

6546

HEALTH LEGISLATION

European Programme

ADVISORY COMMITTEE
Dresden
24 - 26 June 1981



REGIONAL OFFICE FOR EUROPE
World Health Organization
COPENHAGEN

ORIGINAL: FRENCH

1982

ICP/HLE 002

9418 B

Note

The issue of this document does not constitute formal publication. It should not be reviewed, abstracted or quoted without the agreement of the World Health Organization. Authors alone are responsible for views expressed in signed articles.

CONTENTS

	<u>Page</u>
1. Strengthening of WHO's programme in health legislation	1
1.1 World Health Assembly	1
1.2 Regional Office for Europe	2
2. Establishment of an advisory committee on health legislation	3
3. General considerations	3
3.1 Health legislation and "Health for all by the year 2000"	3
3.1.1 Health protection	3
3.1.2 Promotion of lifestyles favourable to health	4
3.1.3 Primary health care	4
3.1.4 Access to health services	4
3.2 Current problems in health legislation	5
3.2.1 Centralization and decentralization	5
3.2.2 Coordination	5
3.2.3 Participation	5
3.2.4 Patients' rights	5
3.2.5 Financing of health services	5
3.3 Components of health legislation	5
3.4 Context of health legislation	6
3.4.1 Health legislation and the social, political, economic, cultural and historic framework	6
3.4.2 Health legislation, information and education	6
3.4.3 Health legislation and ethics	6
3.4.4 The sociology of health legislation	6
3.5 Models of health legislation	7
3.6 WHO's role in health legislation	7
3.6.1 Information	7
3.6.2 Education and training	7
3.6.3 Studies	7
3.6.4 Resource persons	7
4. Medium-term programme in health legislation	7
4.1 Health policy	8
4.2 Health situation	8
4.3 Health legislation services	8
4.4 Exchange of information	8
4.5 Manpower resources	9

	<u>Page</u>
5. Recommendations	9
5.1 Information	9
5.2 Education and training	9
5.3 Studies	10
5.4 Resource persons	10
5.5 Collaboration	10
5.6 Distribution of the report	10
Annex I Resolution WHA30.44	11
Annex II Resolution WHA33.28	12
Annex III Medium-Term Programme - Outline	13
Annex IV Form for notification of new health legislation to the Regional Office	20
Annex V List of participants	21

1. Strengthening of WHO's programme in health legislation

1.1 World Health Assembly

1.1.1 In 1977, the Thirtieth World Health Assembly clearly stated the importance of health legislation, giving the following reasons:

- (a) appropriate health legislation is of paramount importance in the strengthening of health services, and in particular in assuring primary health care for rural and otherwise underserved populations;
- (b) health legislation adapted to national requirements can serve to protect and improve the health of the individual and of the community;
- (c) many Member States still have limited health legislation that may date back to the colonial era, or no legislation at all, and this situation needs to be remedied by adapting legislation to present needs in the countries and developing new health laws to deal with new requirements;
- (d) Member States need to be informed of the health legislation of other countries, particularly that concerning drugs, foodstuffs, and toxic chemicals crossing national frontiers;
- (e) national health services require appropriate health legislation to ensure their adequate implementation.

Accordingly, the Assembly requested the Director-General to strengthen WHO's programme in health legislation, by resolution WHA30.44 (Annex I).

1.1.2 In 1980, the Thirty-Third World Health Assembly considered the Director-General's report on strengthening of WHO's programme in health legislation and adopted resolution WHA33.28 (Annex II).

In his report, the Director-General set out the following principles:

- (1) WHO's programme in health legislation must support the strengthening of national capacities for identifying their needs and for drafting appropriate, socially relevant legislation;
- (2) the need for health legislation can often best be identified through processes in support of health development, such as country health programming;
- (3) the optimum entry point for ascertaining the health legislation situation and needs in a country may well be the health ministry or another appropriate governmental agency, a national health development centre or network, a university department or research institution, or even one or several individuals with recognized expertise;
- (4) such national capacities should be developed mainly through the Organization's regional arrangements, relying on suitable information which has been properly digested and analysed; this approach should facilitate contact with national realities so that proper account is taken of specific country characteristics and requirements;
- (5) WHO's regional offices, in conformity with regional priorities, should assume primary responsibility for supporting governments in building up national capacities, thereby making it possible to build up regional self-reliance, which in turn will foster the development of national capacities in those countries where it requires strengthening;
- (6) in providing support to countries, regional offices should take into account the national cultures, social patterns, and political systems that influence their legislation - hence the need to identify and support individuals and national centres responsible for health legislation at country level; the regional offices will then also be in a better position to ensure the exchange of information and experience between countries through the medium of these responsible individuals and centres;
- (7) national institutions are clearly in the best position to place health legislation in its proper social perspective; some of these national institutions may be recognized by other

countries as subregional or regional centres, others as global centres; certain regional and global centres may be given formal recognition by the Organization as WHO collaborating centres;

(8) the resources of technical institutions (which may in some instances be other international organizations) can be utilized for collating, analysing and distilling legislation dealing with technical matters; such institutions may also make their expertise available to assist national or regional centres in drafting new technical health legislation;

(9) global and regional expertise should be used to promote the above process and the involvement in it of other international and nongovernmental organizations, for example, by encouraging twinning arrangements between institutions and collaborative links between individuals in developed and developing countries;

(10) technical cooperation and information transfer should be regarded as mutually supportive, it being understood that the Digest and associated information services will be reoriented in order to ensure that material that is truly relevant is made available to meet national and regional needs;

(11) the Digest, as its very name suggests, should provide analysed information on health legislation of the type mentioned in paragraph 14 of document GB 65/24; it should be regarded as only one link in a global system for the compilation, analysis, and dissemination of relevant information;

(12) the Organization will retain entire responsibility for both the technical cooperation and information transfer components of the programme, although it will rely to the greatest possible extent on the world's not inconsiderable - yet currently dispersed - resources in the health legislation field, notably individuals, institutions and centres;

(13) the multisectoral implications of health development make it more necessary than ever to collaborate, in the formulation of health and related legislation, with other sectors at the national, regional, and global levels; the Organization will support such collaboration in countries and will itself ensure the necessary liaison with appropriate organizations at regional and global levels, such as the United Nations regional economic commissions, the United Nations Environment Programme, and other international organizations and agencies.

1.2 Regional Office for Europe

Until recently, health legislation was the exclusive responsibility of WHO headquarters. In 1977, however, pursuant to World Health Assembly resolution WHA30.44, it was agreed to strengthen and at the same time decentralize the health legislation activities. Subsequently, in view of the further interest in this approach expressed by the Regional Committee at its twenty-seventh session it was decided to launch health legislation activities in the Regional Office on a consultant basis, with the support of a voluntary contribution by a Member State.

The first important undertaking was the establishment of a network of national counterparts in 1978, in order to strengthen cooperation with countries and assist in the revision of existing, or drafting of new, health legislation.

Some 20 countries have requested the consultant services from the Regional Office. Steps have been taken to assemble a body of information on the existing legislation in Europe, the resource persons available, participating institutes, and national legislation relevant to the Regional Office's programmes.

At the same time particular efforts have been made to coordinate the health legislation activities of the Regional Office with those of other European intergovernmental organizations working in this field. This activity forms part of the implementation of resolution WHA30.44 which stresses the need to "strengthen collaboration with other specialized agencies concerned in the development of guidelines for health legislation on the various subjects of health policies".

In 1979, activities in health legislation were further developed, and the increasing demands upon the Regional Office prompted the establishment of a health legislation unit and the formulation of a medium-term programme for the European Region.

The experience gained in Europe also enabled the Regional Office to assist in drafting proposals on strengthening WHO's health legislation activities, for submission by the Director-General to the Executive Board and the World Health Assembly in January and May 1980. These proposals were strongly supported and a further resolution (WHA33.28) was adopted calling for the formulation of a programme in health legislation on the basis of the approved strategies.

2. Establishment of an advisory committee on health legislation

In 1981, the Regional Office established an advisory committee on health legislation. This committee, the first of its kind, acts as an advisory body of national experts, whose purpose is to assist the Regional Office in the management of the medium-term programme in health legislation. It is expected to meet every third year in order to evaluate the progress achieved and, if necessary, reorient the programme in the light of new developments.

The tasks of the committee are as follows:

- (1) to provide guidance on the major direction of development of the health legislation programme in the European Region;
- (2) to review the medium-term programme in health legislation;
- (3) to suggest programme priorities from the point of view of those responsible for national health matters;
- (4) to recommend the timing and sequence of further activities;
- (5) to review more specific aspects of the programme so that they can be progressively developed by the Regional Office over the coming years;
- (6) to assist in the establishment of ad hoc groups on specific problems;
- (7) to help identify potential resources and collaborative mechanisms available in the Region;
- (8) to provide specific advice on how legislation could enable governments to promote the implementation of regional strategies for health for all by the year 2000.

The committee met for the first time in Dresden from 24 to 26 June 1981 (see Annex V for list of participants).

The committee discussed the following items:

- (1) the major orientations of health legislation;
- (2) the medium-term programme in health legislation drawn up by the Regional Office;
- (3) recommendations.

3. General considerations

3.1 Health legislation and "Health for all by the year 2000"

Health legislation is a very important tool in developing health policies with man and society as their cornerstone. It is not an end in itself, but merely one of the instruments that may be used to implement a given health policy.

In view of the magnitude of health problems and the inadequate and intolerably inequitable distribution of health resources throughout the world, the Thirtieth World Health Assembly in May 1977 decided that the main social target of governments and of WHO should be the attainment by all citizens of the world by the year 2000 of a level of health that will permit them to lead a socially and economically productive life (resolution WHA30.43).

Health legislation can make an important contribution to the Regional Strategy for Health for All by the Year 2000, especially in the following fields.

3.1.1 Health protection

This primarily concerns the protection of people from risks over which they have a limited or no influence, and which they are unable to control on their own. This has a bearing on management of man's environment, in respect of:

- physical and chemical pollution, radioactivity, noise;
- town planning, conservation of the natural environment;

- environmental aspects of accident prevention;
- control of industrial production;
- conventional measures in community health, sanitation, housing, immunization, monitoring of water and food quality, and compulsory health controls for specific groups (school health, maternal and child health).

3.1.2 Promotion of lifestyles favourable to health

This involves giving every encouragement to individuals and groups to alter habits which will harm health and to live in a healthier fashion. Health legislation could serve as an indirect approach for this purpose. This applies to feeding patterns, consumption of different substances, physical exercise, and driving of motor vehicles. Health professionals and politicians have realized that, especially in the industrialized countries, further progress in improving community health will have to come about through such alterations in habits.

3.1.3 Primary health care

On this item, the committee examined the report of the International Conference on Primary Health Care (Alma-Ata, USSR, 6-12 September 1978), stressing the importance of legislation, and referred particularly to:

(a) Article V of the Declaration of Alma-Ata:

"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."

(b) Recommendation 18 "National commitment to primary health care":

"The Conference,

Affirming that primary health care requires strong and continued political commitment at all levels of government, based upon the full understanding and support of the people,

RECOMMENDS that governments express their political will to attain health for all by making a continuing commitment to implement primary health care as an integral part of the national health system within overall socioeconomic development, with the involvement of all sectors concerned; to adopt enabling legislation where necessary; and to stimulate, mobilize, and sustain public interest and participation in the development of primary health care."

(c) Paragraph 125 of the Report of the Conference:

"In some countries, legislation will be required to facilitate the development of primary health care and the implementation of its strategy. Thus, there might be a need for new legislation or the revision of existing legislation, to permit communities to plan, manage and control primary health care and to allow various types of health workers to perform duties hitherto carried out exclusively by health professionals. On the other hand, there often exist laws which are not applied by which, as they stand, might be used to facilitate the development of primary health care."

3.1.4 Access to health services

For everybody to benefit from appropriate health services, there must be equality of access to these services. The right kind of legislation could help to make services available in geographic, social and financial terms. Such legislation is concerned above all with:

- programming, to achieve a balanced distribution of the different services;
- organization, to promote efficiency of health services;
- financing, to remove financial barriers impeding access by all to health services.

3.2 Current problems in health legislation

The committee drew attention to a number of health legislation problems currently faced in the different countries.

3.2.1 Centralization and decentralization

On the one hand an effort must be made to develop a global health law covering all aspects of a country's health system, as in Italy, Portugal, the United Kingdom and the USSR for instance, as opposed to a piecemeal approach to the legislation.

On the other hand it is felt that, as far as possible, regulations having a direct impact on people must be decided upon close to them, at local level. That applies to health promotion and also to the organization of health services, insofar as it can be facilitated at the periphery by private or even voluntary collaboration or initiatives. It is particularly in respect of health protection and health policy that there is an important role to be played by legislation, which can be enacted at central level.

3.2.2 Coordination

There is evidence of excessive differentiation as well as proliferation of health regulations and laws, associated with inadequate coordination between the ministries and departments concerned. The situation is sometimes one of regrettable complexity. The multisectoral aspects of the total health concept make it essential to improve coordination among the various ministries responsible for issuing legislation or regulations on health or related matters.

In many countries, the health administration will have to be remodelled and it might be necessary to issue new legislation to strengthen the coordinating role of health departments and other elements in the national system.

3.2.3 Participation

Participation by the community is essential, given the nature of health problems, whose solution requires not only understanding on the part of the public, but also their support.

The question arises of determining how the providers of health care and consumers can be made to participate in the formulation of health policy and in decision-making.

3.2.4 Patients' rights

In several countries there is evidence of public demand that the rights of patients or the sick be clearly established: the right to information, to protection of privacy, to freedom of choice, to refusal of treatment, etc. Up to now it was essentially a question of the right to health with all that this supposes. Now there is a need to go further and to establish the rights of patients, the rights of those in hospital, the rights of mental patients, the rights of the disabled, etc.

3.2.5 Financing of health services

In view of the world economic crisis, it is felt that many countries are unable to increase resources to cover their health service expenditures. The end of the century is likely to be marked by a low economic growth or even no growth. It would be unwise to count on an appreciable increase in the resources that countries could or would be prepared to devote to health services in the next twenty years.

To a large extent, it will be necessary to correct the shortcomings of health services and meet new needs by making the present systems more efficient, redistributing resources to make them most cost-effective, encouraging people to take greater responsibility for their own health, and reducing the undue burden on services that has resulted from insufficient attention being paid to prevention in the past.

The economic situation we now face calls for appropriate revision of much of the existing health legislation.

3.3 Components of health legislation

Health legislation has six main components:

- the environment: protection of the environment (rivers, coasts and seas), pollution control, development of sanitation standards;
- consumers: protection, promotion, prevention, curative medicine, rehabilitation services;
- providers of care: physicians, pharmacists, dentists, midwives, nurses, paramedical staff;
- institutions: health centres, polyclinics, hospitals, institutions for the chronically ill, rehabilitation centres;
- regulating agencies: legislators, government, ministry of health, other ministries, health insurance bodies, lower level authorities, private organizations;
- financing (capital and operating costs) of health services: State, compulsory health insurance, optional health insurance, combined systems.

3.4 Context of health legislation

3.4.1 Health legislation and the social, political, economic, cultural and historic framework

A country's health legislation must be viewed in the light of its social, political, economic, cultural and historic framework. From this, we can note wide differences between the legislation of countries. They may be divided into different groups according to the systems in force: the socialist countries of eastern Europe, countries where the health services are financed by health insurance, e.g. Belgium, France, the Federal Republic of Germany, the Netherlands, countries with a national health service, e.g. Italy, Portugal, the United Kingdom.

Yet, despite the differences, the health legislation systems have a number of points in common.

3.4.2 Health legislation, information and education

To give effect to a given health policy, a government can use different approaches either directly or indirectly, by encouragement or subsidy of third parties, including:

- public information, through the mass media and other means;
- health education and various methods of health promotion;
- guidance of the training of health professions;
- action by professional associations, especially through each profession's code of ethics;
- negotiations with nongovernmental bodies such as associations of hospitals, health insurance and other institutions;
- action by consumer's associations;
- legislation and regulatory machinery.

3.4.3 Health legislation and ethics

There is a very close link between health legislation and ethics, especially with regard to:

- the problem of infringement of individual liberty which may be raised by compulsory health measures;
- organ transplantation;
- sterilization;
- artificial insemination and embryo implantation;
- euthanasia;
- voluntary termination of pregnancy;
- experimentation on man;
- determination and criteria of death.

3.4.4 The sociology of health legislation

The committee emphasized the difficulty of giving effect to legislation and evaluating its impact on the health situation concerned.

Legislation will be without effect when the support of professionals is insufficient, when cooperation by the public is limited and when the necessary logistic support is lacking. Up to now no sustained efforts have been made to assess the impact of legislation and regulations on health problems.

Any formulation of a sectoral policy, any enactment of a law, any development of regulation, however sound in terms of the effect sought, can be considered valid only insofar as that effect is actually achieved.

We are not justified in saying that professionals or the public are at fault when legislation is either not or only partially complied with. The fact is that the regulations in question pose some problem for those concerned in terms of the values they hold. Clearly, technical authorities, the members of the government they advise and legislators must take account of the strengths and weaknesses of proposed legislation in respect of its actual application.

Effectiveness, applicability, and acceptability of health legislation are very complex problems which require study, preferably by legal sociologists and experts in medical sociology.

3.5 Models of health legislation

The committee felt that health legislation models can be drafted despite social, political, economical, cultural and historic differences between countries.

It is primarily a matter of developing a conceptual framework for health legislation or an outline law on health.

The system could be based on the six components of health legislation mentioned above (para. 3.3), namely: environment, consumers, providers of care, institutions, authorities, and financing. Around these six components, it would be possible to develop health legislation models and to group the different existing laws and regulations clearly and logically.

3.6 WHO's role in health legislation

The committee felt that the WHO Regional Office for Europe could play a fourfold role in health legislation.

3.6.1 Information

- On the one hand, information should be supplied by each country to the Regional Office on any important new legislation.
- On the other, information should be supplied by the Regional Office to a country requesting details of the health legislation of one or more other countries.

The Regional Office could thus act as a documentation centre for health legislation.

3.6.2 Education and training

At present there are several international courses, organized by WHO, on health planning, health service administration, health economics, etc. The committee felt it would also be useful to establish an international course on health legislation.

3.6.3 Studies

The committee felt that the Regional Office could undertake, either directly or indirectly, a series of comparative studies on health legislation.

3.6.4 Resource persons

WHO could draw up a list of health legislation specialists who might serve as consultants both for the developed and for the developing countries.

4. Medium-term programme in health legislation

The committee examined the medium-term programme in health legislation, drawn up by the Regional Office for the period 1980-1985.

The programme comprises five subprogrammes concerned with health policy, the health situation, health legislation services, exchange of information and manpower resources.

4.1 Health policy

The objective is to help countries to adopt adequate legislation likely to improve the operation and effectiveness of their health services, in line with the strategies for achieving health for all.

Two studies are envisaged for this purpose.

The first is a study on trends in public health legislation in Europe (laws on public health, primary health care, health protection and health promotion). It could comprise three components: an analytical approach, a comparative review, and the development of one or more health legislation models.

The second study will be on the measures to be taken by governments to ensure a better distribution (geographical, and by specialization and type) of their health personnel, so as to give all sectors of the population equal access to care.

4.2 Health situation

The objective is to initiate or improve evaluation of the impact of legislative and regulatory measures on the health situation.

Two series of studies will be undertaken.

First there will be studies on the impact of legislative and regulatory measures on the health situation in specific areas in collaboration with other regional programmes: nursing, family planning, health care of the elderly, health education, accident prevention, workers' health, toxicology, food safety, oral health, maternal and child health, etc. It is proposed above all to study the methodology of such research and of comparing the objects and results of health legislation. The committee stressed the value of having a "legislation" component in the different WHO programmes. Legislation should be an integral part of each programme.

Finally, case studies will be performed on the contribution of health legislation measures in effecting behavioural changes. These will be set up in conjunction with government programmes (control of alcoholism, smoking, drug abuse, etc.).

4.3 Health legislation services

The objective of this subprogramme is to stimulate improvements in the structure and functioning of health legislation services in Member States.

The proposed activities are as follows:

- (1) studying the machinery set up to achieve satisfactory coordination between ministries and departments involved in health legislation;
- (2) providing guidelines on health legislation to Member States;
- (3) giving publicity to measures taken to prevent the development of unduly complex legislative systems.

With regard to the latter point, the committee felt that the codification or regrouping of existing legislation would be necessary in order to simplify the very extensive and complex texts.

4.4 Exchange of information

The objective is to facilitate the exchange of information on health legislation between Member States for comparison and decision-making purposes. A review will be made of what has been done in the Region with regard to the adoption of legislation on primary health care and the revision of laws on public health, health protection and health promotion.

The following activities are envisaged:

- (1) establishment and updating of a network of national counterparts, and identification of potential participating institutions and centres;

- (2) setting up of a system for periodic notification to the Regional Office of health legislative measures taken by countries; provision by countries to the Regional Office of essential data on important new laws and regulations; use by national counterparts of the computer form shown in Annex IV (this system is already operational in ten countries of the Region);
- (3) development of an information and advisory service for meeting ad hoc requests from Member States and, as far as possible, teams of researchers in health legislation;
- (4) circulation to countries, by the Regional Office of a periodic record of important new laws and regulations, using the Office's computer facilities;
- (5) study of the extensive range of existing international agreements containing health provisions; preparation of a table of international health agreements to which the European Member States have acceded, whether bilateral, within the framework of other organizations, or with developing countries.

Clearly there will be a need for close collaboration between the Regional Office and WHO headquarters.

4.5 Manpower resources

The objective of the subprogramme is to increase the number of persons available with suitable experience and to enable countries of the Region and developing countries to make use of this manpower.

The following activities are envisaged:

- (1) the compilation of a European directory of education and training facilities in health legislation;
- (2) further development of the system of advice on the placement of fellows in the field of health legislation;
- (3) support of courses, initially by providing lecturers to both developed and developing countries;
- (4) compilation of a regional list of experts in health legislation.

5. Recommendations

5.1 Information

The committee noted that the pilot system already in operation with ten countries of the Region was giving satisfactory results, and it recommended its progressive extension to all countries in the Region.

It would be useful to hold a meeting with national counterparts, in order to study jointly:

- the Regional Office's notification and information system;
- a list of key words identified mainly in terms of the strategy for health for all by the year 2000;
- a list of publications on health legislation.

5.2 Education and training

5.2.1 The committee recommended that the Regional Office invite Member States to take the necessary steps to incorporate health legislation courses in the curricula:

- for medical, paramedical and legal training;
- for public health training (more advanced).

5.2.2 The committee also recommended the holding of an international health legislation course of 3-4 weeks' duration for senior officials in public health systems.

The committee proposed organizing a workshop, which could be prepared by a smaller advisory group, to work out a programme and teaching methods for the course.

5.3 Studies

The committee gave absolute priority to the study on present trends in health legislation with the aim of assessing progress between the present situation and the achievement of health for all by the year 2000 (see para. 4.1).

It recommended setting up an ad hoc working group for detailed formulation of the content of the study and the methodology to be used.

5.4 Resource persons

The committee recommended drawing up a list of experts in different fields: medical law, health law, hospital legislation, environmental legislation, pharmaceutical legislation, food hygiene legislation, etc.

5.5 Collaboration

The committee considered that close collaboration should be maintained and promoted between the Regional Office and:

- national governments;
- WHO headquarters;
- other WHO regional offices;
- other international organizations concerned with health legislation;
- universities and centres specializing in health legislation.

5.6 Distribution of the report

In view of the importance attached to the medium-term programme in health legislation and to the first meeting of the advisory committee, it was recommended that the report be widely distributed.

Annex I

THIRTIETH WORLD HEALTH ASSEMBLY

WHA30.44

19 May 1977

HEALTH LEGISLATION

The Thirtieth World Health Assembly,

Considering that appropriate health legislation is of paramount importance in the strengthening of health services, and in particular in assuring primary health care for rural and otherwise underserved populations;

Recognizing that health legislation adapted to national requirements can serve to protect and improve the health of the individual and of the community;

Noting that many Member States still have limited health legislation that may date back to the colonial era, or no legislation at all, and that this situation needs to be remedied by adapting legislation to present needs in these countries and developing new health laws to deal with new requirements;

Bearing in mind the need for Member States to be informed of the health legislation of other countries, particularly that concerning drugs, foodstuffs, and toxic chemicals crossing national frontiers;

Recognizing the fact that national health services require appropriate health legislation to ensure their adequate implementation;

Noting further the recommendations on legislation adopted by various United Nations conferences, notably the Stockholm Conference on the Human Environment, the United Nations Conference on Human Settlements (Habitat), and the recent United Nations Water Conference;

Bearing in mind that no country can solve its health problems in isolation and that a sharing of experience in the health legislation field is of considerable value, notably for the developing countries;

Recalling resolutions by previous Health Assemblies and Executive Board sessions concerning the Organization's overall programme in health legislation;

1. URGES Member States to fulfil their obligations under Article 63 of the Constitution to forward their important health laws and regulations to the Organization;
2. REQUESTS the Director-General:
 - (1) to strengthen WHO's programme in the field of health legislation, with a view to assisting Member States, upon their request, in the development of appropriate health legislation adapted to their needs, and to enhance technical cooperation in health legislation and its administration, particularly in developing countries;
 - (2) to strengthen collaboration with other specialized agencies concerned in the development of guidelines for health legislation on the various subjects of health policies;
 - (3) to study and implement the optimum means for the dissemination of legislative information in Member countries to serve as guides for the development of new or revised health laws;
 - (4) to submit a report on developments in this sphere to the Health Assembly as soon as possible;
3. REQUESTS the Executive Board to re-examine the criteria for the International Digest of Health Legislation approved by the sixth session of the Board, with a view to updating them to meet the present needs of technical cooperation designed to serve developing countries.

Annex II

THIRTY-THIRD WORLD HEALTH ASSEMBLY

WHA33.28

23 May 1980

HEALTH LEGISLATION

Strengthening WHO's health legislation programme

The Thirty-third World Health Assembly,

Recognizing that obsolete health legislation may constitute an obstacle at the national level to the attainment of health for all;

Noting that appropriate health legislation is an essential component of health care services and environmental health systems for the delivery of both personal and environmental health services;

Having considered the report of the Director-General on the strengthening of WHO's health legislation programme¹ and the comments of the Executive Board thereon;²

1. CONSIDERS that the proposed reorientation of the health legislation programme, in pursuance of resolution WHA30.44, fully reflects the new health policies of WHO and its Member States;
2. REQUESTS the Director-General to proceed with the formulation of a detailed programme of technical cooperation and information transfer in health legislation, on the basis of the strategies presented in his report.

¹ Document EB65/1980/REC/1, p. 77.

² Document EB65/1980/REC/2, p. 240.

Annex III

HEALTH LEGISLATION

MEDIUM-TERM PROGRAMME - OUTLINE

by

G. Pinet

Regional Officer for Health Legislation
World Health Organization
Regional Office for Europe

1. Problem definition

Problem 1: inadequate legislation to support the development of health policies.

Situation analysis

Legislation inadequate or unsuited to present conditions may result in a limitation on health development. Thus, there is a need for new or revised legislation in order to support health policies and in particular the implementation of strategies to achieve health for all.

Problem 2: difficulties in ensuring the implementation of the law and in evaluating its impact on the relevant health situation.

Situation analysis

Legislation remains a dead letter when there is insufficient professional endorsement, poor population adhesion and lack of logistical support. There is not yet a genuine effort to proceed with an evaluation of the impact of laws on the relevant health problems.

Problem 3: too specific, too numerous health laws coupled with unsatisfactory coordination between ministries and departments involved.

Situation analysis

In some cases such factors lead to disadvantageous complexity. The multisectoral aspects of the total health concept make it essential to ensure a better coordination between the various ministries issuing health or health related legislation.

Problem 4: increased need of access at national level to international exchange of information on health legislation.

Situation analysis

The solidarity and interdependence of European countries create a current need to obtain rapidly from other countries available information on health legislation for comparison and decision-making purposes.

Problem 5: limited availability of suitably experienced persons.

Situation analysis

Facilities for teaching in health legislation are not yet a regular feature of public health and/or public law training.

2. Programme perspective

2.1 Salient past events

Until recently, health legislation was the exclusive responsibility of the WHO headquarters. In 1977, pursuant to a World Health Assembly resolution (WHA30.44) it was decided to strengthen and at the same time decentralize health legislation activities.

After interest was expressed at the twenty-seventh session of the Regional Committee, health legislation activities in the Regional Office started in 1977 on a consultantship basis thanks to a voluntary contribution from a Member State.

In 1978, the first major undertaking was the building up of a network of national counterparts; its aim was to enhance cooperation with countries and to assist in the revision of existing legislation and/or the drafting of new texts.

Until now, at their request about 20 countries have been provided with this type of legal advisory service by the Regional Office. A body of information on existing legislation in Europe is being built up including data on resource persons, participating institutes and references on national legislation of relevant to major WHO/European programmes.

Concurrently, a special effort has been made to coordinate the Regional Office's activities in health legislation with those of other European intergovernmental organizations active in this field. This was done in accordance with resolution WHA30.44, which stresses the importance of strengthening collaboration with other specialized agencies concerned in the development of guidelines for health legislation on the various subjects of health policies.

In 1979, activities in health legislation were further developed and the increasing demand upon the Regional Office led to the gradual establishment of a health legislation unit and the elaboration of the regional medium-term programme.

The experience gained in the European context also enabled the Regional Office to contribute to the drafting of proposals for reorientation of the WHO health legislation activities, submitted by the Director-General to the Executive Board and World Health Assembly respectively in January and May 1980. These proposals received widespread support and a new resolution (WHA33.28) was adopted requesting the elaboration of a WHO health legislation programme along the same lines.

2.2 Relationship with other programmes

The health legislation programme has links with the health development and planning programmes which are part of the managerial process for national health development.

In Europe the emergence of "semi-international" legislation reflecting health policy agreed upon by Member States pertaining to subregional groupings makes it essential for the WHO health legislation programme to be closely coordinated with the programmes of other intergovernmental organizations active in this field.

Health legislation appears as a component of almost all other programmes of the Regional Office, and the health legislation unit will provide support and advice for studies and surveys on specific legislative aspects of these programmes. Such collaboration has already started in the fields of nursing, food control, family planning, and care of the disabled, and is foreseen in relation to the programmes on workers' health, toxicology, accident prevention and health education. In this connexion an effort is made to identify and support national centres and nongovernmental organizations engaged in the corresponding fields of health legislation.

This interdisciplinary approach also requires particularly close collaboration with and support from the health information programme. Efforts are being made to develop a computerized information subsystem for the health legislation programme which will be integrated in the overall information system of the Regional Office.

Close links are maintained with three headquarters' services active in this field, namely the unit responsible for issue of the International digest of health legislation; the division of strengthening of health services which is in charge of technical cooperation with countries; and the legal office which deals with international agreements, conventions and constitutional matters.

Subprogramme 1
(Health Policy)

Problem 1: inadequate legislation to support
the development of health policies

objectives	activities	ways and means
1. to support and enable the development of health policies	1.1. study on trends in public health legislation in Europe (e.g. including Public Health Acts, primary health care and health protection and promotion laws)	- updating of Regional Office information through governments' input
	1.2. study on measures taken to ensure a better geographical repartition of health personnel (including incentive measures, taxation policy, civil service for doctors); principle of equity for the access to health services/care by means of a balanced coverage of the population	- gathering of information concerning the practice in different countries
	1.3. review of the wide range of existing international agreements having a health component (one could further envisage to pursue the review at country level and elaborate country profiles)	- in collaboration with other IGOs active in the health field; this activity corresponds to the WHO coordination role in international health matters and to WHO concern for avoiding duplication of activities

Subprogramme 2
 (Health Situation)

Problem 2: difficulties in ensuring the implementation of the law and in evaluating its impact on the relevant health situation

objectives	activities	ways and means
2. incentive to initiate or strengthen the evaluation of the impact of legislative measures on the relevant health situation	2.1. to perform studies on the impact of legislative measures on the health situation in specific areas	<ul style="list-style-type: none"> - in collaboration with EURO programmes using statistics and epidemiological surveys in finding out reason for success or some failure e.g. with programmes such as: nursing, family planning, health care of the elderly, health education, accident prevention, workers' health, toxicology, food safety, oral health, maternal and child health
	2.2. to perform case studies on the contribution of health legislation measures for achieving behavioural changes	<ul style="list-style-type: none"> - to be organized in relation to governments' programmes (e.g. fight against alcoholism, tobacco, drugs)

Subprogramme 3

(Health Legislation Services)

Problem 3: too specific and too numerous health laws coupled with an unsatisfactory coordination between ministries and departments involved

objectives	activities	ways and means
3. to stimulate an improvement of the structure and function of health legislation services in Member States	3.1. study of the mechanisms set up for achieving a satisfactory coordination between ministries and departments involved in health legislation activities 3.2. make available to Member States model patterns in use 3.3. give publicity to measures geared at preventing building up of a too complex legislative framework	- choice of specific countries willing to collaborate in such a study - (advice on feasibility) - (advice on feasibility)

Subprogramme 4
(Exchange of Information)

Problem 4: increased need of access to international exchange of information on health legislation

objectives	activities	ways and means
4. to facilitate the exchange of information on health legislation between Member States for comparison and decision making purpose	4.1. to complete and update a network of national counterparts and further identify potential participating institutes and centres 4.2. to develop an information and advisory service for answering ad hoc requests from Member States 4.3. to set up a periodic health legislation notification system from countries to the Regional Office	- maintain close contacts with countries in particular for monitoring changes - - countries to provide the Regional Office with essential data on important new laws and regulations; national counterparts using a standard form designed for computerized processing
	4.4. the Regional Office to provide countries with a periodic record of important new laws and regulations	- use of Regional Office computer facilities

Subprogramme 5
(Manpower Resources)

Problem 5: Limited availability of suitable
experienced persons

objectives	activities	ways and means
5. to increase the availability of suitable experienced persons and to share manpower resources with developing countries	5.1. to set up a European directory of teaching and training facilities in health legislation	- collection of information on teaching and training centres and programmes and curriculae (sources: collaborating institutions, schools of public health, departments of social medicine)
	5.2. to further develop the system to advise on the placement of fellows in the field of health legislation	- use of knowledge gained through the above mentioned activity for the placement of fellows
	5.3. to support courses, at the initial stage by providing lecturers, for both developed and developing countries	
	5.4. to build up a regional list of experts in health legislation	

Annex IV

Country

Code

**EURO – HEALTH LEGISLATION
NOTIFICATION OF NEW LEGISLATION**

to be forwarded to

**HEALTH LEGISLATION SERVICE
REGIONAL OFFICE FOR EUROPE
8, Scherfigsvej
DK-2100 Copenhagen Ø**

1. * Proposed/enacted
2. * Primary/subordinate legislation (if subordinate, specify parent legislation)
3. Subject (for classification purposes)
4. Title and number
5. Main purpose of legislation
6. Date of:
 - (a) enactment
 - (b) coming into operation
 - (c) expiration (if any)
7. Any other remarks about importance of legislation with regard to national health matters

* Delete whichever is inapplicable.

Please join copy of any explanatory memorandum or note (if available, in English or French).

NB: Please do not interpret the term "legislation" in a restricted sense and feel free to notify other normative measures which could be of international importance.

Annex V

LIST OF PARTICIPANTS

TEMPORARY ADVISERS

- Mr E.N. Afinogenov
Chief, Legal Office, Ministry of Health of the USSR, Moscow, USSR
- Dr F.J. Giménez-Hernandez
Secretariat-General of Technical Services, Ministry of Labour, Public Health and Social Security, Madrid, Spain
- Professor P. Jean
Inspectorate-General of Social Affairs, Ministry of Health and Social Security, Paris, France
- Dr E. Kiss
Head, Department of Administration and Legal Affairs, Ministry of Health, Budapest, Hungary
- Professor H. Klette
Department of Sociology of Law, University of Lund, Sweden
- Professor H.J.J. Leenen
Professor of Social Medicine and Health Law, Institute of Social Medicine, University of Amsterdam, Netherlands
- Dr K. Leppo
Deputy Director, National Board of Health, Helsinki, Finland
- Dr J. Mandel
Head, Legal Department, Ministry of Health, Berlin, German Democratic Republic
- Dr J.F. Martin
Deputy Cantonal Medical Officer, Public Health Service of the Canton of Vaud, Department of the Interior and Public Health, Lausanne, Switzerland
- Professor A.V. Prims
Faculty of Medicine, University of Louvain, Belgium (Rapporteur)
- Professor K. Spies
Vice-Minister of Health, Ministry of Health, Berlin, German Democratic Republic (Chairman)
- Dr M. Violaki-Paraskeva
Honorary Director-General and Consultant on International Affairs to the Minister of Social Services, Athens, Greece (Vice-Chairman)

WORLD HEALTH ORGANIZATION

Regional Office for Europe

- Miss C. Pinet
Regional Officer for Health Legislation (Secretary)
- Dr A. Wojtczak
Director, Research, Planning and Human Resources

Headquarters

- Mr S.S. Fluss
Responsible Officer, Health Legislation