Enhancing health policy development:

A practical guide to understanding the legislative process

WORLD HEALTH ORGANIZATION
Regional Office for the Western Pacific

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About this Guide

Member States of the World Health Organization often seek technical assistance in **health legislation**[*] in the process of development and reform of the health sector.

> This publication is intended as a guide to Ministries/ Departments** of Health in Member States to enable an understanding of the country's legislative structure and process to be gained prior to technical legislative assistance being provided. It will enable relevant materials to be collected and informative descriptions compiled so that the maximum time is available for providing the technical assistance. Even if external technical assistance in health legislation is not being sought, the carrying out of the tasks covered in this Guide will provide a Ministry of Health with an essential legislative resource that will be available to all concerned with the development and implementation of health policy.

Health legislation is a tool in implementing health policy, providing a framework for its implementation. The adoption of new law is not an end in itself but can provide the administrative basis for the development and management of health systems and programmes. The potential functions of law are many. Law can give legal rights and impose legal obligations. Its effect can be to regulate behaviour, authorise programmes, regulate resources for health services including human resources and provide for the financing of health care services. So it is a tool with many potential uses but whatever is drafted and introduced to the country's legislature should be the best tool suited to support the health policy.

* To assist the reader, words in bold are defined further in the Glossary of terms at the end of this booklet.
**For brevity, "Ministries of Health" will be used throughout the remainder of this document.

New law should be placed appropriately within the hierarchy of legislation. An overarching objective should be to ensure that any new law, whatever its level, is both workable and appropriate to the resources available. It should also aim, by the inclusion of rights and duties, to balance the public interest and the rights of individuals, as well as achieving a balance of the interests of various groups in society, resolving any conflict of interest between those groups.

> In order to provide the most effective legislative drafting assistance, it is necessary for the drafter to:
>
> - Have knowledge of the country's **legislative structure;**
> - Have knowledge of the country's **legislative process**;
> - Obtain copies of any existing drafts, laws, decrees or sub-laws such as regulations;
> - Understand the policy sought to be implemented; and
> - Have knowledge of resource constraints.

It is appreciated that not all Ministries of Health have in-house lawyers. This Guide is designed to ensure that it is not necessary for the preliminary legislative work to be carried out by trained legal personnel. The carrying out of these tasks will have the additional benefit of providing the individual with knowledge of the existing health legislation, and the process to achieve legislative change, in his or her own country.

Sometimes assistance will be available from others in Ministries and offices that are concerned with legal matters, such as an Attorney General's Department or Crown Law Office. This can result in invaluable opportunities for collaboration and cooperation between Ministries in achieving legislative change in order to implement health

policy. The formulation and implementation of legislation dealing with aspects of public health, such as food law and environmental issues, necessarily depends upon successful inter-sectoral collaboration between various Ministries and other sectors of Government.

What is legislation?

Legislation is law that is written down. Legislation may be created by the main legislative body, often a parliament, or by another body, holder of office or authority that is given the power to create it. A law is only recognised as such if it is created in any manner that has been specified. For example, where there are two houses of parliament, it may be required that the law be passed by a majority of both houses and then be assented to by a monarch or president.

Primary legislation created by Parliament

Law that is created by a parliament can be classified as **primary legislation**. The power to make law for a particular jurisdiction (a country, collection of countries or a geographical area such as a region) may be given to a parliament by a **Constitution** (which may actually be a piece of legislation of another jurisdiction).

Legislation is the most flexible way to make law. The parliament decides what the law is and legislation can be used either to create a new legal rule or to alter or change existing legal rules. Laws created by parliaments are generally called **Acts of Parliament** or **statutes**. The word Act merely refers to the fact that the parliament has *acted* in its capacity as the legislature.

Legislation by parliament is primary legislation because the parliament is the highest law making body. However, even when a parliament has passed legislation, it has to be assented to and brought into force. Primary legislation may delegate power to another body to create more detailed sub-law on the subject, known as **subordinate legislation**.

Subordinate legislation

Subordinate legislation is legislation that is subordinate to primary legislation, and is made under a delegated power contained in a law. Such legislation may also be referred to as **secondary** or **subsidiary legislation**. It is very important to note that subordinate legislation cannot be contrary to the primary legislation.

As the scope of Government activities have increased, so has the existence of legislation of a subordinate character. Regulations, by-laws, orders in council and other administrative orders, Ministerial decisions, or rules are examples of subordinate legislation.

In many countries, the quantity of written sub-laws made under delegated legislative authority far exceeds the volume of the laws contained in statutes.

Most Acts of Parliament give a regulation making power to executive government. This allows the government, or a particular Minister, Ministry or statutory authority, to give detailed effect to the more general intentions that have been expressed in the primary Act. So, quite apart from the process of making legislation in parliament, many Ministers, Ministries and Government Departments are involved, through delegated legislation, in the processes of law making.

Placing detailed provisions within subordinate legislation has the advantage that the detail can be changed comparatively easily. The work of a parliament is limited by the times of its sittings and the breadth of work and the passing of new laws can take considerable time. Sometimes a parliament lacks the technical expertise necessary to consider detailed rule making and technical detail may be best prepared by those with the technical skills. However, reliance on an increasing amount of subordinate legislation does come at a price.

It is difficult for everyone, including citizens of the country, to keep up with new regulations and by-laws. In an attempt to inform, procedures are often put in place to try and ensure knowledge through publication at least in an

official place. It is said that knowing the procedure for making subordinate legislation is as important as knowing who can exercise the power. This is because there are often requirements for subordinate legislation to be published in an official government publication, such as a gazette, or for copies to be deposited with a certain office.

Difficult legal issues can also be raised with respect to whether or not subordinate legislation, such as regulations, has been validly made. This depends upon the legislator acting within the scope of the powers to legislate that have been delegated. Such questions are required to be answered by a court. Subordinate legislation must always be within the extent of the power given or its validity can be challenged as being **ultra vires** (literally "beyond the power"). Where, for example, a regulation making power is given to a Minister, but the power is to be exercised "with the approval of Cabinet", Cabinet's approval of any regulations must be obtained for the regulations to be "within the power", or **intra vires**.

A further issue raised by reliance on an increasing amount of delegated legislation relates to questions of democracy. In countries where democratically elected representatives form the government, citizens expect those elected to make law. However, democratic ideals are challenged where subordinate legislation is made by unrepresentative officials or authorities. Given the increasing reliance on subordinate legislation, there must be adequate checks upon the exercise of delegated powers. To some extent control is exercised by the courts, but this control is dependent upon the initiative of a challenge being raised in a court. Better control is exercised by the parliament itself.

> In delegating the subordinate law making power, the parliament should make the limits of the power clear in the primary legislation.

This is normally done by including a general power to make subordinate legislation, such as *"The Minister may, with the approval of Cabinet, make regulations, not*

inconsistent with this Act, prescribing matters necessary or convenient for carrying out or giving effect to this Act". This general power may then go on to specify particular matters for which regulations may be made by use of words such as *"and, in particular, for the following purposes ..."* with any matters contained within the primary legislation requiring further detail or specification then being listed.

Your country's legislative structure

History of the legislative structure

It is important to know how the current legislative structure in a country has evolved as legislation provided under a previous structure may still be relevant. Countries with a colonial past may, upon achieving independence or nationhood, have decided to rely upon law put in place during a period of colonisation until there has been an opportunity to replace it with law of the country. In other cases, there may be a provision that, in the absence of law dealing with a particular topic, the law of another country shall be deemed to apply.

Where there are laws of the country in place, it is not unusual to discover old law that is entirely inappropriate to prevailing conditions. For example, a law aimed at ensuring that certain animals are kept within a pen, so accidents are not caused or property damaged by straying animals, that defines "cattle" as meaning "a cow, pig, horse, sheep or other animal" is not appropriate to a country with a climate that is too hot for a sheep to survive there. Such a provision would have been appropriate to the country of its source and then adopted inappropriately without adaptation.

Nowadays, while **legal precedents** (examples of legislation that are in place elsewhere) are used to assist legal drafting, there is an emphasis upon the importance of ensuring that the law is appropriate to both the conditions and resources of the country. Even though precedents from other countries are not necessarily appropriate to be imported without amendment, they can still be very useful as they are effective to illustrate matters that other countries have considered important enough to be included in their law.

> Any law that is drafted must be "made to measure", with any precedents used adapted to what is appropriate to effectively implement the country's planned policy.

The date of any legislative structural change should also be noted as it might be stated that legislation up until a particular date shall be the law of another country, but any laws passed after that date are solely a sovereign matter for the country i.e. only the country has the power to pass laws for its governance.

Common or civil law

Systems of law can generally be classified as being either a **civil law system** or a **common law system**. The characteristics of the two systems differ and they have different **sources of law**. A source of law refers to a source in the particular legal system that has the authority to declare a rule to be a law.

The most important characteristic of a common law system is called the **doctrine of precedent**. In this case, the word precedent is not being used in the sense of examples of written laws. The doctrine of precedent refers to the respect and obedience of judges to previous judicial decisions when they are deciding subsequent cases with similar facts or issues. If a **decision** was made by a court that is higher in the country's hierarchy of courts than the court deciding a current case then, under the doctrine of precedent, a later judge is bound to apply the **reasoning** of a previous decision. Thus previous judicial decisions become part of the law of the country. This does not mean that case law can never be changed. One of the most common ways to change case made law is by a higher court overturning the previous decision or by statutory law being made.

In a common law system, the recording of previous decisions in a form that is available to judges making decisions in later cases is essential. This is why **law report**s are produced in many jurisdictions. They are accepted as

authoritative statements of case law and are referred to (**cited**) in later cases.

In common law systems, the sources of the law are both from laws passed by a parliament (**statutory law**) and laws made by judges (**decisions**).

Civil law systems have their origin in Roman law. In civil law systems, respect and obedience is given to a complete **code** of written law. The duty of the judge is to administer this written law. Whereas later judges may respect a line of decisions that give the same interpretation of a written law, they are not bound to follow the decision in a later case. Thus civil and common law systems can be contrasted by the comparative disregard for the previous decisions of judges and a consequential lack of laws created by judicial decisions in civil law systems. The detail of the written code of law in a civil law system varies from country to country but it is the written code for that country that is the source of law.

The system of law that has evolved within a country again has its roots in history. If at one time the country was the subject of colonisation, the law of the colonial power up until a certain date might have been imported to become the system of law of the country. If that imported system was either a civil law system or a common law system, then it is to be expected that the current legal system will reflect the colonial past, or at least retain some of its elements.

Existence and scope of a Constitution

The **constitution** of a country is at the top of the **hierarchy of legislation**. It is likely to establish the form and composition of the legislative body such as a parliament, and may specify the manner in which legislation is made.

> Analysis of the constitution will be required in order to ascertain whether it prescribes the legislative process to be followed. Particular rights and freedoms are also frequently protected under a constitution or under a bill of rights. Of particular note are any protections that are relevant to the provision of health care, such as rights to personal liberty and the care and protection of children. The constitutional analysis should make note of any such rights that may be affected by health legislation.

Rights given in a constitution are generally not absolute. When a right is given, the circumstances in which it might be suspended or curtailed will also be included, such as when the curtailment is in the interest of public health.

The pre-eminent place of a constitution will usually be obvious by the way in which the constitution itself contains provisions that make the constitution very difficult to change. An example is a requirement for constitutional change only to occur when a decision is made by a **special majority** in parliament, such as two thirds. This can be contrasted to the **simple majority** normally required to change other legislation.

International obligations

> Countries that have become signatories to international **Conventions** are under a binding obligation to incorporate protections provided by such international agreements into their **domestic law.**

Three important documents of this nature are together referred to as the **International Bill on Human Rights**. They are the Universal Declaration of Human Rights (**UDHR**), the International Covenant on Civil and Political Rights (**ICCPR**) and the International Covenant on Economic, Social and Cultural Rights (**ICESCR**). Thus, if a country is a member of the United Nations, it is important

to determine whether, and when, it became a signatory to all of the documents comprising the International Bill on Human Rights.

Details of signatories of international Conventions, and any declarations or reservations made by a country upon signature, are available at the United Nations website at http://untreaty.un.org/, which also gives access to the text of the Covenants and the two Optional Protocols to the ICCPR.

The most recent international Convention to be developed of particular relevance to the Health Sector is the Framework Convention on Tobacco Control (FCTC), which was unanimously adopted by the 192 members of the World Health Organization at the 56th World Health Assembly in May 2003. This is the first international treaty negotiated under the auspices of the World Health Organization. This Convention aims to curb tobacco-related deaths and disease, and, once bought into force by having 40 parties contracting to the FCTC (achieved through ratification, acceptance, approval, formal confirmation or accession), will require countries to impose restrictions on tobacco advertising, sponsorship and promotion, establish new labelling and clean indoor air controls and strengthen legislation to clamp down on tobacco smuggling.

Apart from the legally binding Conventions, there are other **international standards** established by United Nations General Assembly Resolutions. While not legally binding, the content of such resolutions establish standards that have been agreed to by the member countries and, as such, are both influential and useful in considering the potential content of domestic health legislation. Again, the detail of such international standards can be accessed at the United Nations website.

In addition, the constitution of WHO authorizes it to adopt regulations concerning sanitary and quarantine requirements and other procedures designed to prevent the international spread of disease. Pursuant to this authority, WHO has adopted two international health regulations: the Nomenclature Regulations, and the International Health

Regulations (IHR). The purpose of the IHR is to ensure maximum security against the international spread of disease with a minimum interference with world traffic. Today, the IHR remain the only international health agreement on communicable disease that is binding on Member States of WHO.

Hierarchy of legislation

Because there are both primary and secondary sources of law in a country, each jurisdiction will have its own hierarchy of legislation.

> In order to assess the legislative level required for new legislation, it is necessary to examine the hierarchy and to appreciate:
>
> - what forms of legislation can be created at each level;
> - who has the power to create such legislation and;
> - how such legislation is to be created.

Your country's legislative process

The process and procedure used in a country to create and pass legislation is best understood if it is viewed in the chronological order in which it operates. When looked at this way, there are three stages in creating parliamentary legislation:

- the **formulation stage** prior to consideration by parliament;
- the **enactment stage** by parliament; and
- the **operation stage** when the law comes into force.

> A drafter of legislation must understand the legislative process and the preliminary activity should include writing a short description of the order of activity in creating legislation, who undertakes what, and the likely timetable for the process to occur.

The formulation stage

A description of the legislative process should commence with a recognition of which body or bodies may take initiative in introducing potential new legislation. Some countries require the responsible Minister to have a policy approved by a group such as a Cabinet prior to legislative initiatives being taken. This would involve the responsible Minister presenting a policy document to the Cabinet, justifying introduction of such a policy and outlining the scope of legislative change required to implement the policy.

Many countries have parliamentary counsel, law reform or law review committees who carry out the drafting of legislation, or at least review all drafts prepared by a Ministry prior to their submission to Parliament. In some

cases there is a Ministry or Office whose staff are skilled in drafting legislation but, often, that Ministry or Office also carries out a significant role in public prosecutions of crime, as well as providing services to a whole range of ministries. Resource constraints within that Ministry or Office often lead to an inability to accommodate drafting in response to a request from a Ministry of Health. Thus the Ministry itself may need to accept the responsibility to ensure that at least an initial draft is produced.

> Whoever writes an initial draft, the work should always be informed by knowledge of the policy that is to be supported by the legislation. A policy document should be prepared by the Ministry of Health that outlines:
>
> - why regulation of a particular area of activity by legislation is necessary;
> - the purpose of the legislation; and
> - any matters of decided policy.

The issue of why legislation is necessary is really addressing the fact that while health legislation has great power, it also has limitations. There are other tools available to implement health policy apart from the legal tool. Is the matter or its affect upon legal rights or interests significant enough to warrant a legislative response? It must always be remembered that a legislative response will mean the creation of legally enforceable rights and obligations. Consideration should be given to whether a better outcome might be achieved by health education or the provision of health information, or perhaps guidelines will be effective. If the legislative option is selected, then the purpose of the legislation should be stated, together with any policy matters that have already been decided.

It is often impossible to contemplate every policy issue that might be raised. The drafting process itself often raises points of policy that are required to be addressed as they are presented. It is important to ensure that the drafter has access to someone to whom to address such matters.

Decisions of policy can effectively dictate the shape of the legislation.

For example, in legislation to regulate the sale of alcohol or tobacco products, the question of age of the customer must be addressed if one wishes to make sales to customers below a certain age an offence. The insertion of a particular age will then lead to policy questions about how the age of the customer is to be ascertained, raising such issues as to whether the customer should have documentation to prove age.

Typically, before a draft law is presented to Parliament, it will have gone through several drafts. In some countries, all drafts are reviewed by a committee or a sub-grouping of Parliament to ensure that accepted legislative drafting style is used.

Legislative drafting styles

Some countries produce legislative drafting style guides which set out such key information as:

- the words to be used to begin a law or sub-law;
- whether legislation in the country may be divided into parts or chapters;
- whether section or article numbers are used;
- how subsections, paragraphs and subparagraphs are numbered and set out;
- whether schedules may be created; and
- other matters that may be the subject of a domestic Interpretation Act.

Where a style guide is not available, consideration of a number of examples of existing law will lead to an understanding of the drafting principles that have been applied in the past.

Numbering

A frequently encountered legislative numbering system takes the following form:

1. Section

    (1) Subsection

        (a) Paragraph

            (i) Subparagraph

When a series of subsections or subparagraphs is by nature of a list, rather than true subsections, some countries continue to use the same numbering method. Others go to the next available indented option. Here are two examples to illustrate the difference, using the numbering system presented above:

Example 1 : Retaining same system for a list

1. Section

    (1) Subsection

        (a) List component

        (b) List component

Example 2: Next available indented option for a list

1. Section

    (1) Subsection

        (i) List component

        (ii) List component

Punctuation

There will also be a preference for using either dashes (-) or colons (:) prior to a subsection, paragraph or sub-paragraph. Semi-colons (;) are used at the end of subsections and subparagraphs, with a full stop (.) at the end of the section. When a series of subsections or paragraphs create

alternatives, it must be ascertained whether the word 'or' is normally used after each alternative, or just before the last alternative.

Numbering of References

If reference is made to a subsection within the same section, just the subsection number is used. If reference is made to a subsection within another section, it is usual to express this as section X (x), or subsection X (x).

Numbers

It is important to know whether numbers should be included in the text of legislation in numeric form (12) rather than being written as the word twelve, as in:

> "*The Council shall meet as required and shall prepare annually a report of its activities during the preceding 12 months and this report shall be made to the Minister".*

Interpretation

If there is an Interpretation Act in existence, a copy should be gained as it may clarify such matters as whether "he" is always interpreted to mean "he or she". If so, the legislation need only say "he" where the person referred to may be of either gender.

Specifying penalties

A law will always contemplate what is to occur should it not be observed, and how compliance might be enforced. In some jurisdictions, **penalty units** are used in place of fixed amounts of monetary **fines**. The fine is expressed as being a number of penalty units. Within an Interpretation Act, the monetary equivalent of one penalty unit is expressed.

When inflation occurs and the amount of a fine needs to be increased, this is achieved by a simple amendment of the Interpretation Act of the monetary amount equal to one penalty unit. This negates the need to amend every Act that includes a fine expressed as a monetary amount. If penalty units are utilised, the drafter of legislation needs to be aware of the current value of a penalty unit.

There may also be particular words used where alternative forms of penalty are provided for, such as when a penalty can be either in the form of imprisonment or in the form of a monetary fine, as in:

> "*Any person who obstructs an authorized officer commits an offence and is liable on conviction to a fine not exceeding $1000.00 or to a term of imprisonment not exceeding 6 months.*"
>
> And:
>
> "*Any person who contravenes or fails to comply with any provision of this Act or any regulation made under this Act commits an offence, and on conviction shall, where no other penalty is provided, be liable to a fine not exceeding $1000.00, or imprisonment for a term not exceeding 6 months, or both and, in the case of a continuing offence, to a fine not exceeding $100 for every day or part of a day during which the offence has continued".*

Some penalties may be expressed in terms of a maximum available penalty. There is thus some discretion exercised in fixing the penalty in a particular case. Offenders are given a penalty that reflects the seriousness of the offence when compared with the worst possible example. It is quite logical to find both offences for which there is a maximum penalty and offences for which there is a stated fixed penalty within the same legislation.

Arrangement of sections

The positioning of certain sections should also be considered. It may be usual to include a commencement section and a definition section at a particular place (and perhaps to use standard language within those sections), and to include a section dealing with the repeal or saving of any previous legislation as the final section.

Language

The choice of particular words in legislation can come down to the individual preference of the drafter, but some who promote plain language drafting consider that the word 'shall' should not be used when the drafter is meaning 'must'.

The enactment stage

The parliamentary system may be unicameral (one house of parliament) or bicameral (an upper and lower house system) where a law has to be passed by a majority of both houses.

There will be rules about how many times a draft law **(bill)** has to pass through the legislature. Every time draft legislation is introduced into a parliament it is referred to as a reading of the bill. In some countries it is unacceptable for a bill to be read more than once at any one sitting of parliament unless there is proven urgency for adoption of the law.

It may be usual in a country for the Minister responsible for the bill to introduce it to parliament, in others it is a particular Minister such as the Minister of Justice.

> It is appropriate for the drafter of legislation to prepare a summary of the bill in the form of an **explanatory statement or explanatory notes**. There may be a particular style used for this document and examples should be obtained, together with a copy of the legislation to which they refer.

The summary document should set out the intention of the legislation, draw attention to matters of policy and give a brief description of significant provisions.

In many countries the explanatory documents accompanying a bill are under the name of the Minister of Justice or Attorney General. However, should revision of drafts of new laws occur prior to their introduction into Parliament, it is necessary to ensure any consequential amendments are made to the explanatory document.

The timing of Parliamentary sessions is relevant in planning the introduction of new legislation. Some countries have a system whereby a smaller parliamentary group, such as a cabinet of Ministers, Privy Council or Senate, fix a parliamentary timetable, including when particular draft laws might be introduced, or when a law is to be reviewed. In many cases, a committee or officer, such as an officer of an Attorney General's Department, reviews all proposed laws prior to introduction to parliament.

Parliamentary language

In some countries, the language of discussion in Parliament may not be the language in which the bill is drafted. There may also be a necessity for bills to be presented both in the original language used for drafting and the language of the country. Therefore, translations of the drafts need to be obtained and verified prior to submission to Parliament. Apart from the cost of translation, which must be budgeted for, it is often time-consuming and difficulties can arise equating an expression used in the original as, in many languages, there are no words that are exactly equivalent, or a particular word can vary in meaning depending on its context.

The operation stage

Once a law has been passed by Parliament, there is usually a requirement that the law be assented to by the Head of State before it is brought into force.

Sometimes a date when the law will come into force is inserted into the law itself. In other cases, the coming into force is stated to be 'on a date to be proclaimed'. This device may be used in cases where more detailed provisions for effective implementation, such as regulations, are required to be put in place before the legislation takes effect. However, it has the disadvantage that the development of such secondary processes may be delayed or deferred so that, as a consequence, the legislation is never proclaimed.

It is also possible to phase in a law, or selected parts or a section of a law, so that gradually the entire law can become operational. Similarly, initial application of a law might be to a particular geographical area, and later its application is extended to the whole country.

Collection of your country's health and health-related legislation

> One of the most time-consuming requirements in considering the need for new legislation, and ascertaining the context in which it will be placed, is to obtain any relevant legislation that is already in existence or proposed.

Some countries have brought together all their primary legislation into official volumes. Such a collection is sometimes held by an officer of the Ministry of Health. In other cases, the Ministry itself has recognised the need to know what law exists that can loosely be called 'health law' and has compiled an unofficial collection. However, such collections may not be complete if, for example, they contain all the law up until a certain date but nothing after that date. They are an extremely valuable starting point for a collection of legislation, but often laws passed since the volume date are not included, and subordinate legislation may also be absent or incomplete. This may be the case if the Ministry responsible for such regulations or orders is a Ministry other than Health, such as a Ministry of the Environment or Ministry of Works.

> Access to a complete collection of all primary and secondary law that impacts upon health is essential for anyone concerned with drafting health legislation designed to support health policy.

Consideration and understanding of what already exists is an essential prerequisite in considering new legislative initiatives to ensure that:

- there is a need for new legislation and not just a need to make existing legislation workable and/or enforceable;

- any outmoded legislation is repealed or amended by new legislation;
- new legislation is appropriately placed within the legislative structure;
- new legislation does not inadvertently work in conflict with existing structures or provisions; and
- any necessary intersectoral collaboration and cooperation occurs in the development of new legislation.

Existing legislation

The audit and bringing together of a collection of laws that impact upon health requires a broad view when considering the potential sources of the law. Ideally, every Ministry and Government Department should be requested to provide copies of all primary and secondary law that has the potential to impact upon health.

> The objective is to compile an inventory of all relevant laws, orders and regulations relating to health or having health-related implications. This must also include reference to any constitutional or international obligations.

It must be recognised that such laws do not necessarily contain the word 'health' in their title. In fact the title of a law, and even its stated purpose, may be quite misleading as to whether or not the law has health-related implications. In all cases the entire law must be scrutinised for any relationship with health.

The inventory will necessarily include laws where the Ministry or Minister responsible for administering the law may be other than Health. For example, a Ministry with responsibilities for tourism in a country may have put in place laws that establish water and sanitation standards for establishments that provide accommodation, a Ministry responsible for ensuring building standards, such as the

provision of adequate fire escapes, may not be the same as that responsible for the public health, and a Ministry responsible for the enforcement of vehicle standards may not view the fitting and use of vehicle seat belts, or a requirement to use lead-free petrol, as actually being aspects of health law.

> In liaising with other Ministries and Departments in order to obtain copies of existing law, it will also be necessary to discuss any proposals for new developments being considered by those other sources. It is not unusual to find that more than one area of Government has recognised a particular legislative need while not appreciating the inter-sectoral nature of the problem.

Existing drafts

Draft proposals from any relevant Ministry should be sought, including any drafts of proposed primary or secondary legislation. Where another Ministry is reluctant to provide legislative drafts, because of their nature as drafts, they may provide a policy statement as to what is proposed. Sometimes this information might be shared more readily at the Ministerial level.

What is the policy to be implemented?

The inventory of legislation will need to be rigorously considered in light of the policy to be implemented. A concise written expression of the policy will also be useful in expressing the objectives of proposed new legislation and in assessing the place of proposed legislation in the legislative hierarchy in order to ensure the most effective legislative tool is selected. Detailed questions of policy are likely to be raised during the drafting process in the shaping of the legislation.

The policy statement should also outline any known restrictions on effective implementation, such as resource constraints, both economic and those related to the availability of qualified personnel.

Annex: Essential activities in Understanding the Legislative Process

(checklist)

- ☐ Compile a short history of your country's legislative process, including key dates when changes such as Independence or obtaining legislative sovereignty occurred.
- ☐ Determine the sources of law in your country.
  - ☐ Statutory law and decisions (common law system)
  - ☐ Code of law (civil law system)
  - ☐ Combination system
- ☐ Obtain a copy of any Constitution/Bill of Rights.
- ☐ Analyze constitutional documents with respect to:
  - ☐ Legislative structure requirements
  - ☐ Legislative process requirements
  - ☐ Rights that are protected
- ☐ Has your country become a signatory or ratified any part of the International Bill on Human Rights?
  - ☐ ICCPR? Date
  - ☐ ICESCR? Date
  - ☐ UDHR? Date
- ☐ Has your country ratified, confirmed, accepted, approved or acceded to Framework Convention on Tobacco Control (FCTC)?
- ☐ Note any declarations or resolutions upon signing or ratification.
- ☐ Compile a hierarchy of legislation for your country making reference to the forms of legislation that may be created at each level.

- ☐ Explain the formulation stage of each form of legislation.
- ☐ Explain the enactment stage of each form of legislation.
- ☐ Obtain or prepare a legislative drafting style guide.
- ☐ Will translation and verification of draft legislation be required?
- ☐ Prepare proposed timetable for enactment.
- ☐ Collect all health and health related legislation.
- ☐ Obtain proposals and, if possible, drafts for all proposed primary and subordinate health or health related legislation.
- ☐ Read and review all legislation noting any provisions that might need to be amended or repealed by new legislation.
- ☐ Obtain or prepare a policy document for the legislation that is to be drafted. Include:
    - ☐ An explanation of why regulation of this area by legislation is necessary
    - ☐ The purpose of the legislation
    - ☐ Any matters of policy that have already been decided
    - ☐ Known restrictions that will impact on effective implementation
- ☐ Assess the appropriate level of new legislation.

Glossary of terms

Act of Parliament Law that is made by a parliament. Also known as a statute and statutory law. The word 'Act' refers to parliament having acted in its capacity as the legislature.

bill A draft law that is presented to parliament for reading and debate. Once passed by parliament in the required manner the bill becomes an Act of Parliament.

cited Making reference to a decided case in a later court case.

civil law system A system of law with its origins in Roman Law where respect and obedience is given to a complete code of written law. Generally contrasted with a common law system. Judges may respect a line of decisions that give the same interpretation of a written law, but they are not bound to follow the decision. The written code is the source of law.

code (i) The source of law in a civil law country. (ii) Body of laws and regulations governing a specific field.

common law system A system of law where the sources of law are both statutory law and law made by judges. Generally contrasted with civil law systems. The most important characteristic of a common law system is the doctrine of precedent.

constitution The most authoritative piece of legislation in a country that may establish the legislature, executive government and the courts. It may include rights of citizens and may actually be a statute of another country. In some countries, however, there is no single written constitution, for it may be embodied in a number of disparate sources (legislation, common law, convention, the rule of law, founding treaties, and other documents) and this can make analysis difficult or complicated.

Conventions International agreements that impose binding obligations upon countries that sign or ratify them to incorporate protections in the agreements into domestic law.

decision The law as stated by a judge in a case.

doctrine of precedent The most important characteristic of a common law system where judges give respect and obedience to previous judicial decisions. If a decision was made by a court that is higher in the hierarchy of courts than the court deciding the current case (and sometimes when the earlier case was at the same level), the later judge is bound to apply the reasoning of the previous decision. The recording of previous decisions in a form that is available to judges making decisions in later cases is essential.

domestic law The internal law of a country.

enactment stage The stage of the legislative process when draft primary legislation is considered by parliament.

explanatory statement May also be known as explanatory notes. This document is a short explanation of the main components of a bill, its purpose and the policy sought to be implemented prepared for the advice of parliament.

FCTC The Framework Convention on Tobacco Control. More information is available at http://www.who.int

fines Monetary penalties imposed on a person who breaches a law. The imposition of a fine can be by a court or, where provided for in the law, by an official such as an authorised officer or police officer.

formulation stage The initial stage of the legislative process where policy is formed and a draft of legislation prepared.

health legislation Branch of law regulating a wide range of matters pertaining to health.

hierarchy of legislation A description of the available forms of legislation in a country, arranged in the order of constitutional provisions, primary law and forms of subordinate law.

ICCPR The International Covenant on Civil and Political Rights, one of the three documents forming the International Bill on Human Rights. It remains open for signatures and ratification and any country that signs or ratifies is obliged to incorporate its protections into the country's domestic law.

ICESCR The International Covenant on Economic, Social and Cultural Rights, one of the three documents forming the International Bill on Human Rights. It remains open for signatures and ratification and any country that signs or ratifies is obliged to incorporate its protections into the country's domestic law.

international standards Standards established by resolutions of the United Nations General Assembly.

intra vires Literally means acting within the power. Used in connection with an assessment of the validity of subordinate legislation.

jurisdiction A country, collection of countries or geographical area such as a region over which a particular body, such as a parliament, has power to make law.

law reports Official reports of decided cases used in a common law system.

legal precedents Examples of legislation in place elsewhere.

legislation Law that is written down.

legislative process The process and procedure in a country to create and pass legislation.

legislative structure The structure in a country available to create legislation at different levels.

operation stage The stage when a law comes into force.

penalty units Used in place of fixed amounts of monetary fines where each fine is expressed as a number of penalty units. The monetary value of a penalty unit is expressed in a single piece of separate legislation. When the amount of fines is to be increased, the value of a penalty unit is increased instead of having to amend every piece of legislation containing fines.

primary legislation Also known as statutory law. Law that is created by a parliament or by the primary law making body.

reading The consideration of a bill in parliament.

simple majority Where half of those voting plus one vote in favour.

secondary legislation Also known as subordinate or subsidiary legislation. Secondary to primary legislation as it is created under a power delegated in primary legislation. Subordinate legislation cannot be contrary to the primary legislation.

sources of law Sources of the law in a legal system. In civil law systems, a written law or code is the single source of law. In common law systems, the sources of law are statutory law and law made by judges.

sovereign matter When only a country has the power to make laws for its governance.

special majority Where a matter has to be voted for by a greater majority than a simple majority. Often fixed at 75% of those voting and used to seek to entrench constitutional provisions.

statutes/statutory law Laws made by a parliament or supreme law making body.

subordinate legislation Also known as secondary or subsidiary legislation (refer to secondary legislation).

subsidiary legislation Also known as secondary or subordinate legislation (refer to secondary legislation).

UDHR The Universal Declaration of Human Rights, one of the three documents comprising the International Bill on Human Rights. It remains open for signatures and ratification and any country that signs or ratifies is obliged to incorporate its protections into the country's domestic law.

ultra vires Literally means "acting beyond the power." Used in connection with an assessment of the validity of subordinate legislation.