



EIGHTH GENERAL PROGRAMME OF WORK  
COVERING THE PERIOD 1990-1995

Global Medium-Term Programme

Programme 3.4

HEALTH LEGISLATION

WHO's health legislation programme has one over-riding objective: to work with Member States, using an integrated approach that combines information transfer and technical cooperation, in the strengthening of their health legislation and its reorientation towards the health-for-all approach. Such legislation is perceived as a key supportive element, in many national contexts, in the development and delivery of comprehensive health care systems based on the primary health care approach. Legislation is moreover nearly always essential to implement environmental health policies designed to minimize human exposure to biological, chemical and physical hazards. Internationally, WHO has a role to play, particularly in making available valid information needed to formulate international instruments in the health and environmental sectors and to promote authoritative comparative analyses of key areas of health legislation. The programme's resources are limited, and external centres of expertise will hence be utilized wherever possible. Linkages with other programmes concerned with health system infrastructure or with health science and technology will be based on the philosophy that many such programmes need legislative underpinning at the national level, while legislation itself must be a true expression of health policy.

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## GLOBAL MEDIUM-TERM PROGRAMME FOR HEALTH LEGISLATION

1. Introduction and policy basis

The Global Strategy for Health for All by the Year 2000, adopted by resolution WHA34.36, draws attention to the possible need for new or revised legislation in order to carry out essential health reforms. In this respect, the Strategy may be regarded as addressing a key problem identified by the World Health Assembly in resolution WHA33.28, namely the fact that "obsolete health legislation may constitute an obstacle at the national level to the attainment of health for all". That resolution had endorsed the reoriented health legislation programme developed in response to WHA30.44, which, *inter alia*, called for the redefining of the premises on which the programme was based in order to meet the needs of technical cooperation with developing countries. Health legislation is an element of health development that is often essential to put into effect new, enlightened health policies and strategies, based on the principles of social justice and equity of access. It is widely recognized that legislation often has a significant supportive role to play in many fields of health science and technology, such as national drug and vaccine policies, maternal and child health, mental health, workers' health, communicable and noncommunicable disease control, the control of biotechnology and genetic manipulation, and promotion of environmental health (including food safety and the control of toxic chemicals). Many of the strategies and programmes formulated in the Eighth General Programme of Work may well necessitate, in at least some national contexts, the provision of an adequate legislative and regulatory base for implementation and enforcement. The role of legislation in promoting health of groups at risk, such as pregnant and nursing women, the disabled, and the elderly, is widely acknowledged, as is the potential contribution of a legislative component in national strategies to combat smoking and other forms of tobacco use, drug abuse, and certain categories of accidents. An appropriate legislative basis is, moreover, essential if the various categories of health personnel, both men and women, are to provide health care in a manner that is suited to their training as well as to community needs and priorities. Likewise, legislation is of prime importance in assuring the maintenance of necessary standards of care by health personnel and facilities.

2. Situation analysis

It must be clearly recognized that countries are in very unequal stages of development as far as their health legislation is concerned. To examine the developing countries first, it has to be acknowledged that vestiges of the colonial era remain in many such countries, even though a quarter of a century or more may have elapsed since independence. This is clear in many English- and French-speaking countries, in particular, and indeed some of those countries have not yet succeeded in developing methodologies, on the one hand, for formulating strategies for the process of updating their legislation in many key sectors and, on the other, for mobilizing the expertise and resources needed to introduce and implement new and reoriented health legislation. The problems are manifold and often country- and in some instances culture-specific. There are often a host of priorities in public health and legislation tends to be neglected, if only because of the inherent difficulties and obstacles to optimizing interaction and cooperation between the ministries concerned; it is obvious that in many cases non-intersectoral approaches, and approaches that fail to integrate health and environmental concerns with overall economic, social and developmental goals, will fail to attain fully the anticipated results. Pure inertia, possible opposition by conservative professional or commercial groupings, the lack of priority accorded to health legislation on often overcrowded legislative agendas, uncertainty as to the validity of other countries' experiences in this field, or even a sheer lack of information, are all factors that may impede the development of "appropriate" health legislation. WHO is sensitive to these and

other problems and regularly commissions and publishes practically-oriented studies designed to clarify the issues involved and to examine alternative approaches to resolving the problems. A whole series of WHO publications and documents, as well as other published materials, have had an undoubted impact. Witness what can only be described as the socially progressive and carefully conceived and drafted public health codes and statutes - as well as sectoral legislation - now being adopted in developing countries in several WHO regions. It is clear that WHO's philosophy, as embodied in the health-for-all strategy, has in many instances been one of the key guiding forces that have inspired the health leadership of the countries concerned to assure the adoption, either by the national legislature or by a decree of the Head of State, of legislation that reflects the acceptance of the right to health as one of the fundamental human rights and of the desire that the right should become a reality in practice (especially for women - still often subject to discrimination - and other currently underserved groups).

Countries receive invaluable guidance from the policies laid down by WHO's governing bodies or recommended in the reports of expert committees, study groups, and the like. They are unlikely, on the other hand, to benefit much if at all from standardized laws or regulations, except possibly in highly technical areas (such as, for example, model regulations on the hygiene of catering establishments, model guidelines on the sampling of drinking-water, or guidelines on the testing of new drugs for safety and efficacy). For many "core" health issues, there can be no blueprints, no universally applicable models. What there can be, and what WHO can foster and promote, is the sharing of positive (and negative) experiences with health legislation in a multiplicity of areas of health infrastructure and health science and technology.

In the course of 1978-1979, WHO conducted in-depth studies on certain aspects of the status of health legislation at the national level. Information covering approximately 100 countries, including many developing countries in all regions, was obtained and analysed. The results of this endeavour clearly demonstrated that in many developing countries the critical mass of expertise and information needed to resolve problems in the health legislation sector is lacking and that, while self-reliance is a reality or at least readily attainable in some countries, there is no alternative in a substantial number of countries to appropriately conceived and well-executed technical cooperation and training programmes. The outcome of a similar study planned for 1988-1989 will be implemented in the development of the programme.

The developed, industrialized countries do, in general, possess the expertise and experience needed to identify and resolve their problems in the health legislation field. Sharing of information and exchange of experiences can, however, help to avoid costly and duplicative efforts to seek adequate solutions to such key issues as cost containment in health services, the control of toxic chemicals, hazardous wastes and other environmental risk factors, the development of national drug and vaccine policies, the promotion of healthy lifestyles, the strengthening of preventive health services, the more effective protection of human rights, the development of approaches to deal with key ethical issues in the health sector, and the formulation of legal approaches to safeguard the health and wellbeing of children, adolescents, the elderly and the disabled. Both developed and developing countries are concerned with such far-reaching issues as how legislation could contribute to the effective organization (or reorganization) of health systems based on primary health care, with particular reference to the delivery of services at the crucial district and local levels, and how legal and other approaches can provide more equitable in access to health care by all sectors of the population.

Current efforts to promote technical cooperation between countries in the same or different regions in finding practical legislative solutions to specific problems in health policy need to be intensified and broadened to cover "core" issues such as alternative

approaches to the organization of health systems based on primary health care or to the development of legislative policies designed to enhance and promote the contribution of women to health and development and to eliminate vestiges of discrimination.

It must be recognized that in the field of legislation a given target is not attained merely by the passing of a statute or the issuance of regulations, no matter how appropriate and relevant to national needs. What is fundamental is the actual implementation of legislation. In this domain, political will, community acceptance and manpower and other resources are critical and basically dependent on national action rather than international programmes (though the latter can undoubtedly provide valuable pointers on the kind of approaches to implementation that may prove successful at the national level).

It should of course be acknowledged that an enforceable legislative framework is not necessarily a prerequisite for national health development based on primary health care. In some regions, legislative activity in this domain has been particularly significant and this is perhaps one explanation why the programme is at different stages of development in the different regions, as reflected in planned activities. One noteworthy element in recent years has been the enactment of legislation, often at the subnational level, designed to strengthen primary health care programmes at the district level.

### 3. Objective

The programme's objective is to support and foster national efforts to formulate and implement health legislation that is in harmony with, and supportive of, national strategies for health for all.

### 4. Targets

This programme's activities aim at fostering national and international action so that by 1995 more than 50% of countries will have health legislation supportive of their national for health-for-all strategies.

In order to reach the above target, the following specific targets have been formulated:

Specific Target 1 - Technical cooperation with Member States: During the period 1990-1995, an increasing number of countries will have formulated or will be in the process of formulating health legislation in harmony with, and supportive of, national health-for-all strategies.

Specific Target 2 - Information exchange: By 1995, Member States will be making full use, as and when required, of the system for the international exchange of relevant information on health legislation operated by WHO in cooperation with a network of institutions and centres of expertise throughout the world.

### 5. Approaches

The following will be the principal approaches:

5.1 Technical cooperation with Member States in efforts to strengthen national capacities to formulate health legislation required for their national health systems in line with HFA policies and to identify any factors that may hinder the implementation of such legislation. Particular attention will be paid to supporting countries in introducing any legislation that may be required to carry out policies that have been collectively endorsed in the World Health Assembly.

- 5.2 Encouragement of countries to strengthen existing mechanisms for identifying and drafting necessary legislation, whether in ministries of health or justice or the like, as well as to use other mechanisms such as national health councils and development networks.
- 5.3 Development of guidance for legislation aimed at extending health coverage to the entire population, providing for a more rational distribution of resources between promotive, preventive, curative, rehabilitative, and long-term care and supportive activities, and ensuring the necessary infrastructure, resources and manpower for the essential elements of PHC; such guidance will be developed in close consultation with the relevant technical programmes.
- 5.4 The promotion of the international exchange of health legislation that has been analysed by the WHO Secretariat and by a network of collaborating agencies and institutions. The primary mechanism for such exchange will continue to be the International Digest of Health Legislation. Particular attention will be given to disseminating information on legislation that facilitates the introduction of promotive and preventive health measures, is conducive to healthy lifestyles, ensures greater equity in access to health care, reorients the health budget towards more relevant technologies, supports the development of new types of health workers where necessary, facilitates the employment of traditional practitioners and birth attendants, where applicable, and promotes an intersectoral approach to key issues, including environmental health.
- 5.5 Use of existing facilities in developed countries and centres of expertise in developing countries to initiate and foster programmes for the training of national experts in health legislation.
- 5.6 Drawing on international expertise, through appropriate mechanisms and in the light of available resources, for formulating recommendations on health legislation in support of HFA.
- 5.7 Identification, in close consultation with technical programmes and national experts, of priority issues in health legislation and commissioning comparative studies thereon.
- 5.8 Subject to available resources, conducting (1) analyses of trends in health legislation, and (2) evaluations of the relevance and impact of legislative measures for dealing with specific health problems (e.g. by monitoring literature on the effectiveness of legislation as a means of dealing with serious public health problems, such as AIDS and HIV infection, as a tool for modifying harmful behavioural patterns and practices, as in the tobacco consumption and alcohol and substance abuse fields, and for promoting better infant nutrition practices).
- 5.9 Cooperation with technical programmes by providing legislative input as required, thereby contributing to their impact on health status.

## 6. Activities

Details of specific activities during 1990-1995, classified according to the specific targets mentioned in section 4, are given below.



Activities	1990-1991	1992-1993	1994-1995	Linkages
<u>Training activities</u>				
6. Organization of national training programmes for lawyers and public health personnel		AFRO		HMD
7. Promotion of training courses in health legislation in public health and nursing schools		AFRO, WPRO		HMD
8. Organization of international course on health legislation, designed to promote the optimal use of legislative mechanisms in attaining HFA		EURO, HQ (global course)		HMD
9. Fellowships and study visits in health legislation		EMRO		HMD
<u>Advisory bodies and external collaboration</u>				
10. Convening of biennial (Regional) Advisory Committee on Health Legislation		EURO		
11. Cooperation with UNEP in implementation of relevant environmental law components of UNEP's System-Wide Medium-Term Environment Programme		HQ, countries		PEH, LEG

SPECIFIC TARGET 2 - Information exchange: By 1995, Member States will be making full use, as and when required, of the system for the international exchange of relevant information on health legislation operated by WHO in cooperation with a network of institutions and centres of expertise throughout the world.

Activities	1990-1991	1992-1993	1994-1995	Linkages
1. Continued publication of the IDHL in English and French editions, on the basis of principles set forth in Director-General's report (1980) and resolution EB65.R13; continued operation of information transfer activities based on strategies formulated in that report, in cooperation with regional and international centres		HQ and regions, countries		WHO technical programmes and global network of institutions and individuals
2. Continuous investigation of improved methods for collection and analysis of legislative information		HQ and regions		ISS
3. Operation of computer-based clearinghouse system for monitoring, analysing and reporting on significant new and amended health legislation in EUR countries (with annual reporting by subject, by country and by HFA target)		EURO, countries		
4. Cooperation with mass media and social organizations with a view to disseminating information on health legislation to the public		AFRO		
5. Compilation and analysis of information on alternative approaches to the organization of health systems based on PHC (legislative and policy aspects)		HQ and regions, as appropriate		PHC
6. Systematic monitoring of and reporting on significant national and international legal instruments dealing with all aspects of AIDS and HIV infection, including regular updating of list of legislation		HQ and regions		SPA

## 7. Programme management and resources

The emphasis will be placed on mutually supportive activities involving global and regional staff, guided by the philosophy that information transfer and technical cooperation activities are interlinked and interdependent. Effective technical cooperation cannot be realized without relevant information, and information exchange without a thorough understanding of national needs identified by technical cooperation will be less than optimally effective. Approximately two-thirds of WHO's Member States still fail to comply fully with Article 63 of the Constitution, thereby depriving other Member States of rapid access to what may well be important and innovative approaches to the resolution of key health problems, and even to the achievement of health for all. Every effort will be made, within existing resources, to stimulate countries to ensure the timely communication of information to WHO.

At both the global and regional levels, the programme will be managed in close cooperation with other programmes concerned with the health system infrastructure, while bearing in mind that many health science and technology programmes may well be dependent on a legislative framework for effective delivery in at least some national contexts. The capacity of WHO to respond to needs at the country level has been significantly strengthened in recent years by the nomination of focal points for the programme in each of the regional offices and, in particular, the appointment of staff with full-time (as in EURO) or half-time (as in AFRO) responsibilities for health legislation.

Global and regional staff (including WRs) will endeavour to trace developments in health legislation at the national level that have benefited from WHO input. There is little doubt that WRs could play a more active role in the programme by alerting governments to what WHO has to offer in this sector and by informing regional offices and headquarters of important new developments in health legislation.

WHO will seek to prepare rosters of experts, institutions and nongovernmental organizations capable of analysing and identifying possible solutions to problems in the reorientation of health legislation while taking full account of specific national needs and capabilities; substantial emphasis will be placed on the gradual establishment of a formally constituted network of collaborating centres, although the Secretariat will continue to enlist the support, where appropriate, of acknowledged experts in health legislation.

Extrabudgetary resources (which could well include seconded national experts) will certainly be needed if all the approaches enumerated in Section 5 are to be systematically applied and if current and foreseeable future needs in this sector are to be fully met. These resources will essentially be channelled through the regional offices in view of their more ready access to information on the specific legal frameworks of, and health problems and policies in, individual countries.

If and when an expert advisory panel is established, that body's functions could well include the provision of advice on how best to promote bilateral and other forms of technical cooperation (e.g. the encouragement of twinning arrangements between institutions and collaborative links between individuals in developed and developing countries). Guidance on the orientation of the health legislation programme of the Regional Office for Europe will continue to be provided by its Advisory Committee on Health Legislation.

## 8. Monitoring, evaluation and indicators

The programme will be evaluated as comprehensively as possible in relation to each of the targets mentioned in Section 4. In the evaluation process, it will of course be borne in mind that other programmes may well have contributed to the actual policy decisions that gave

rise to the need for new legislation. For policy and legislation are part of the same continuum, legislation being merely the principal vehicle whereby national orientations are endorsed and formulated in a binding manner by the executive or legislative branch of the government or at the ministerial or other appropriate level.

Particular attention will be paid to legislative texts that enshrine the health for all principle, that are indicative of a strong commitment to some or all of the essential elements of primary health care, that provide for community involvement in health development and decision-making, or that implement resolutions adopted by WHO's governing bodies.

With regard to information transfer, a useful mass of quantitative data on the utility of this WHO activity was compiled in 1978 by means of consultant visits to selected countries in all regions and by a questionnaire addressed to all Member States (both activities were developed in response to resolution WHA30.44); the information collected - from approximately 100 countries - will serve as a useful baseline in the event of such an exercise being repeated. It is hoped that a corresponding, although possibly differently structured, endeavour - designed to seek the views of Member States on the existing information transfer programme and how it could be further improved - will be undertaken in 1988-1989. Given the complex methodology whereby health legislation is generally drafted, and the frequent involvement of ministries other than the health ministry, there would seem to be no other realistic and objective way of determining the true impact of information exchange activities. The mere transmission of information, however relevant, provides no guarantee that it will be used. Nor is even the best draft prepared by the most sensitive consultant in a spirit of true technical cooperation of value unless it is adopted and implemented in a manner consonant with national needs and priorities.

In searching for appropriate indicators to determine the effectiveness of technical cooperation activities, it may prove useful to determine the approaches used by other agencies in the UN system that engage in parallel activities in their own spheres (e.g. FAO, ILO, UNEP, and UNFPA).

#### 9. Linkages

There will be close cooperation between the programme and other programmes concerned with health system infrastructure, particularly the managerial process for national health development, organization of health systems based on primary health care, and development of human resources for health. At the same time, every effort will be made to continuously strengthen existing and create new links with health science and technology programmes (those grouped under protection and promotion of the health of specific population groups as well as protection and promotion of mental health, promotion of environmental health, health risk assessment of potentially toxic chemicals, diagnostic, therapeutic and rehabilitative technology, tobacco or health, and disease prevention and control, including the Special Programme on AIDS).

For certain activities, implementation of international aspects will lead to closer linkages with appropriate programmes. This will be the case, for example, with the promotion of environmental health programme in regard to elements of the environmental law component of UNEP's System-Wide Medium-Term Environment Programme. In this particular instance, linkage will also be maintained with the Office of the Legal Counsel.

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