspects of food security. Finally, Professor Tom Riley used the model of *Clostridium*

*difficile* to demonstrate *the importance of better understanding transboundary diseases* between animals and humans, as an example of the One Health approaches needed to meet these disease risks.

**Disease Emergence**

The first day's emphasis on emerging infectious diseases provided a discussion of their global drivers and strongly linked with those Themes dealing with trade, people density, people and animal movement, changing agricultural practices and climate change, and, also importantly, local and regional level drivers. Professor Ron Atlas emphasized the need for a One Health approach *for surveillance to ensure the early detection of evolving pathogens and to determine where and when the critical events in the evolution of new pathogens occur.* He also suggested the need for a new paradigm to broaden the meaning of the term zoonoses to recognize that the *flow of microbes and their genes can be multi-directional and include environmental reservoirs.*

A session on the human-animal interface describing joint collaboration between WHO, OIE, FAO, the International Union for Conservation of Nature, United Nations Environment Program, and the Global Outbreak Alert and Response Network (and partners) in outbreak investigation and response was chaired by Dr Pierre Formenty. Presentations included a discussion on Rift Valley fever virus outbreaks in Madagascar, Tanzania and Sudan; Ebola-Reston outbreaks in the Philippines; searching for the reservoir hosts of SARS-coronavirus; the importance of *in situ* conservation organizations in surveillance, as exemplified by the Wildlife Conservation Society using hunter-based surveillance for Ebola virus in the Congo; and the need to ensure behavioural and social interventions are a fundamental component for preparedness and response to zoonotic outbreaks. Indeed the latter paper made the very important message that an inclusive, *holistic view of "strategic health communication" is needed that embraces multiple approaches and methodologies, a*nd with clear expectations of its purpose and role. It might be that we need to invest and strengthen capacities at key critical levels, but the end result could be an important vehicle for demonstrating the principles and foundation of the One Health concept in practice.

Extensive research into bat ecology and bat viruses provided an insight into the application of One Health, enabling a better understanding of risk to populations and potential solutions such as habitat management. Molecular laboratory work is as important as considering climate patterns and wind stream movements. *The development of bat cell lines will enable research into the wide diversity of viruses,* both species wise and within species, found in bats. Rift Valley Fever outbreaks in South Africa show that virus isolates have little diversity but were capable of spreading under the right climatic conditions.

The emergence of significant wildlife disease such as Chytridiomycosis and marine pathogens reflect insufficient risk perception and assessment and capacity limitations. There is simply not enough awareness and knowledge.

The avian influenza virus, H5N1 is still evolving in wild bird reservoirs and has been isolated from domestic pets. Resistance to the neuraminidase inhibitor, oseltamivir

(Tamiflu), is now being found in many environments and there is the potential for resistance to occur in wild birds. It was argued that *a reactive response to avian influenza alone* is insufficient; culling of infected birds does not address the underlying reasons for emergence of H5N1.

**Environmental Drivers**

In the Plenary session, Dr Peter Daszak, President of the EcoHealth Alliance, provided an in depth look at the *'hotspots' driven by people and trade movements* and the likelihood of potential emergency infectious diseases (EID) in different parts of the world. Dr David Waltner-Toews, a Canadian veterinarian, defined health as '*an outcome of constantly complex interactions among the social and ecological conditions in which society is embedded'*. He emphasized the need for an ecological approach to systems thinking at all levels and to support the development of people's capacity at the local level to apply such an approach. He argued that *there is no one discipline that fully addresses or which could take responsibility for One Health, although public health is a discipline that should provide a leadership role.*

Papers on climate change and the ensuing discussions recognized that clearly climate change is happening yet its impacts and how the world responds is uncertain. Agricultural practices impact on climate and are likely to be impacted by climate change in the future. This and *increasing meat consumption will cause global food insecurity and animal/environment nutritional stresses*. Changes in temperature and rainfall are adding to other drivers such as population density and movements, impacting on the emergence of infectious disease. One Health needs to consider the wider ramifications of climate change such as ocean warming and changes to water currents and air streams. As an example, Inuit populations are already feeling these impacts with the levels of dioxin in Inuit mothers' breast milk having been found to be higher than anywhere else in the world, largely due to deposition of chemicals in the Arctic by air and sea current flows. To improve health in Inuit populations it is necessary to look at global causes. *Understanding impacts of current cycles, for example, the drought-rainfall cycle in Australia, may provide models to improve resilience in other parts of the globe.*

It was shown in a number of papers that *surveillance systems need to be integrated geographically and across disciplines*. Surveillance of animal health is poor and surveillance of wildlife and ocean life are almost non-existent. In Australia, for example, integration could be possible between the Australian Biosecurity Intelligence Network and the Wildlife Health network. The World Small Animal Veterinary Association (WSAVA*)* is advancing incorporation of companion animal disease surveillance. The *Russian Anti Plague System* has been adapted to collect information on environmental, human and animal components. Connecting Health Organizations for Regional Diagnosis and Surveillance (CHORDS) demonstrates sharing of data, methodologies and standards and resources across countries in Southeast Asia.

**Trade, Food Security and Food Safety**

In the Plenary session, David Nabarro described the UN system High Level Task Force (HLTF) on the Global Food Security Crisis and the Updated Comprehensive

Framework for Action (UCFA). He highlighted the many actions being taken to address food security in a comprehensive and collective way that recognized *the right to food, the need for effective ecosystem management but with access to land and water security that would underpin addressing adequate nutrition including urban hunger*. This thought provoking presentation clearly embraced all elements of One Health.

In the subsequent sessions many papers dealt with surveillance and risk assessment approaches that are needed to underpin both trade and food safety. Tools such as *Epicollect*, which uses mobile phone technology, are increasingly able to be effective in many settings including remote conditions. MAX management which incorporates such factors as monitoring animal movements, is an example of software utilised to predict and map livestock outbreaks. Infection Ecology and Epidemiology (IEE), a new movement in Sweden, includes coordination of funding and education initiatives as well as information exchange. Specifically it includes interest and work on impact of co infections with non-highly pathogenic agents such Ebola Reston. The IEE *'facebook and friend finder' and the open access journal are mechanisms effective in disseminating information widely*. Papers covering Risk assessment and predictive modeling covered for example the association of months of dry weather prior to Hendra outbreaks in Australia, and other factors from previous outbreaks to inform risk assessment. Risk assessment enables outbreaks to be anticipated and allows for preventive action to take place. For example, flooding for potential increase in leptospirosis, anti flea campaigns for plague, capture of wild dogs or ensuring domestic animals health for rabies, removal of pigs from urban setting, to reduce the chance of Japanese encephalitis. Complex predictive models are tools used for risk assessment of emerging infectious diseases as well as for other areas such as:

- the design of vaccination programs like Q fever in the Netherlands
- the social and private cost of disease such as brucellosis in Krygystan
- cost-benefit assessment of public health interventions such as the REV-1 (brucellosis) vaccination.

*The involvement of community people is essential* in predictive modeling as are tools such as satellite telemetry (GPS) and remote sensing.

A number of papers focused on the broader aspects of community engagement and broaden the stakeholder groups involved. The One Health Alliance of South Asia (OHASA) aims to predict and prevent emerging infectious diseases on the Indian subcontinent, incorporating consideration of population growth and movement, food insecurity, public health threats and fragile ecosystems. Healthscape, an initiative in Kings County, Washington State, has developed a Development Impact Assessment tool which takes into account land use, transport, air quality and potential climate change to predict impact on public health. Further examples included HPAI in Indonesia, bush meat pathogens in Ghana, equine influenza outbreaks in Australia, West Nile virus in the USA, Rift Valley fever and rabies in Kenya and milk purity in Mali, and all indicated that *different communities often have different perceptions and understandings and there is much to be gained by increasing knowledge and awareness.* Setting up Animal Health Clubs in Africa has assisted in knowledge of animal-human environment interactions.

*'Post normal science - prepare the decision-makers to the need for new/different science perspectives in addressing different problems. With increasing uncertainty, it makes it harder to communicate with our stakeholders including the public. So with this imperfect science, we need to feel comfortable with ambiguity and adapting with new data being produced.'*
*Peter Black.*

This awareness in turn enables behaviour change in prevention and timely response. Social factors such as gender and culture must be incorporated in implementing disease prevention and response, for example respecting the role of dogs in Australian Aboriginal culture and promoting dog health rather than dog eradication.

The knowledge and evidence base for One Health is improved by sharing research directions, methodologies and findings. EPIZONE, an EU-based network, shares technology as well as information to further understand and promote action for epizootic disease.

*The genomic revolution will change agriculture and medicine and, along with this, it will be essential to develop the science of bioecology in depth*. One Health organizations need to rely on not only socioeconomic studies but also political economy studies in areas such as the link between money, power and debt relations. *Any change will always involve political economic factors,* which need to be handled with sensitivity. The importance of this clearly reflected in the refusal of Indonesia to share HPAI viral strains believing that any outcomes from such sharing would not benefit developing countries.

Access to and distribution of medicines and vaccines underlie the crucial involvement of the veterinary and medical pharmaceutical industry. Similarly, it has, along with animal human health care workers, a pivotal role in turning the tide of antimicrobial resistance. Vancomycin resistant Clostridium difficule (VRCD) and methicillin resistant Staphlococci aureus (MRSA) are now causing significant burden of disease. Harmonizing international rules and trade, reducing and monitoring antibiotic use in animals, limiting or banning routine antibiotic prophylaxis in animals are steps that should be taken to reduce antimicrobial resistance.

Eradication of disease may be, in itself, not a complete answer. We must consider such questions as that put forward by Richard Kock from the Royal Veterinary College in London "*If we have eradicated Rinderpest, could we be disrupting an unknown ecological niche"?*

**Science Policy and Political Action**

This Plenary Session sought to bring together many of the thoughts of the past two days and both keynote speakers highlighted the need for concerted political action to genuinely move forward the One Health agenda both at the national and international level. However it is clear that National Governments and International Organizations have recognized the benefit of One Health. The United States Government by setting up the USDA One Health Multi-Agency Coordination Group. Canada is applying a One Health approach to zoonoses. Regional developments include the OHASA (South Asia) group, EPIZONE (Europe) and IEE (Sweden).

A challenge for One Health and International Organizations in particular is to develop *a language* that can be understood by all players. Leadership is required in integration of One Health elements in a 'top down' approach. UN Organizations have combined in an unprecedented way to look at pandemic action forged through the United Nations Systems Influenza Coordination (UNSIC) group. Dr David Nabarro, Senior UN System Co-ordinator for Avian and Human Influenza, noted that many of the positive elements of this collaboration are being progressed to further promote integration between international agencies.

In the accompanying session, *education, training and involvement of the community were emphasised* across all areas of One Health but particularly in farm management, surveillance predictive modeling and prevention and response to emerging infectious diseases. *Cross discipline training is necessary* and in the developing world the health care worker is considered a key figure in promoting One Health approaches. Non Government Organisations such as the Sikkim Anti-Rabies and Animal Health *(SARAH*) program tend to have a 'ground-up' approach and are usually able to identify effective roles and training at the community level.

Programs such as *TUSK* allow file-sharing across the world and offer online courses to facilitate cross sectional learning. *Initiatives such as a shared curriculum, specific curriculum, development of specific workforce roles and development of multidisciplinary workshops at different levels will enable effective One Health practice.* Public-private partnerships, which are essential in addressing for example, neglected zoonotic diseases which that do not attract traditional commercial interest and must be sponsored.

**Specific Hosted Sessions**

*On the need to embrace community involvement*

This need to embrace societal interventions was echoed in a special session sponsored by the International Development Research Centre of Canada (IDRC), which demonstrated eco-health research with a central focus of *community development as a key enabler at the local level.* Dominique Charron from IDRC, along with many other speakers, argued for integral involvement of other disciplines such as social science, economics and anthropology in moving forward in One Health thinking.

*On previous One Health Initiatives*

Important presentations were made by Dr Joe Annelli, United States Department of Agriculture (USDA) and Dr Carol Rubin, Centres for Disease Control and Prevention (CDC) on the Stone Mountain Meeting held last year to operationalize One Health. This meeting had followed on from an earlier meeting held in 2009 in Winnipeg, Canada and hosted by the Public Health Agency of Canada, entitled "One World, One Health: from ideas to action", the purpose of which was to discuss a Strategic Framework and to identify and shape country-level recommended actions to globally advance this framework. The Stone Mountain meeting, held May 2010 and hosted by CDC, was aimed at moving the concept of One Health forward by defining a series of specific action steps. A specific goal was to develop sustainable inter-sectoral collaboration at international, regional, national, and sub-national levels by

identifying concrete opportunities for implementing One Health strategies and recognizing key barriers and possible options for overcoming these barriers. At the Stone Mountain meeting seven key activities were selected as fundamental to moving forward the One Health agenda in order to reach the three to five year vision. These were:

1. *Training:* Develop and build skills, expertise, and competencies through a One Health training curriculum and identify opportunities to integrate One Health approaches into existing curricula.
2. *One Health Global Network (OHGN):* Advocate and garner international support for One Health through a network that serves as a vehicle for further global collaboration on One Health programs and projects.
3. *Information Clearing House:* Promote One Health advocacy through a centralized area where One Health success stories are gathered and made available to a wide-ranging audience.
4. *Needs Assessment:* Develop country level self-assessment methods to identify programmatic areas that could benefit from a One Health approach and areas for targeting improvement.
5. *Capacity Building:* Identifying ways to leverage existing programs and capacity-building efforts in order to have a major impact at very little cost.
6. *Proof of Concept:* Demonstrate through a retrospective and prospective evidence base that the use of One Health interventions leads to better cross-species health outcomes.
7. *Business Plan:* Articulate the subject area of One Health more clearly and present it to policy-makers and donors at the global level.

Each group was asked to develop One Health plans and partnerships that would occur within a designated timeframe. The groups developed specific goals and objectives and will convene and continue their development process. The invitation only status of the Stone Mountain meeting was noted although ongoing processes and meetings will be transparent and many initiatives will arise embracing a much wider community and disciplines.

*On an International Society for One Health*

There was wide support for the Stone Mountain initiatives, and a strong feeling that they were providing a major platform through which One Health activities could progress on a broad front. However, although the Stone Mountain movement was warmly applauded, there was also a feeling that the One Health dialogue needed to be broader and more transparent, especially by encouraging developing country participation in the ongoing discussions. *Many zoonoses, especially the recent examples of novel agents, were seen to originate in developing countries and this has also been reflected in the importance of a One Health approach to zoonoses in the Asia Pacific Strategy for Emerging Diseases,* as described earlier by Dr Takeshi Kasai. This was, in essence, the background to the suggested International Society for One Health. The convening of an International Society for One Health was discussed at an early morning meeting and while the general concept was agreed, further discussion to define the parameters and scope was required. Indeed there was a strong indication that a loose association or network might be preferable to a 'society', together with a mechanism to hold further One Health congresses and an avenue in

which to feed information into the ministerial discussions held by WHO, FAO and OIE. As such, a further meeting was suggested and this is currently being planned for June this year.

**Closing Plenary**

In the closing plenary, Dr David Heymann, Head and Senior Fellow of the UK Centre on Global Health Security, joined Dr David Nabarro in noting the consensus in spirit on a broad approach incorporating the principles of collaboration and holistic ecohealth system thinking, but to move forward quickly where possible. This was echoed by Ms Jane Halton, Secretary of Australia's Department of Health and Ageing, who urged for clarity and a clear business case to take forward to policy makers and to move forward on the 'do-able'. Jorgen Schlundt, of the National Food Institute, Technical University of Denmark, emphasised the importance of tackling surveillance and response to emerging infectious disease as an immediate do-able.

Many participants were articulate in reminding all the speakers of the need for a broad vision for One Health but at the same time to have targeted and focus actions to deliver tangible outcomes. Developing the interconnectedness, collaboration and principles needed to fully practice One Health was seen as a must, as was still aiming for progress in goals that can be achieved immediately.

Discussions have begun already with interested countries on the Second International One Health Congress, to be held in 2013.

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Abstracts can be accessed in a special supplement of the EcoHealth Journal: 2011, Volume 7, Supplement 1 and can be accessed on line at www.springerlink.com.

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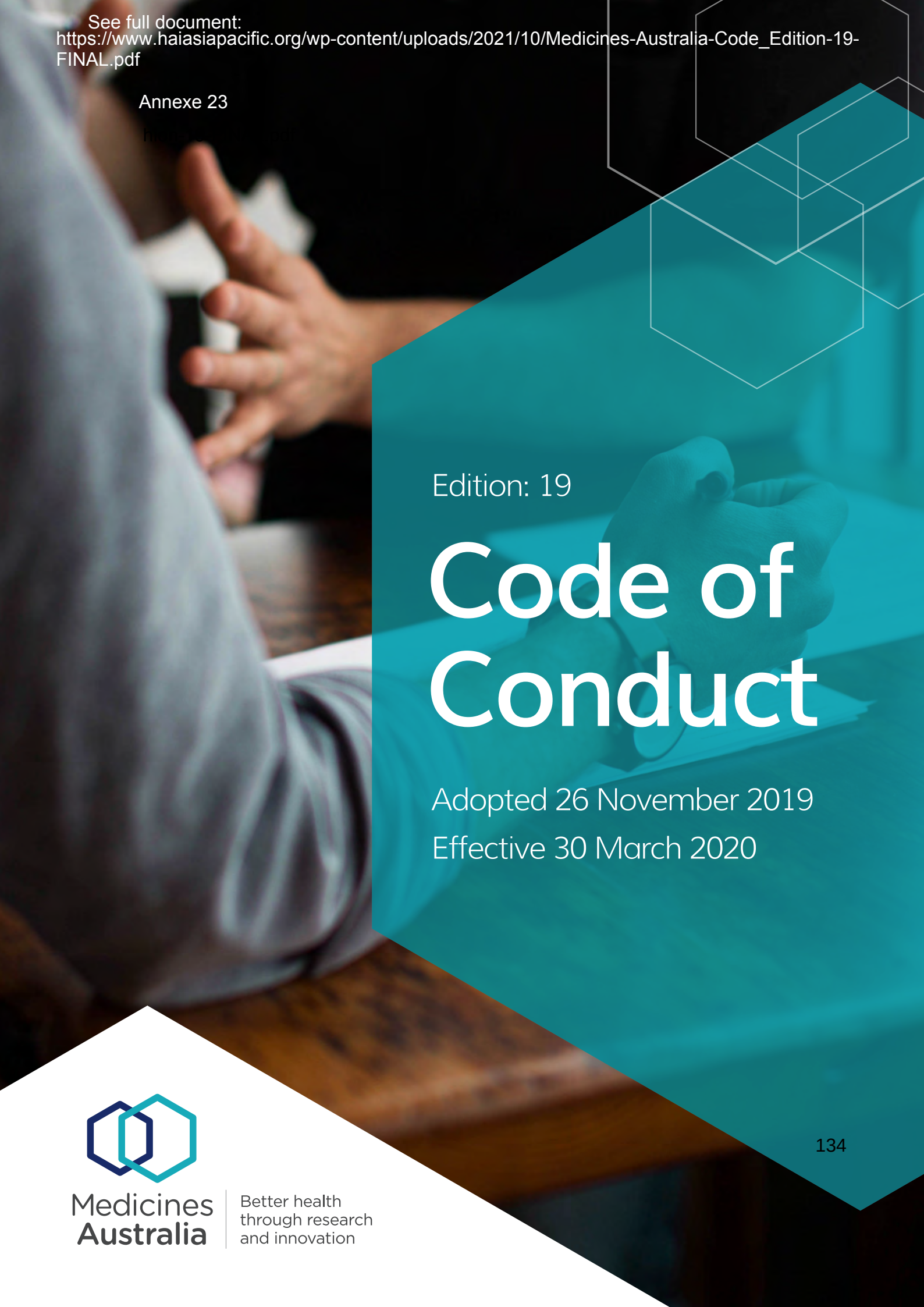
The Organizing Committee was co-chaired by Professor Martyn Jeggo, Director of CSIRO's Australian Animal Health Laboratory, and Professor John MacKenzie, previous Director of the Australian Cooperative Research Centre in Emerging Infectious Diseases and a Consultant to the World Health Organization.

Sponsors to the Inaugural One Health International Conference were:

- Commonwealth Scientific and Industrial Research Organization (CSIRO)
- European Union
- Department of Health and Ageing, Australia
- Department of Agriculture, Fisheries and Forestry, Australia
- Food and Agriculture Organization of the United Nations (FAO)
- International Development Research Centre of Canada
- The Australian Agency for International Development (AusAID)
- Life Technologies
- Animal Health Australia
- Public Health Agency of Canada
- CEVA Animal Health

- GALVmed
- Deakin University, Australia
- Pfizer Animal Health
- Department of Primary Industries, Victoria, Australia
- Australian Biosecurity Intelligence Network
- Burnet Institute, Melbourne, Australia
- ConservAction.org
- DAI
- CAPPE
- Abbott Molecular



Edition: 19

# Code of Conduct

Adopted 26 November 2019

Effective 30 March 2020



Medicines Australia

Better health through research and innovation

# Contents

## Introduction

Medicines Australia leads the research-based pharmaceutical industry of Australia. Our members discover, develop and manufacture medicines and vaccines that help people live longer, healthier lives and bring social and economic benefits to Australia. Our members invest in Australian medical research and take local discoveries and developments to the world.

Australia's innovative pharmaceutical companies support the quality and safe use of medicines. As the custodians of our medicines we conduct ourselves ethically, appropriately communicating relevant information to those relying on our medicines, including patients, their carers and families, healthcare professionals and the broader community. We join together, as Medicines Australia, make sure that our conduct is of the highest standard and that the environment in which we provide access to our medicines is sustainable and fair. The Australian pharmaceutical industry participates in and is recognised by the National Medicines Policy as a vital part of achieving these aims. This Code is the embodiment of our ongoing efforts to ensure we meet these obligations and achieve these goals appropriately and ethically.

The Constitution of Medicines Australia Limited provides that each Member Company must conform to and be bound by both the Constitution and the Code of Conduct.

## Interpreting this Code

This Code of Conduct provides a principles-based framework for appropriate and ethical decision making by Companies when promoting prescription products and interacting with healthcare professionals, health consumer organisations and the general public. It includes overarching principles that govern all activities covered by this Code, as well as more detailed provisions to support these activities.

To enhance understanding and application of this Code, Medicines Australia has created the Code of Conduct Resource Tool Kit. This manual is produced as a separate publication. The Code of Conduct and Code of Conduct Resource Tool Kit are available from Medicines Australia's website.

## A Global Committment

Medicines Australia recognises its place as a global leader in ethical behaviour in the innovative medicines industry. As Medicines Australia, we are a signatory to the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Code of Practice and ensure its principles are reflected within this Code.

Further, Medicines Australia is a member of the IFPMA leadership group and is a foundation signatory to the *Australian Ethical Health Alliance's Australian Consensus Framework for Ethical Collaborations in the Healthcare Sector*, which is available from the AEHA's website.

## Where To Find Assistance

If you have any questions or enquiries in relation to the Code of Conduct, please contact Medicines Australia:

**Ethics and Compliance Team**
Medicines Australia
17 Denison Street
Deakin ACT 2600

**Phone:** (02) 6147 6500

**Email:** codehelpdesk@medaus.com.au

**Web:** www.medicinesaustralia.com.au

To lodge a complaint, or for information on the complaints process, please email **secretarycodecommittee@medaus.com.au**

# Part A

## Australian Pharmaceutical Industry Code of Conduct: Overarching Principles

In keeping with our commitment to ethical behaviour in the Australian pharmaceutical industry, Companies must ensure that these overarching principles are reflected in all activities covered by this Code.

1. All activities undertaken by Companies have the purpose of supporting the quality use of medicines.
2. Companies are committed to transparency in their interactions with healthcare professionals and other stakeholders, to maintain trust and confidence in the industry.
3. As the primary repository of information relating to their products, Companies are responsible for providing current, accurate, balanced, and scientifically valid information on products to support their appropriate use. The same standards apply to all other Company communications.
4. Company employees, and anyone acting on behalf of a Company, will be appropriately trained on the Code and maintain a high standard of ethical conduct and professionalism in the discharge of their duties.
5. Consistent with our ethical undertakings, nothing is offered or provided by a Company in a manner or with conditions that would have an inappropriate influence on the approval, recommendation, prescribing, and/or use of a product.
6. Companies' interactions with all stakeholders are at all times professional, consistent with all legislative requirements, and appropriate to the information needs of the respective audience.
7. Information relevant to prescribing, in particular product and safety information, are clearly communicated in all promotional materials. Promotional materials are designed by Companies to not only create awareness of Therapeutic Goods Administration (TGA) approved medicines, but to support proper assessment of their risks and benefits.
8. All promotional claims are consistent with the Australian Product Information document, including claims about competitor products, irrespective of the source on which the claim is based.
9. All events, initiated or sponsored by Companies, are reasonable and appropriate with respect to hospitality, travel and accommodation, therefore upholding the integrity and reputation of the industry.
10. All activities undertaken by Companies are clearly identified to their audience as a Company activity by the inclusion of the Company's name and city/town of the Company's Australian office.

## Shortfalls of medical education

***Dr Qasem Chowdhury, Vice Chancellor, Gono Bishwabiddyaloy, Institute of Health Sciences, Bangladesh*** in his overview stated that although there has been tremendous advancement of medical technology during the last decades, the health status of the majority of the people in the world has not improved but deteriorated further. Thus, we face a global health crisis, characterized by growing inequalities within and between countries. New threats to health are continually emerging compounded by negative forces of globalization which prevent the equitable distribution of resources with regard to the health of the people and especially that of the poor.

Though the socio-economic factors like poverty, illiteracy and politics are major determinants of the health status of the people, health services still have an important role to play. A lot depends on the doctors and health workers to improve the health status of the people within the existing constraints of the socio-political system of the country.

In spite of commitment by all the countries of the world to provide health to all its people through the Alma Ata declaration in 1978, recommendations and policy formulations to reorient medical education to produce socially motivated healthcare providers have mostly remained in papers. The existing system of medical education in most of the countries still produces professionals with urban bias, tendency towards specialization and penchant for clinical practice. This is compounded by commercialization, privatization and high tech care.

Agreeably, a new type of educational programme for health personnel that will make them responsive to the needs of the majority of the population in countries is needed. Such training is most effective if it is carried out in close relation to the actual community in which health personnel are later to work. Community based education, if we may call it so, is therefore, not an end in itself but a means of ensuring that health personnel are responsive to the health needs of the people and for improving healthcare systems through a new kind of education for future doctors.

Although curriculum in many countries has been updated several times it still fails to achieve the above goal. There is now a growing realization that medical education is teacher-centered, top down and ivory towered. It does not give enough emphasis on skills development. The communication between teachers and students is through lectures. There is an urgent need to change it to become learner-centered, student and situation driven, community oriented and geared to skills development. Due to the rigidity and resistance of the specialists who dominate the medical schools, changes in the curricula to make it more closely in line with the health needs of the majority of the people could not be achieved.

Medical education now in practice is curative and preference is given to the treatment of patients instead of prevention of diseases. Training puts more emphasis on departmental, subject centered curriculum linked with high technology. Less priority is given to community health and as a result fundamental sciences like medical sociology, medical anthropology, medical economics, environment and gender aspects necessary to understand the community are absent.

The training is mostly restricted within the four walls of the hospital. As a result the entire education had been limited to a narrow field. The graduate comes in contact with sick people usually at the terminal stage. Since the whole education is restricted within the cities in most

cases, the students are alienated from the society and they develop a different value system than that of the masses. In fact, they become physicians for the majority of the rich people and prefer to work in the urban medical centers. Students are never trained to manage problems in a peripheral situation utilizing existing facilities and resources. In reality doctors at the periphery are unable to perform their duties efficiently and effectively.

The medical institutes and hospitals involved in the medical care of patients hardly play a role in the health system of the country. As such there is no feedback given to schools regarding skills, knowledge, attitude and competency that a medical graduate will need to deliver these services. Medical education and the regular health services therefore must be more closely linked.

The need for professional training/orientation and skill development in pedagogy to enhance the educators' role in the faculty of medical colleges has not been adequately stressed. Teachers' training is still not mandatory. Most medical college teachers continue the didactic culture of their own teachers, most of whom had not received any training either. There is a need to develop a Medical Education Unit or department in every college for the training of teachers at the time of induction, in pedagogy; aptitude testing for teaching cadre and teacher evaluation.

The evaluation system is such that it compels the students to spend long period of their training in memorizing text books rather than gaining skills in practice. Students' capacity to understand or analyze a problem is not evaluated. There is no provision for evaluation of teachers or curricula which is very important for further improvement of education. Present education system has been instrumental in developing an attitude among the graduates who look towards health as a commodity. Graduates sell their skills to consumers. Hence, the professional success of a physician is determined by his or her success in private medical practice. As a result 'Doctors of Disease' gain priority over 'Doctors of Health'.

He also pointed out the complete ignorance of traditional medicine, although a major part of the population receives treatment with traditional and alternative medicines.

In some countries the government has encouraged the private sector to get involved in the establishment of medical colleges to supplement and create opportunity for higher education in the country. While private sector support to higher education may not be a negative trend it is now alleged that some of these medical colleges are running on commercial basis making profit and their quality of education is also questionable. Time has come to clearly differentiate between 'privatization' and 'commercia lization'. The challenge ahead of us is how we can use the private sector to provide relevant and quality education in their institution for the development of the right kind of doctors for the country. Continuing education in medical science is yet again crucial to keep the health professional updated by providing technical information. Serious efforts are needed to initiate continuing the medical education process directed to all existing members of the health care service particularly Primary Health care (PHC) providers. This will help to overcome the serious problem of health professionals being inadequately informed and inadequately skilled.

Dr Chowdhury in conclusion stated that "health for all" will not be a reality, unless medical education is reoriented to meet the healthcare needs of the majority of the people.

## Pharmacy education: what is lacking

***Prof Dato Dzulkifli Abdul Razak, Vice Chancellor, Universiti Sains Malaysia*** sharing some of his sentiments with the audience on the development of pharmacy education stated that the pharmacy practice today is a far cry from what it used to be, more so in the developed economies.

In general, pharmacists are taught about the preparation, use, composition and effects of drugs and medications. They are taught to dispense medicine prescribed by doctors and provide information to patients about the medication and their use. They are also prepared for practice in various fields of work - hospital, community and industry, other than those who choose to work as academics or continue with postgraduate studies. They are introduced to sub-disciplines such as pharmacology, pharmaceutical chemistry, pharmacognosy and pharmaceutical technology. Later, clinical pharmacy, social and administrative pharmacy, and pharmaceutical care are introduced which are relatively new to this part of the world.

Regardless of what the areas of practice are pharmacy is a professional career equipped with abilities, skills and attitudes which are necessary to achieve outcomes related to the following:

- Developing and managing medication distribution and control systems
- Managing and administering the pharmacy
- Providing pharmaceutical care to patients and clients
- Providing drug information and education to professionals and the public

However, with the introduction of a clinical dimension in the practice of pharmacy the abilities, skills and attitudes of pharmacists gradually expanded to include:

- communication skills for effective interaction with patients and with practitioners of other health professions
- knowledge integration that is necessary for clinical exposure, and application for solution of real problems
- responsibility for monitoring the drugs taken by patients and also of the general methods of diagnosis and patient care specifically related to drug therapy.

Increasingly too pharmacy education is supplemented with business and management studies so as to enable pharmacists to participate in pharmacy practice as part of business ventures, an area commonly designated as pharmacy administration. It may include aspects of pharmacoeconomics - the latest addition to the professional development of pharmacists.

All these are exciting developments in areas of pharmacy education and practice. However, by and large, the main goals are still centered around the provision of curative service essentially focused on drug therapy. Though the profession of pharmacy has progressed by leaps and bounds in a matter of just a decade, its "curative-approach" has not changed significantly.

One of the global events that are forcing us to re-visit the realm of pharmacy, and take a hard look at how it is coping with future needs, beyond just the "curative-oriented" practice is the Tsunami tragedy of 2004, December 26, be it in Acheh, South Thailand or Sri Lanka. During calamities such as these, what is abundantly clear is that the health of the people is made most vulnerable and it faces a greater threat. This was again demonstrated by Hurricane Katrina that hit the Gulf Coast of the US. It does not matter whether you are in a very technologically advanced country or in a developing nation it is at times like these that the usefulness of pharmacy as a frontline and primary health care concern is being challenged in an unprecedented way.

Citing the relief efforts Universiti Sains Malaysia has undertaken in Acheh and to a limited extent in Sri Lanka he stated the Tsunami tragedy as the "most effective teacher" and an eye-opener for us all. The event has traumatized us all the same, that health is such a fragile thing.

Pharmacy on the whole, certainly in Malaysia, has captured the imagination of only a small segment of the population as a vibrant profession with hard-nosed public health and societal mission. For example, as HIV/AIDS is ravaging many developing countries of Asia, Africa and South America, we do not see many pharmacists taking an active role in the campaign to prevent its widespread. Likewise on junk food, SARS, "bird flu" and related issues of public health dimension we do not see enough pharmacists championing activities directed towards its eradication. Maybe in many of these instances, there are no conclusive or effective curative regimens to talk about such that many pharmacists are not well positioned to take an active role. Yet these are the type of "dis-ease" that will take away many more lives in our part of the world as any "curable" condition would. But the pharmacists collectively remain helpless, worse still oblivious. Instead pharmacists continue to enjoy themselves in their narrow comfort zones, in the "back rooms" or behind the counter doing the pharmaceutical "thing". To a lesser extent some are engaged with their patients in the clinical settings. Not that these are unimportant functions, but this is not what pharmacy is all about. As a result the public health role and image of pharmacy, in the sense of preventive and promotive care, continue to suffer.

In addition to this, most of us have lost the wisdom of indigenous health knowledge which by and large advocates preventive and promotive care using nature's pharmacy as its resource. The rich traditional health practices of Asia with all its diversity is gradually being supplanted by the notion of "a pill for every ill" or at least adulterated by it. Traditional health knowledge and practices serve no more than a conduit for the discovery of more potent "modern" pills to be exploited by the marketplace. "Biopiracy" in the various megadiversities of Asia is now a growing concern as Asians themselves are unable to "scientifically" exploit their own backyard; neither can they protect them from being plundered by parties with vested interest.

He later made a suggestion that pharmacy in Asia, and developing

countries in general, to make a difference by advocating more aggressively "preventive and promotive, social-based" pharmacy. Make "pharmacy" more community-friendly as a thought process, based on age-old wisdom "prevention is better than cure" especially in the context of Education for Sustainable Development.